File No. CT-2024-006

COMPETITION TRIBUNAL

IN THE MATTER OF the *Competition Act*, R.S.C. 1985, c. C-34 (the "**Act**");

AND IN THE MATTER OF an application by JAMP Pharma Corporation for an order pursuant to section 103.1 of the Act granting leave to bring an application under section 79 of the Act;

AND IN THE MATTER OF an application by JAMP Pharma Corporation for an order pursuant to sections 79 of the Act;

BETWEEN:

JAMP PHARMA CORPORATION

Applicant

– and –

JANSSEN INC.

Respondent

AFFIDAVIT OF SUKHAD JUNEJA
(Pursuant to section 103.1 of the *Competition Act*)

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– and –

JANSSEN INC.

Respondent

AFFIDAVIT OF SUKHAD JUNEJA

(Pursuant to section 103.1 of the *Competition Act*)

I, SUKHAD JUNEJA, of the City of Boucherville, in the Province of Quebec, **MAKE OATH AND SAY**:

1. I am employed by JAMP Pharma Corporation ("**JAMP**") as Senior Vice-President, Global Portfolio & Scientific Affairs, and as such I have personal knowledge of the matters herein deposed, except where I rely on information provided by other persons, in which case, I believe that information to be true.

2. This affidavit is sworn in support of an application being brought by JAMP for an order pursuant to section 103.1 of the *Competition Act* ("**Act**") for leave to bring an application against the Respondent under section 79 of the Act.

I. CURRICULUM VITAE

3. I was originally hired by JAMP in 2013. Since that time, I have been employed in a number of increasingly senior roles. My responsibilities have included overseeing the evaluation of potential new products for financial opportunity, the oversight of commercial and regulatory planning for products that JAMP has decided to launch and business development. At present, I am responsible for overseeing JAMP's operations globally, across all of JAMP's divisions. These responsibilities include overseeing new product development and new product launch. I am a member of JAMP's executive committee and I report directly to Mr. Louis Pilon, who is the President and Chief Executive Officer of JAMP.

4. I hold a Bachelor of Science degree from Panjab University in Pharmaceutical Sciences and a Master of Business Administration degree from the Indian Institute of Foreign Trade.

II. THE PARTIES

A. JAMP

5. JAMP is a company incorporated under the laws of Canada. JAMP, through its various divisions, offers high-quality, affordable medicines (both generic and branded drugs), vitamins, nutritional supplements and cosmetics, among other products. Since being

founded in 1988, JAMP's generics division has become a leader in generic product launches, receiving 40 different product approvals from Health Canada just last year. Across its operations, JAMP employs over 800 individuals between its head office in Boucherville, Quebec and its Canadian and Indian manufacturing and research facilities. This includes the recently-acquired manufacturing facility in Lévis, Quebec, and the multi-purpose research, manufacturing and centre of excellence in Hyderabad, India.

6. JAMP's operations are conducted through seven separate divisions: JAMP Pharma (which offers generic drugs); BioJAMP (which offers biosimilar products, and operates through a strategic partnership with Alvotech (described in more detail below)); Orimed Pharma (which offers brand name drugs in Canada in partnership with non-Canadian companies that originally developed the drugs); Wampole (which offers vitamins and supplements); Laboratoire Suisse (which offers natural health products in Canada); Cosmetic Import (which distributes beauty products); and Acure Care & Injectables (which specializes in products administered in hospitals and other healthcare facilities).

B. The Respondent

7. Janssen Inc. ("**Janssen**") is a Canadian pharmaceutical company.

8. Johnson & Johnson ("**J&J**") is a New Jersey-based multinational pharmaceutical, biotechnology and medical technologies corporation. I have attached to this affidavit as Exhibit "J1" a copy of J&J's Annual Report for the fiscal year ended December 31, 2023. As set out on page 167 of Exhibit J1, Janssen is a wholly-owned subsidiary of J&J. According to Exhibit J1, Jansen and its foreign affiliates focus on developing and

marketing innovative medicines, and form J&J's Innovative Medicine Division. J&J also operates a separate MedTech division.

9. According to its website, Janssen's operations are divided into six different areas of therapeutic focus: Pulmonary Hypertension, Oncology, Immunology, Infectious Diseases and Vaccines, Cardiovascular & Metabolic Diseases, and Neuroscience. To the best of my information, the Janssen products described below are all sold by its Immunology therapeutic area.

III. THE REGULATION AND ECONOMICS OF DRUGS IN CANADA AND THE PROVINCES

A. Small Molecule Drugs, Biologic Drugs and Biosimilar Drugs

10. It is possible to classify prescription drugs as either small molecule drugs or biologics. Generally, these drugs differ in the size of the molecule and complexity of the manufacturing process. Small molecule drugs are chemically derived, simple in their structure and relatively simple to manufacture. By contrast, biologics are extracted from living cells, such as animal cells, bacteria or yeast. As a result, biologics feature comparatively larger molecules and are more complex to manufacture. Because they are extracted from living cells, there is more variety in each biologic drug.

11. It is possible for a generic drug company to produce a chemically identical version of an originator company's small molecule drug. By contrast, it is not possible to produce a chemically identical "generic" version of a biologic drug. However, a highly similar drug can be produced – that is, a new biologic drug that has no expected clinically meaningful

differences in efficacy and safety compared to a biologic drug that was already authorized for sale by the originator company (the "originator" or "reference" biologic). When such a new drug has at least one indication in common with the reference biologic, it is referred to as a "biosimilar".

B. Approval for New Biologics and Biosimilars

12. In order to obtain market authorization, an innovative biologic drug product must obtain regulatory approval from Health Canada. Specifically, a sponsor company must file a New Drug Submission ("**NDS**") seeking a Notice of Compliance ("**NOC**") for its innovative biologic drug. Among other information and data, a NDS relies upon a phase III clinical trial (or trials) in a large number of patients for each indication (*i.e.*, therapeutic use) for which approval is sought. Health Canada will only issue a NOC after it is satisfied that the biologic drug product is safe and effective. Without a NOC, a biologic drug product cannot be marketed and sold. Phase III clinical trials are expensive and can take many years to conduct.

13. A sponsor for a biosimilar drug must also obtain market authorization by way of a NDS. However, as described in Health Canada's biosimilar guidance document attached as Exhibit "J2" the regulatory approval of a biosimilar is based upon a comparison to an approved, innovative biologic drug product, which is referred to as the Reference Biologic Drug ("**RBD**"). The dosage form, strength and route of administration of the proposed biosimilar drug product and the RBD should be the same. Exhibit J2 specifies that a sponsor for a biosimilar drug product must demonstrate that the biosimilar drug product

and the RBD are "highly similar" and have no clinically meaningful differences in efficacy and safety.

14. Typically, a NDS for a biosimilar drug relies upon a phase III clinical trial in a large number of patients for at least one of its indications. I understand from Exhibit J2 at section 2.3.4 that Health Canada will then typically permit the sponsor of the proposed biosimilar drug to extrapolate from the RBD's clinical data for other indications in which a clinical trial has not been conducted. Given this ability to extrapolate from a single clinical trial, the development work required for a NDS for a biosimilar drug, while very substantial, is less time-consuming and expensive than that required for a NDS for an innovative biologic drug.

C. Time-Limited Protection from Competition for Innovative Drugs

15. Parliament has created time limited protections from competition for innovative drugs, including biologics.

16. Pursuant to section C.08.004.1 of the *Food and Drug Regulations*, an innovative drug (including a biologic drug) is eligible for data protection. Attached to this affidavit as Exhibit "J3" is a guidance document regarding such data protection. I understand from Exhibit J3 at sections 1.2 and 2.1, among others, that this data protection effectively creates an 8-year monopoly for innovative drugs from the date that a NOC is issued. Health Canada maintains an online Register of Innovative Drugs that provides the 8-year "no approval" date for each innovative drug, which allows sponsors of generic/biosimilar drugs to plan

their affairs accordingly. A copy of such register last updated July 4, 2024 is attached to this affidavit as Exhibit "J4".

17. I have attached to this affidavit as Exhibit "J5" Health Canada's guidance to the *Patented Medicines (Notice of Compliance) Regulations* ("**PM(NOC) Regulations**"). My understanding, including from Exhibit J5 at section 1.1, is that Canada's pharmaceutical patent policy objective, which applies to both small molecules and biologic drugs, is to balance effective patent enforcement over new and innovative drugs with the timely entry of their lower-priced generic/biosimilar competitors.

18. The regulatory approval of a biosimilar drug is directly linked to patents protecting the RBD by way of section 55.2 of the *Patent Act* and the associated PM(NOC) Regulations. The PM(NOC) Regulations provide an opportunity for originator drug companies to list certain types of patents[1] against individual drugs in a register, with this patent register being maintained by the Minister of Health. Attached as Exhibit "J6" is an extract of the online patent register for each innovative drug, which allows sponsors of generic/biosimilar drugs to plan their affairs accordingly. The regulatory approval of a biosimilar drug is directly linked to the patents listed on the patent register for the RBD, because a NOC cannot be issued for a proposed biosimilar unless and until all patents are addressed.

[1] Specifically, the patents that may be listed (provided other timing requirements are met) are patents containing a claim for the medicinal ingredient; a claim for the formulation; a claim for the dosage form; or a claim for the use of the medicinal ingredient.

19. Sponsors of biosimilar drugs can address patents listed on the patent register for the RBD by way of a Notice of Allegation alleging that the patents are invalid and/or not infringed. The PM(NOC) Regulations provide an opportunity for the originator firm to bring a *quia timet* patent infringement action against the sponsor of the proposed biosimilar seeking a declaration that the making, constructing, using or selling of the biosimilar would infringe any listed patent(s). The commencement of this action effectively triggers a 24-month preclusion on the issuance of a NOC for the proposed biosimilar (which period permits the action to be litigated through trial).

IV. USTEKINUMAB AND JANSSEN'S DRUGS

20. I have attached as Exhibit "J7" a research paper describing the discovery and mechanism of ustekinumab. I understand from Exhibit J7 that ustekinumab is a biologic medicine that doctors prescribe to treat several life-threatening autoimmune diseases.

21. I understand that an autoimmune disease is a disease where the body's immune system begins to attack the body instead of protecting it. These internal attacks can take various forms, including prolonged inflammatory responses that damage the body's vital organs. Psoriasis, including psoriasis and psoriatic arthritis, is one such inflammatory disease, which effects the body's skin and joints. Crohn's disease and ulcerative colitis are two other inflammatory autoimmune diseases, characterized by a chronic inflammation of the gastrointestinal tract. Left untreated, these diseases can result in life-threatening damage to the stomach, large and small intestines, oral cavity, anal canal, pharynx, and esophagus.

22. I understand from Exhibit J7 that ustekinumab was originally developed by Centocor Research & Development ("**Centocor**"), a division of J&J.

B. Stelara and its Indications

23. I understand Stelara is the brand under which Janssen registered and marketed ustekinumab.

24. I have reviewed relevant portions of the Canada Notice of Compliance Database. I have attached as Exhibit "J8" an extract from that database, which records that Janssen received a NOC from Health Canada for Stelara on December 12, 2008.

25. I have attached as Exhibit "J9" Stelara's product monograph. That monograph lists the conditions for which Stelara is indicated. These indications include: for the treatment of adult patients with moderate to severe plaque psoriasis; for the treatment of adult patients with active psoriatic arthritis alone or with methotrexate; for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response, loss of response or were intolerant to either immunomodulators or one more tumor necrosis anti-TNF alpha, or have had an inadequate response, intolerance or demonstrated dependence on corticosteroids; and for the treatment of adult patients with moderately to severely active ulcerative colitis. All of these indications were obtained prior to 2022.

C. Stelara and its Financial Success

26. I have reviewed J&J's annual reports for the years between 2012 to 2023. These report the sales of Stelara separate from other drugs. These are attached to this affidavit as Exhibits "J10" to "J20". I have reviewed sales data of Stelara in Canada available from IQVIA between 2009 to 2023. From these sources, I understand that in 2010 J&J generated revenues from sales of Stelara across the world of approximately USD $393 million; Janssen generated revenues from sales of Stelara in Canada of approximately CAD $14.0 million (up from $5.3 million in 2009). I understand that, in the years thereafter, J&J's global sales and Janssen's Canadian sales from Stelara grew every year. I understand that in 2023 J&J generated revenues from sales of Stelara across the world of approximately USD $10.858 billion; Janssen generated revenues from sales of Stelara in Canada of approximately CAD $912.8 million.

27. From the IQVIA data, I understand that in Canada Janssen sells Stelara for at least $4,000 per dose on a wholesale basis. After the initial doses, Stelara is typically administered to a patient approximately four times per year.

D. Protection from Competition for Stelara, and Janssen's Attempts to Extend It

28. Page 39 of the Register of Innovate Drugs (Exhibit J4) indicates that Stelara's data protection under the *Food and Drug Regulations* ended on December 12, 2016.

29. As I understand from paragraph 20 of the Federal Court decision attached to this affidavit as Exhibit "J21", there has been no patent listed against Stelara on the patent register since August 9, 2021. Given the prior expiry of data protection, this means that there has been

no other barrier to regulatory approval and entry for a biosimilar to Stelara since August 9, 2021.

30. However, based on paragraph 34 of Exhibit J21, I understand that on July 25, 2022, Janssen attempted to list Canadian Letters Patent No. 3,113,837 (the "**837 Patent**") on the patent register against Stelara. I understand from that same decision that the Minister of Health declined to list the 837 Patent on the patent register because the relevant regulatory submission was not related to a change in use of the medicinal ingredient and, had Janssen attempted to list the 837 Patent in respect of the regulatory submission that did relate to a change in use of the medicinal ingredient, then Janssen would have been clearly out of time.

31. I understand that subsection 4(6) of the PM(NOC) Regulations clearly provides that, where a patent is not listed on the patent register contemporaneously with a NDS, it may only be subsequently listed where two timing requirements are met: (i) the relevant patent list must be submitted within 30 days after the issuance of the patent; and (ii) the application giving rise to the patent must have been filed in Canada prior to the filing of the relevant regulatory submission. These timing requirements are well-known to those in the pharmaceutical industry because they have historically and consistently been applied very strictly by the Federal Court (and the Minister of Health).

32. I understand from Exhibit J21 that the application giving rise to the 837 Patent was filed in Canada on September 24, 2019, and the relevant regulatory submission for a change in use of the medicinal ingredient was filed by Janssen on February 15, 2019. It therefore was and

is apparent that Janssen was simply out of time to list the 837 Patent against Stelara. I understand and do verily believe that, during the summer of 2022, shortly after the 837 Patent issued on July 12, 2022, JAMP had independently considered and understood that Janssen would be unable to ever list the 837 Patent against Stelara given this timing conundrum.

33. In the face of the Minister's straight-forward decision, Janssen commenced a judicial review application in the Federal Court of Canada arguing that the Minister's decision was unreasonable and that the relevant (and governing) provision in the PM(NOC) Regulations was *ultra vires*. That Notice of Application for such application is attached to this affidavit as Exhibit "J22". In addition, I understand from Exhibit J22 that Janssen sought retroactive relief so as to list the 837 Patent as early as July 19, 2022, presumably to force any sponsor filing a NDS for a ustekinumab biosimilar before that date to have to address the 837 Patent pursuant to the PM(NOC) Regulations before being able to receive regulatory approval.[2] The Federal Court, as shown in Exhibit J21, dismissed Janssen's judicial review application on June 21, 2023.

34. Rather than accepting the Federal Court's decision, Janssen pursued an appeal at the Federal Court of Appeal, which was dismissed from the bench on November 21, 2023. Such dismissal is attached to this affidavit as Exhibit "J23".

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[2] Biosimilar sponsors need only address patents listed at the time they file a NDS (and need not address subsequently listed patents). This creates certainty for planning purposes and an incentive to file sooner rather than later.

E. Finlius, its Indications and the Attempt to Protect it from Competition

35. On April 18, 2023 Janssen received approval from Health Canada to market Finlius ("**Finlius**"); a drug identical to Stelara except in name. I have attached as Exhibit "J24" an extract from the Canada Notice of Compliance Database, which records that Janssen received a NOC from Health Canada for Finlius on April 18, 2023. Exhibit J24 shows that Finlius has the exact same active ingredient (ustekinumab), dosage form, routes of administration and strengths as Stelara. The submission class of the NOC is "Labelling Only" and "Reason for Submission" is "Administrative - Additional product name".

36. Hence, as is clear from the Notice of Application attached to this affidavit as Exhibit "J25" at paragraph 3, which was prepared by Janssen in litigation before the Federal Court: "Finlius is merely another name for Stelara but is otherwise an identical product".[3] This is further confirmed by the product monograph for Finlius (July 7, 2023 version), attached to this affidavit as Exhibit "J26", which identifies the same clinical trials for Finlius as for Stelara (*i.e.*, PHOENIX 1, PHOENIX 2 and ACCEPT).[4] Typographical details in the Finlius product monograph also demonstrate its relationship to Stelara. For example, the metadata properties of the file containing the Finlius product monograph[5] indicate that the document's title (which is distinct from the file's name) is "STELARA Product

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[3] Notice of Application dated April 26, 2023 in Federal Court File No. T-873-23, ¶3. ("NDS 267289 seeks approval of FINLIUS, which is identical to the approved drug STELARA I.V. ("STELARA") but is a distinct product and will have its own Drug Identification Number(s)").

[4] Compare page 44 of the Finlius product monograph to page 34 of the Stelara product monograph (attached to this affidavit as Exhibit J9).

[5] To access these properties, open Exhibit J26 in Adobe, click on "File", and click on "Properties."

Monograph_EN". By further example, the Finlius product monograph on the first page says that its "date of initial authorization" was December 12, 2008, which is when Stelara received its initial authorization; as noted in paragraph 35, Finlius was not authorized until April 18, 2023.

37. Finlius is not a biosimilar to Stelara – it is Stelara by another name. Health Canada's Guidance on the Information and Submission Requirements for Biosimilar Biologic Drugs (Exhibit J2) clearly requires a "biosimilar" to mean a biologic that: (i) obtains market authorization subsequent to a reference biologic authorized in Canada, and (ii) with demonstrated similarity to such a reference biologic drug, relying in part on prior information regarding safety, efficacy and effectiveness that is deemed relevant due to the demonstration of similarity to the reference biologic drug. In addition, biosimilars should include a statement indicating the product as a biosimilar of a reference biologic. Finlius relies on the same clinical trials as Stelara and does not indicate in its monograph (Exhibit J26) that it is a biosimilar.

38. Just as with Stelara, Janssen attempted to have the 837 Patent listed on the patent register against Finlius. In late 2022 and early 2023, the Minister of Health declined to list the 837 Patent against Finlius because the NDS for Finlius was submitted under the administrative pathway and was not the type of NDS that could give rise to the listing of patents on the patent register. In other words, Finlius was not an innovative drug.

39. It would appear that Janssen was using Finlius to attempt to overcome its inability to list the 837 Patent on the patent register against Stelara because of the timing restrictions in

subsection 4(6) of the PM(NOC) Regulations. In particular, Janssen was attempting to rely upon subsection 4(5), which only requires that a patent list be filed at the time a NDS to which the patent list relates is filed. Unable to list the 837 Patent directly against Stelara, Janssen generated a NDS for Finlius, which is identical to Stelara, presumably in order to utilize subsection 4(5) to list the 837 Patent against Finlius.

40. In the face of the Minister's straight-forward decision that Janssen could not do indirectly (through Finlius) what it could not do directly (through Stelara), Janssen commenced a judicial review application in the Federal Court of Canada arguing that the Minister's decision regarding Finlius was unreasonable. That application was commenced on April 26, 2023, just days after Janssen received regulatory approval for Finlius. As set out in the relevant Federal Court File record attached to this affidavit as Exhibit "J27", Janssen sought a stay of its application in May 2023, pending resolution of its application regarding the listing of the 837 Patent for Stelara. Janssen only discontinued its Finlius judicial review application on February 28, 2024, which was almost three months after the dismissal of its appeal regarding the 837 Patent and Stelara, and only after a request for a status update from the Federal Court.

41. Although a NOC for Finlius was issued on April 18, 2023, Janssen only commenced marketing of Finlius on July 2, 2024.

V. BIOJAMP'S BIOSIMILAR BUSINESS AND BIOSIMILARS

A. JAMP's Relationship with Alvotech

42. The JAMP Pharma division searches for business opportunities that improve healthcare outcomes for patients while providing savings to payors. As an increasing share of healthcare expenditures has shifted to biologics, JAMP Pharma investigated the development of biosimilars.

43. JAMP began entering into a series of agreements with Alvotech hf ("**Alvotech**"), a world-class biopharmaceutical company based in Iceland that specializes in the development and manufacturing of biosimilar drugs, including with respect to the supply of ustekinumab.

44. On January 14, 2020, JAMP and Alvotech announced to the public their exclusive "strategic partnership" for the sale of biosimilar drugs in Canada. This announcement is attached as Exhibit "J28".

B. Creation of BioJAMP and Role of JAMP Care

45. As described in paragraph 6, above, JAMP's operations are conducted through different divisions. On February 1, 2022, prior to JAMP's launch of any biosimilar products, JAMP announced the creation and launch of a new division, BioJAMP, dedicated to the sale of biosimilar products. This announcement is attached as Exhibit "J29". JAMP announced that its patient support program, JAMP Care, would support physicians and patients with the administration of JAMP's biosimilar drugs.

C. BioJAMP's First Biosimilar, Simlandi

46. On April 14, 2022, JAMP announced the launch of BioJAMP's first biosimilar drug in Canada, Simlandi™ ("**Simlandi**"). This announcement is attached as Exhibit "J30". Simlandi is a biosimilar to Humira (adalimumab), which is marketed by AbbVie.

47. Prior to the launch of Simlandi, BioJAMP prepared a detailed forecast of expected demand. Among other things, the forecast made conservative assumptions about AbbVie's ability to retain share of adalimumab sales, and the share of sales that other manufacturers of adalimumab biosimilars might retain. BioJAMP priced Simlandi at a discount to Humira.

48. BioJAMP's forecast for Simlandi proved broadly accurate, and Simlandi has been a significant success for BioJAMP. As reported by IQVIA, in 2022 (when Simlandi was only marketed for approximately seven months) BioJAMP generated more than $7 million in sales of Simlandi on a wholesale basis. In 2023, BioJAMP generated more than $37 million in sales of Simlandi on a wholesale basis.

D. BioJAMP's Second Biosimilar, Jamteki

49. JAMP submitted a NDS for a second biosimilar, Jamteki, on November 24, 2022. Jamteki is a biosimilar to Stelara, which is marketed by Janssen.

50. During the pendency of JAMP's NDS for Jamteki, there were no patents listed on the patent register against Stelara. However, Janssen's judicial review application relating to the registration of the 837 Patent on the patent register for Stelara remained pending until November 21, 2023. As described in paragraph 30 and following, above, Janssen was

seeking retroactive listing of the 837 Patent to as early as July 19, 2022, which, if granted, could have at least theoretically resulted in JAMP needing to address the 837 Patent pursuant to the PM(NOC) Regulations before being able to receive a NOC for Jamteki.

51. In addition, as described in paragraph 38 and following, Janssen's judicial review application relating to the registration of the 837 Patent on the patent register for Finlius was commenced on April 26, 2023, and remained pending until February 2024.

52. In addition, JAMP was aware that Janssen had asserted patents covering Stelara in other jurisdictions and that it was probable that Janssen would assert infringement of equivalent Canadian patents (including the 837 Patent) if JAMP launched Jamteki without a licence to Janssen's patents.

53. Beyond the significant cost of patent litigation, given there were no prior biosimilar entrants in the ustekinumab market in Canada, JAMP knew that if it were to launch Jamteki "at risk", JAMP would be exposed to potential patent litigation and a claim for damages in the form of Janssen's lost profits on lost sales of Stelara. Hence, every JAMP sale of Jamteki at a discounted price (and lower profit margin than Stelara) would expose JAMP to the risk of damages at the higher price (and higher profit margin) of Stelara. Given that Janssen's 2023 revenues from Stelara in Canada exceeded $900 million, JAMP knew that launching without a licence to Janssen's patents would expose it to a potentially catastrophic damages award, especially given that patent litigation takes years to result in a trial judgment (with potential liability accruing throughout).

54. [redacted]. Jamteki received a NOC from Health Canada on November 9, 2023. An extract of the Canada Notice of Compliance Database for Jamteki is attached to this affidavit as Exhibit "J31". BioJAMP subsequently announced the launch of Jamteki on March 1, 2024. A copy of the press release making such announcement is attached as Exhibit "J32".

55. Prior to the launch of Jamteki, BioJAMP prepared a detailed forecast of expected demand. That forecast, and the resulting performance of Jamteki, are described in the affidavit of Amélie Faubert.

VI. OTHER USTEKINUMAB BIOSIMILARS

56. I understand that along with Jamteki, Wezlana™ ("**Wezlana**") is the only biosimilar of Stelara currently approved for sale in Canada. Wezlana is sold by Amgen Canada Inc. ("**Amgen**"). Wezlana received a NOC from Health Canada on December 27, 2023. Amgen first marketed Wezlana on March 1, 2024. I understand from data published by IQVIA that Amgen's sales of Wezlana are roughly comparable to JAMP's sales of Jamteki.

57. I understand from Health Canada's listing of the Drug and Health Product Submissions Under Review that, as of May 31, 2024, there are at least five new drug submissions currently under review for biosimilars of Stelara. The companies that have submitted these new drug submissions for a Stelara biosimilar and the date of such submission are: (i)

Samsung Bioepis Co., Ltd. (October 2023); (ii) Celltrion Healthcare Co Ltd (August 2023); (iii) Fresenius Kabi Canada Ltd (March 2024); (iv) Accord Healthcare Inc (May 2024); and (v) Biosimilar Collaborations Ireland Limited (May 2024). Because I am familiar with the time frame associated with the approval for a biosimilar drug, it is my expectation that [redacted]

VII. JANSSEN'S REMICADE AND OMVYENCE

58. I have attached as Exhibit "J33" a research paper describing the discovery and mechanism of infliximab. I understand from Exhibit J33 that infliximab is a biologic medicine that is approved for a number of indications, including the treatment of Crohn's disease, ulcerative colitis, rheumatoid arthritis, and psoriasis. I also understand from Exhibit J33 that infliximab was originally developed by a foreign affiliate of Janssen, which obtained approval from the US Food and Drug Administration for a drug whose active pharmaceutical ingredient was infliximab under the name of Remicade in 1998.

59. I have reviewed the Canada Drug Product Database. I have attached as Exhibit "J34" an extract from that database, which records that Janssen obtained approval from Health Canada for Remicade and originally marketed Remicade in Canada in 2001.

60. Like Stelara, Remicade is expensive and it has generated significant revenues for Janssen in Canada. According to data I have reviewed from IQVIA and an article in the Globe and Mail that I have attached as Exhibit "J35", in 2016, Janssen sold Remicade for $987.56 per vial (and patients required multiple vials per infusion). According to data I obtained from IQVIA, between 2016 and 2021 inclusive, Janssen generated more than $1 billion in annual revenue from sales of Remicade in Canada.

61. I understand that Remicade was protected by competition for many years, including by the operation of patents that Janssen registered on Remicade and which were subject to extensive litigation.[6] Ultimately, however, the protection that Janssen enjoyed from competition in infliximab expired and other drug manufacturers were able to seek approval from Health Canada for biosimilars to Remicade. Based on information I obtained from the Canada Drug Product Database and which I have attached as Exhibit "J36" to "J39", I understand that those biosimilars include (i) Inflectra (approved in 2014), (ii) Renflexis (in 2018), (iii) Avsola (in 2020) and (iv) Remsima (in 2021). None of these products are marketed by JAMP.

62. I understand that, in 2018, the Competition Bureau commenced an inquiry into Janssen's practices regarding the sales of Remicade that allegedly inhibited the sale of biosimilars. At the conclusion of its inquiry, the Bureau issued a position statement, which I have attached as Exhibit "J40". That position statement confirmed that Janssen had engaged in

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6 See, for example, *Janssen Inc. v. Celltrion Healthcare Co.*, Ltd, 2016 FC 525. https://canlii.ca/t/gs2hf

predatory pricing and exclusive contracting in response to entry by biosimilars, among other practices, but did not identify sufficient evidence that those practices had prevented or lessened competition substantially. The Bureau's position statement expressed concern that companies that sell reference biologics might engage in conduct that undermines efforts by provincial drug plans to encourage substitution of lower cost biosimilar drugs, including spreading false or misleading information.

63. In or around 2020, I believe that Janssen filed a New Drug Submission for a new drug whose active ingredient was also infliximab, to be called Omvyence. Based on information I obtained from the Canada Drug Product Database and which I have attached as Exhibit "J41", Janssen obtained approval from Health Canada for Omvyence in Canada in December 2020. That same record explains that, while Janssen has obtained approval for Omvyence, Janssen has never marketed Omvyence. Omvyence has the exact same active ingredient, dosage form, routes of administration and strengths as Remicade. I believe that Omvyence is merely another name for Remicade but is otherwise an identical product.

64. In approximately 2020, I understand the Competition Bureau commenced an inquiry regarding so-called "relabelled biologics." According to a June 2022 position statement that the Bureau issued at the conclusion of its inquiry that I have attached as Exhibit "J42" "relabelled biologics" are biologic drugs that bear a second brand name, but that are identical to a drug manufacturer's original biologic drug. The Bureau's position statement explained that, because the relabelled biologic drugs that were the subject of the investigation had not been marketed, the Bureau closed its investigation. However, if the

relabelled biologics were to be marketed and covered by insurers as an option for patients, then harm to competition might occur.

65. I do not know of any business reason why a drug manufacturer would incur the cost associated with the preparation of a New Drug Submission and obtain approval from Health Canada for a drug, but never market the drug. Such activities would result in costs to the drug manufacturer, but no revenues or profits.

SWORN remotely by Sukhad Juneja, stated as being at the City of Boucherville, in the Province of Quebec, before me at the City of Toronto, in the Province of Ontario, on July 25, 2024, in accordance with O. Reg. 431/20, Administering Oath or Declaration Remotely

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)

Sukhad Juneja

A Commissioner, etc.
Name: Arash Rouhi

Name: Sukhad Juneja

Exhibit “J1”

This is Exhibit “J1” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.
Arash Rouhi

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2023
or

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
for the transition period from to

Commission file number 1-3215

Johnson & Johnson

(Exact name of registrant as specified in its charter)

New Jersey	**22-1024240**
(State of incorporation)	**(I.R.S. Employer Identification No.)**
One Johnson & Johnson Plaza **New Brunswick, New Jersey**	**08933**
(Address of principal executive offices)	**(Zip Code)**

One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
(Address of principal executive offices)
Registrant's telephone number, including area code: (732) 524-0400

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, Par Value $1.00	JNJ	New York Stock Exchange
0.650% Notes Due May 2024	JNJ24C	New York Stock Exchange
5.50% Notes Due November 2024	JNJ24BP	New York Stock Exchange
1.150% Notes Due November 2028	JNJ28	New York Stock Exchange
1.650% Notes Due May 2035	JNJ35	New York Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☑
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☑ No ☐
If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐
Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑
The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $430 billion.
On February 9, 2024, there were 2,408,767,228 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III: Portions of the registrant's proxy statement for its 2024 annual meeting of shareholders filed within 120 days after the close of the registrant's fiscal year (the "Proxy Statement"), are incorporated by reference to this report on Form 10-K (this "Report").

Item

Cautionary note regarding forward-looking statements

This Annual Report on Form 10-K and Johnson & Johnson's other publicly available documents contain "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Management and representatives of Johnson & Johnson and its subsidiaries (the Company) also may from time to time make forward-looking statements. Forward-looking statements do not relate strictly to historical or current facts and reflect management's assumptions, views, plans, objectives and projections about the future. Forward-looking statements may be identified by the use of words such as "plans," "expects," "will," "anticipates," "estimates" and other words of similar meaning in conjunction with, among other things: discussions of future operations; expected operating results and financial performance; impact of planned acquisitions and dispositions; impact and timing of restructuring initiatives, including associated cost savings and other benefits; the Company's strategy for growth; product development activities; regulatory approvals; market position and expenditures.

Because forward-looking statements are based on current beliefs, expectations and assumptions regarding future events, they are subject to uncertainties, risks and changes that are difficult to predict and many of which are outside of the Company's control. Investors should realize that if underlying assumptions prove inaccurate, or known or unknown risks or uncertainties materialize, the Company's actual results and financial condition could vary materially from expectations and projections expressed or implied in its forward-looking statements. Investors are therefore cautioned not to rely on these forward-looking statements. Risks and uncertainties include, but are not limited to:

Risks related to product development, market success and competition

- Challenges and uncertainties inherent in innovation and development of new and improved products and technologies on which the Company's continued growth and success depend, including uncertainty of clinical outcomes, additional analysis of existing clinical data, obtaining regulatory approvals, health plan coverage and customer access, and initial and continued commercial success;
- Challenges to the Company's ability to obtain and protect adequate patent and other intellectual property rights for new and existing products and technologies in the United States and other important markets;
- The impact of patent expirations, typically followed by the introduction of competing generic, biosimilar or other products and resulting revenue and market share losses;
- Increasingly aggressive and frequent challenges to the Company's patents by competitors and others seeking to launch competing generic, biosimilar or other products and increased receptivity of courts, the United States Patent and Trademark Office and other decision makers to such challenges, potentially resulting in loss of market exclusivity and rapid decline in sales for the relevant product sooner than expected;
- Competition in research and development of new and improved products, processes and technologies, which can result in product and process obsolescence;
- Competition to reach agreement with third parties for collaboration, licensing, development and marketing agreements for products and technologies;
- Competition based on cost-effectiveness, product performance, technological advances and patents attained by competitors; and
- Allegations that the Company's products infringe the patents and other intellectual property rights of third parties, which could adversely affect the Company's ability to sell the products in question and require the payment of money damages and future royalties.

Risks related to product liability, litigation and regulatory activity

- Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the United States Food and Drug Administration (U.S. FDA) (or international counterparts), declining sales, reputational damage, increased litigation expense and share price impact;
- The impact, including declining sales and reputational damage, of significant litigation or government action adverse to the Company, including product liability claims and allegations related to pharmaceutical marketing practices and contracting strategies;
- The impact of an adverse judgment or settlement and the adequacy of reserves related to legal proceedings, including patent litigation, product liability, personal injury claims, securities class actions, government investigations, employment and other legal proceedings;

- Increased scrutiny of the healthcare industry by government agencies and state attorneys general resulting in investigations and prosecutions, which carry the risk of significant civil and criminal penalties, including, but not limited to, debarment from government business;
- Failure to meet compliance obligations in compliance agreements with governments or government agencies, which could result in significant sanctions;
- Potential changes to applicable laws and regulations affecting United States and international operations, including relating to: approval of new products; licensing and patent rights; sales and promotion of healthcare products; access to, and reimbursement and pricing for, healthcare products and services; environmental protection; and sourcing of raw materials;
- Compliance with local regulations and laws that may restrict the Company's ability to manufacture or sell its products in relevant markets, including requirements to comply with medical device reporting regulations and other requirements such as the European Union's Medical Devices Regulation;
- Changes in domestic and international tax laws and regulations, increasing audit scrutiny by tax authorities around the world and exposures to additional tax liabilities potentially in excess of existing reserves; and
- The issuance of new or revised accounting standards by the Financial Accounting Standards Board and regulations by the Securities and Exchange Commission.

Risks related to the Company's strategic initiatives, healthcare market trends and the realization of benefits from the separation of the Company's Consumer Health Business

- Pricing pressures resulting from trends toward healthcare cost containment, including the continued consolidation among healthcare providers and other market participants, trends toward managed care, the shift toward governments increasingly becoming the primary payors of healthcare expenses, significant new entrants to the healthcare markets seeking to reduce costs and government pressure on companies to voluntarily reduce costs and price increases;
- Restricted spending patterns of individual, institutional and governmental purchasers of healthcare products and services due to economic hardship and budgetary constraints;
- Challenges to the Company's ability to realize its strategy for growth including through externally sourced innovations, such as development collaborations, strategic acquisitions, licensing and marketing agreements, and the potential heightened costs of any such external arrangements due to competitive pressures;
- The potential that the expected strategic benefits and opportunities from any planned or completed acquisition or divestiture by the Company may not be realized or may take longer to realize than expected;
- The potential that the expected benefits and opportunities related to past and ongoing restructuring actions may not be realized or may take longer to realize than expected;
- The Company's ability to divest the Company's remaining ownership interest in Kenvue Inc. (Kenvue) and realize the anticipated benefits from the separation; and
- Kenvue's ability to succeed as a standalone publicly traded company.

Risks related to economic conditions, financial markets and operating internationally

- The risks associated with global operations on the Company and its customers and suppliers, including foreign governments in countries in which the Company operates;
- The impact of inflation and fluctuations in interest rates and currency exchange rates and the potential effect of such fluctuations on revenues, expenses and resulting margins;
- Potential changes in export/import and trade laws, regulations and policies of the United States and other countries, including any increased trade restrictions or tariffs and potential drug reimportation legislation;
- The impact on international operations from financial instability in international economies, sovereign risk, possible imposition of governmental controls and restrictive economic policies, and unstable international governments and legal systems;
- The impact of global public health crises and pandemics;

- Changes to global climate, extreme weather and natural disasters that could affect demand for the Company's products and services, cause disruptions in manufacturing and distribution networks, alter the availability of goods and services within the supply chain, and affect the overall design and integrity of the Company's products and operations;
- The impact of global or economic changes or events, including global tensions and war; and
- The impact of armed conflicts and terrorist attacks in the United States and other parts of the world, including social and economic disruptions and instability of financial and other markets.

Risks related to supply chain and operations

- Difficulties and delays in manufacturing, internally, through third-party providers or otherwise within the supply chain, that may lead to voluntary or involuntary business interruptions or shutdowns, product shortages, withdrawals or suspensions of products from the market, and potential regulatory action;
- Interruptions and breaches of the Company's information technology systems or those of the Company's vendors, which could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action;
- Reliance on global supply chains and production and distribution processes that are complex and subject to increasing regulatory requirements that may adversely affect supply, sourcing and pricing of materials used in the Company's products; and
- The potential that the expected benefits and opportunities related to restructuring actions may not be realized or may take longer to realize than expected, including due to any required approvals from applicable regulatory authorities.

Investors also should carefully read the risk factors described in Item 1A of this Annual Report on Form 10-K for a description of certain risks that could, among other things, cause the Company's actual results to differ materially from those expressed in its forward-looking statements. Investors should understand that it is not possible to predict or identify all such factors and should not consider the risks described above and in Item 1A to be a complete statement of all potential risks and uncertainties. The Company does not undertake to publicly update any forward-looking statement that may be made from time to time, whether as a result of new information or future events or developments.

Part I

Item 1. Business

General

Johnson & Johnson and its subsidiaries (the Company) have approximately 131,900 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the healthcare field. Johnson & Johnson is a holding company, with operating companies conducting business in virtually all countries of the world. The Company's primary focus is products related to human health and well-being. Johnson & Johnson was incorporated in the State of New Jersey in 1887.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Company's two business segments: Innovative Medicine (previously referred to as Pharmaceutical) and MedTech. Within the strategic parameters provided by the Committee, senior management groups at U.S. and international operating companies are each responsible for their own strategic plans and the day-to-day operations of those companies. Each subsidiary within the business segments is, with limited exceptions, managed by residents of the country where located.

Segments of business

Following the completion of the separation of the Consumer Health business (Kenvue) in August 2023, the Company is now organized into two business segments: Innovative Medicine and MedTech. Additional information required by this item is incorporated herein by reference to the narrative and tabular descriptions of segments and operating results under: Item 7. Management's discussion and analysis of results of operations and financial condition of this Report; and Note 17 Segments of business and geographic areas of the notes to consolidated financial statements included in Item 8 of this Report.

Innovative Medicine

The Innovative Medicine segment is focused on the following therapeutic areas: Immunology (e.g., rheumatoid arthritis, psoriatic arthritis, inflammatory bowel disease and psoriasis), Infectious Diseases (e.g., HIV/AIDS), Neuroscience (e.g., mood disorders, neurodegenerative disorders and schizophrenia), Oncology (e.g., prostate cancer, hematologic malignancies, lung cancer and bladder cancer), Cardiovascular and Metabolism (e.g., thrombosis, diabetes and macular degeneration) and Pulmonary Hypertension (e.g., Pulmonary Arterial Hypertension). Medicines in this segment are distributed directly to retailers, wholesalers, distributors, hospitals and healthcare professionals for prescription use. Key products in the Innovative Medicine segment include: REMICADE (infliximab), a treatment for a number of immune-mediated inflammatory diseases; SIMPONI (golimumab), a subcutaneous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis and moderately active to severely active ulcerative colitis; SIMPONI ARIA (golimumab), an intravenous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis and active ankylosing spondylitis and active polyarticular juvenile idiopathic arthritis (pJIA) in people 2 years of age and older; STELARA (ustekinumab), a treatment for adults and children with moderate to severe plaque psoriasis, for adults with active psoriatic arthritis, for adults with moderately to severely active Crohn's disease and treatment of moderately to severely active ulcerative colitis; TREMFYA (guselkumab), a treatment for adults with moderate to severe plaque psoriasis and active psoriatic arthritis; EDURANT (rilpivirine), PREZISTA (darunavir) and PREZCOBIX/REZOLSTA (darunavir/cobicistat), antiretroviral medicines for the treatment of human immunodeficiency virus (HIV) in combination with other antiretroviral products and SYMTUZA (darunavir/cobicistat/emtricitabine/tenofovir alafenamide), a once-daily single tablet regimen for the treatment of HIV; CONCERTA (methylphenidate HCl) extended-release tablets CII, a treatment for attention deficit hyperactivity disorder; INVEGA SUSTENNA/XEPLION (paliperidone palmitate), for the treatment of schizophrenia and schizoaffective disorder in adults; INVEGA TRINZA/TREVICTA (paliperidone palmitate), for the treatment of schizophrenia in patients after they have been adequately treated with INVEGA SUSTENNA for at least four months; SPRAVATO (Esketamine), a nasal spray, used along with an oral antidepressant, to treat adults with treatment-resistant depression (TRD) and depressive symptoms in adults with major depressive disorder (MDD) with suicidal thoughts or actions; CARVYKTI (ciltacabtagene autoleucel), a chimeric antigen receptor (CAR)-T-cell therapy for the treatment of patients with relapsed/refractory multiple myeloma; ZYTIGA (abiraterone

acetate), a treatment for patients with prostate cancer; ERLEADA (apalutamide), a next-generation androgen receptor inhibitor for the treatment of patients with prostate cancer; IMBRUVICA (ibrutinib), a treatment for certain B-cell malignancies, or blood cancers and chronic graft versus host disease; DARZALEX (daratumumab), a treatment for multiple myeloma; DARZALEX FASPRO (daratumumab and hyaluronidase-fihj), a treatment for multiple myeloma and light chain (AL) Amyloidosis; XARELTO (rivaroxaban), an oral anticoagulant for the prevention of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery, to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, and for the treatment and reduction of risk of recurrence of DVT and PE to reduce the risk of major cardiovascular events in patients with coronary artery disease (CAD) and peripheral artery disease (PAD), for the treatment and secondary prevention of thromboembolism in pediatric patients, and for thromboprophylaxis in pediatric patients following the Fontan procedure; OPSUMIT (macitentan) as monotherapy or in combination, indicated for the long-term treatment of pulmonary arterial hypertension (PAH); UPTRAVI (selexipag), the only approved oral and intravenous, selective IP receptor agonist targeting a prostacyclin pathway in PAH. Many of these medicines were developed in collaboration with strategic partners or are licensed from other companies and maintain active lifecycle development programs.

MedTech

The MedTech segment includes a broad portfolio of products used in the Interventional Solutions, Orthopaedics, Surgery and Vision categories. Interventional Solutions include electrophysiology products (Biosense Webster) to treat heart rhythm disorders, the heart recovery portfolio (Abiomed) which includes technologies to treat severe coronary artery disease requiring high-risk PCI or AMI cardiogenic shock, and Neurovascular care (Cerenovus) that treats hemorrhagic and ischemic stroke. The Orthopaedics portfolio (DePuy Synthes) includes products and enabling technologies that support Hips, Knees, Trauma, and Spine, Sports & Other. The Surgery portfolios include advanced and general surgery technologies (Ethicon), as well as solutions that focus on breast aesthetics (Mentor), and Ear, Nose and Throat (Acclarent) procedures. Johnson & Johnson Vision products include ACUVUE Brand contact lenses and TECNIS intraocular lenses for cataract surgery. These products are distributed to wholesalers, hospitals and retailers, and used predominantly in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

Geographic areas

Johnson & Johnson and its subsidiaries (the Company) have approximately 131,900 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the healthcare field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The products made and sold in the international business include many of those described above under Segments of Business – Innovative Medicine and MedTech. However, the principal markets, products and methods of distribution in the international business vary with the country and the culture. The products sold in international business include those developed in the U.S. and by subsidiaries abroad.

Investments and activities in some countries outside the U.S. are subject to higher risks than comparable U.S. activities because the investment and commercial climate may be influenced by financial instability in international economies, restrictive economic policies and political and legal system uncertainties.

Raw materials

Raw materials essential to the Company's business are generally readily available from multiple sources. Where there are exceptions, the temporary unavailability of those raw materials would not likely have a material adverse effect on the financial results of the Company.

Patents

The Company's subsidiaries have made a practice of obtaining patent protection on their products and processes where possible. They own, or are licensed under, a significant number of patents in the U.S. and other countries relating to their products, product uses, formulations and manufacturing processes, which in the aggregate are believed to be of material importance to the Company in the operation of its businesses. The Company's subsidiaries face patent challenges from third parties, including challenges seeking to manufacture and market generic and biosimilar versions of the Company's key

pharmaceutical products prior to expiration of the applicable patents covering those products. Significant legal proceedings and claims involving the Company's patent and other intellectual property are described in Note 19 Legal proceedings—Intellectual property of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Sales of the Company's largest product, STELARA (ustekinumab) accounted for approximately 12.8% of the Company's total revenues for fiscal 2023. Accordingly, the patents related to this product are believed to be material to the Company. Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson, owns patents specifically related to STELARA. The latest expiring United States composition of matter patent expired in 2023. As a result of settlements and other agreements with third parties, the Company does not anticipate the launch of a biosimilar version of STELARA before January 1, 2025 in the United States. The latest expiring European composition of matter patent (Supplementary Protection Certificate) expires in 2024.

Sales of the Company's second largest product, collectively DARZALEX (daratumumab) and DARZALEX FASPRO (daratumumab and hyaluronidase-fihj), accounted for approximately 11.4% of the Company's total revenues for fiscal 2023. Accordingly, the patents related to this product are believed to be material to the Company. Genmab A/S owns two patent families related to DARZALEX, and Janssen Biotech, Inc. has an exclusive license to those patent families. The two patent families both expire in the United States in 2029, and in Europe, compound patent protection in select countries extends to 2031/2032. Janssen Biotech, Inc. owns a separate patent portfolio related to DARZALEX FASPRO.

Trademarks

The Company's subsidiaries have made a practice of selling their products under trademarks and of obtaining protection for these trademarks by all available means. These trademarks are protected by registration in the U.S. and other countries where such products are marketed. The Company considers these trademarks in the aggregate to be of material importance in the operation of its businesses.

Seasonality

Worldwide sales do not reflect any significant degree of seasonality; however, spending has typically been heavier in the fourth quarter of each year than in other quarters. This reflects increased spending decisions, principally for research and development activity.

Competition

In all of their product lines, the Company's subsidiaries compete with companies both locally and globally. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, both internally and externally sourced, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products, as well as protecting the underlying intellectual property of the Company's product portfolio, is important to the Company's success in all areas of its business. The competitive environment requires substantial investments in continuing research.

Environment

The Company is subject to a variety of environmental laws and regulations in the United States and other jurisdictions. The Company believes that its operations comply in all material respects with applicable environmental laws and regulations. The Company's compliance with these requirements is not expected to have a material effect upon its capital expenditures, cash flows, earnings or competitive position.

Regulation

The Company's businesses are subject to varying degrees of governmental regulation in the countries in which operations are conducted, and the general trend is toward increasingly stringent regulation and enforcement. The Company is subject to costly and complex U.S. and foreign laws and governmental regulations and any adverse regulatory action may materially adversely affect the Company's financial condition and business operations. In the U.S., the pharmaceutical product and medical technology industries have long been subject to regulation by various federal and state agencies, primarily as to product safety, efficacy, manufacturing, advertising, labeling and safety reporting. The exercise of broad regulatory powers by the U.S. Food and Drug Administration (the U.S. FDA) continues to result in increases in the amounts of testing and documentation required for U.S. FDA approval of new drugs and devices and a corresponding increase in the expense of product introduction. Similar trends are also evident in major markets outside of the U.S.

The new medical device regulatory framework and the evolving privacy, data localization, and emerging cyber security laws and regulations around the world are examples of such increased regulation. Within the U.S., an increasing number of U.S. States have enacted comprehensive privacy laws and federal regulators (e.g., the U.S. FDA, FTC and HHS) continue to stress the intersection of health and privacy as a compliance and enforcement priority. In the EU, multiple directives and laws (including NIS2, EHDS, the Data Act, the Cyber Resilience Act, and the AI Act) are rapidly changing privacy and cybersecurity compliance requirements while introducing new enforcement risks. In addition, China has introduced broad personal information protection and data security regulations, with more anticipated, thereby increasing China's scrutiny of company compliance and data transfer practices. With other jurisdictions enacting similar privacy laws, local data protection authorities will force greater accountability on the collection, access and use of personal data in the healthcare industry. These laws can also restrict transfers of data across borders, potentially impacting how data-driven health care solutions are developed and deployed globally in a compliant manner. Moreover, as a result of the broad scale release and availability of Artificial Intelligence (AI) technologies such as generative AI, a global trend towards more comprehensive and nuanced regulation (e.g., White House's Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence; the EU AI Act) to ensure the ethical use, privacy, and security of AI is underway that includes standards for transparency, accountability, and fairness, which will require compliance developments or enhancements.

The regulatory agencies under whose purview the Company operates have administrative powers that may subject it to actions such as product withdrawals, recalls, seizure of products and other civil and criminal sanctions. In some cases, the Company's subsidiaries may deem it advisable to initiate product recalls regardless of whether it has been required or directed to.

The U.S. FDA and regulatory agencies around the globe are also increasing their enforcement activities. If the U.S. FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our pharmaceutical products or medical technologies are ineffective or pose an unreasonable health risk, the U.S. FDA could ban such products, detain or seize adulterated or misbranded products, order a recall, repair, replacement, or refund of such products, refuse to grant pending applications for marketing authorization or require certificates of foreign governments for exports, and/or require us to notify health professionals and others that the products present unreasonable risks of substantial harm to the public health. The U.S. FDA may also assess civil or criminal penalties against us, our officers or employees and impose operating restrictions on a company-wide basis, or enjoin and/or restrain certain conduct resulting in violations of applicable law. The U.S. FDA may also recommend prosecution to the U.S. Department of Justice. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and limit our ability to obtain future clearances or approvals, and could result in a substantial modification to our business practices and operations. Equivalent enforcement mechanisms exist in different countries in which we conduct business.

The costs of human healthcare have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. In the U.S., attention has been focused by states, regulatory agencies and Congress on prices, profits, overutilization and the quality and costs of healthcare generally. Laws and regulations have been enacted to require adherence to strict compliance standards and prevent fraud and abuse in the healthcare industry. There is increased focus on interactions and financial relationships between healthcare companies and healthcare providers. Various state and federal transparency laws and regulations require disclosures of payments and other transfers of value made to certain healthcare practitioners, including physicians, teaching hospitals, and certain non-physician practitioners. Federal and foreign laws governing international business practices require strict compliance with anti-bribery standards and certain prohibitions with respect to payments to any foreign government official. Payors and Pharmacy Benefit Managers (PBMs) are a potent force in the marketplace, and increased attention is being paid to the impact of PBM practices on healthcare cost and access in the U.S.

Our business has been and continues to be affected by federal and state legislation that alters the pricing, coverage, and reimbursement landscape. At the federal level, in August 2022, President Biden signed into law the Inflation Reduction Act

(IRA), which includes provisions that effectively authorize the government to establish prices for certain high-spend single-source drugs and biologics reimbursed by the Medicare program, starting in 2026 for Medicare Part D drugs and 2028 for Medicare Part B drugs. On August 29, 2023, the Centers for Medicare & Medicaid Services ("CMS") published the first "Selected Drug" list, which includes XARELTO and STELARA as well as IMBRUVICA, which is developed in collaboration and co-commercialized in the U.S. with Pharmacyclics LLC, an AbbVie company. The Selected Drug list also included other medicines targeting disease states that are prevalent in the Medicare population. There remains uncertainty, however, regarding how the federal government will establish prices for the selected products, as the IRA specifies a ceiling price but not a minimum price. In any event, we anticipate that the selected products will be subjected to a government-established price for the Medicare population.

The IRA also contains provisions that impose rebates if certain prices increase at a rate that outpaces the rate of inflation, beginning October 1, 2022, for Medicare Part D drugs and January 1, 2023, for Medicare Part B drugs. Separate IRA provisions redesign the Medicare Part D benefit in various ways, including by shifting a greater portion of costs to manufacturers within certain coverage phases and replacing the Part D coverage gap discount program with a new manufacturer discounting program. Failure to comply with IRA provisions may subject manufacturers to various penalties, including civil monetary penalties.

In July 2023, Janssen Pharmaceuticals, Inc. (Janssen) filed litigation against the U.S. Department of Health and Human Services as well as the Centers for Medicare and Medicaid Services challenging the constitutionality of the Inflation Reduction Act's (IRA) Medicare Drug Price Negotiation Program. The litigation requests a declaration that the IRA violates Janssen's rights under the First Amendment and the Fifth Amendment to the Constitution and therefore that Janssen is not subject to the IRA's mandatory pricing scheme. The impact of the IRA on our business and the broader pharmaceutical industry remains uncertain, as litigation filed by Janssen and other pharmaceutical companies remains ongoing and CMS has yet to publicly announce the maximum fair price for each of the selected drugs.

Additionally, we expect continued scrutiny on drug pricing and government price reporting from Congress, agencies, and other bodies at the federal and state levels, which may result in additional regulations or other mechanisms to increase pricing transparency and controls.

There are a number of additional bills pending in Congress and healthcare reform proposals at the state level that would affect drug pricing, including in the Medicare and Medicaid programs. This changing legal landscape has both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of federal and state law, and potential modification or repeal of these laws, will ultimately affect the industry. The IRA and any other federal or state legislative change could affect the pricing and market conditions for our products.

In addition, business practices in the healthcare industry have come under increased scrutiny, particularly in the U.S., by government agencies and state attorneys general, and resulting investigations and prosecutions carry the risk of significant civil and criminal penalties. Of note is the increased enforcement activity by data protection authorities in various jurisdictions, particularly in the European Union, where significant fines have been levied on companies for data breaches, violations of privacy requirements, and unlawful cross-border data transfers. In the U.S., the Federal Trade Commission has stepped up enforcement of data privacy with several significant settlements (including settlements concerning the downstream sharing of personal information and use and disclosure of personal health data) and there have been a material increase in class-action lawsuits linked to the collection and use of biometric data and use of tracking technologies.

Further, the Company relies on global supply chains, and production and distribution processes, that are complex, and subject to increasing regulatory requirements that may affect sourcing, supply and pricing of materials used in the Company's products. These processes also are subject to complex and lengthy regulatory approvals.

Employees and human capital management

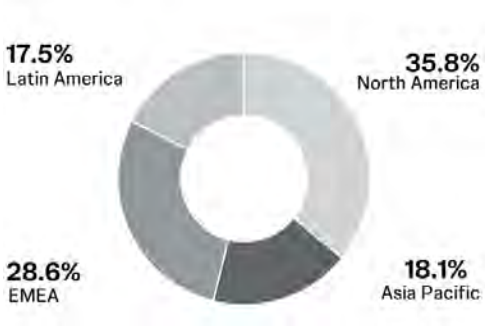
As of December 31, 2023, the number of employees was approximately:

	2023
Employees[1]	134,400
Full-time equivalent (FTE) positions[2]	131,900

1 "Employee" is defined as an individual working full-time or part-time, excluding fixed term employees, interns and co-op employees. Employee data may not include full population from more recently acquired companies and individuals on long-term disability are excluded. Contingent workers, contractors and subcontractors are also excluded.

2 FTE represents the total number of full-time equivalent positions and does not reflect the total number of individual employees as some work part-time.

Employees by region (in percentages)



Strategy

The Company believes that its employees are critical to its continued success and are an essential element of its long-term strategy. Management is responsible for ensuring that its policies and processes reflect and reinforce the Company's desired corporate culture, including policies and processes related to strategy, risk management, and ethics and compliance. The Company's human capital management strategy is built on three fundamental focus areas:

- Attracting and recruiting the best talent
- Developing and retaining talent
- Empowering and inspiring talent

Underpinning these focus areas are ongoing efforts to cultivate and foster a culture built on diversity, equity and inclusion (DEI), innovation, health, well-being and safety, where the Company's employees are encouraged to succeed both professionally and personally while helping the Company achieve its business goals.

Culture and employee engagement

At the Company, employees are guided by Our Credo which sets forth the Company's responsibilities to patients, consumers, customers, healthcare professionals, employees, communities and shareholders. Employees worldwide must adhere to the Company's Code of Business Conduct which sets basic requirements and serves as a foundation for the Company policies, procedures and guidelines, all of which provide additional guidance on expected employee behaviors in every market where it operates. The Company conducts global surveys that offer its employees the ability to provide feedback and valuable insight to help address potential human resources risks and identify opportunities to improve. In 2023, 94% of global employees across 76 countries participated in Our Credo Survey which was offered in 36 languages.

Growth and development

To lead in the changing healthcare landscape, it is crucial that the Company continue to attract and retain top talent. In 2023, the Company's voluntary turnover rate was 7%. The Company believes that its employees must be equipped with the right knowledge and skills and be provided with opportunities to grow and develop in their careers. Accordingly, professional development programs and educational resources are available to all employees. The Company's objective is to foster a learning culture that helps shape each person's unique career path while creating a robust pipeline of talent to deliver on the Company's long-term strategies. In furtherance of this objective, the Company deploys a global approach to ensure development is for everyone, regardless of where they are on their career journey. To prioritize learning, the Company recently held Johnson & Johnson's first Global Learning Day. Employees were encouraged to set aside a full day to explore skill-building courses across five areas: leadership, business skills, digital upskilling, DEI, and well-being, on J&J Learn, the Company's new learning platform.

Diversity, equity, and inclusion (DEI)

The Company is committed to workplace diversity and to cultivating, fostering, and advancing a culture of equity and inclusion. The Company's evidenced-based global enterprise Diversity, Equity and Inclusion strategy recognizes how DEI accelerates the Company's ability to meet the changing needs of the communities the Company serves in, as outlined in Our Credo. The Company's DEI Vision is: *Be yourself, change the world*. The Company's DEI Mission is: *Make diversity, equity and inclusion how we work everyday*. The Company's enterprise DEI Strategy is aligned to the DEI Vision and Mission and rests on four core pillars:

- Build a workforce of individuals with diverse backgrounds, cultures, abilities and perspectives
- Foster a culture of inclusion where every individual belongs
- Transform talent and business processes to achieve equitable opportunities for all
- Drive innovation and growth with our business to serve diverse markets around the world

The Company's DEI strategy is guided by internal and external insights, global best practices and continual employee feedback and recognizes that while diversity changes by location, inclusion is the same everywhere.

Compensation and benefits

As part of the Company's total rewards philosophy, the Company offers competitive compensation and benefits to attract and retain top talent. The Company is committed to fairness and equitable treatment in its compensation and benefits for employees at all levels. The Company observes legal minimum wage provisions and exceeds them where possible. The Company's total rewards offerings include an array of programs to support its employees' well-being, including annual performance incentive opportunities, pension and retirement savings programs, health and welfare benefits, paid time off, leave programs, flexible work schedules and employee assistance programs. In recognition of the Company's commitment to help employees balance their personal and professional responsibilities, the Company enhanced its caregiver, bereavement, and volunteer paid leave benefits, effective July 2023.

Health, wellness and safety

The Company's investment in employee health, well-being and safety is built on its conviction that advancing health for humanity starts with advancing the health of its employees. With the right awareness, focus, practices and tools, the Company ensures that all its employees around the world, as well as temporary contractors and visitors to the Company's sites, can work safely. The Company has continuously expanded health and well-being programs throughout the Company and across the globe, incorporating new thinking and technologies to keep its offerings best-in-class and to help employees achieve their personal health goals. The programs and practices the Company advances for total health—physical, mental, emotional and financial—ensure employee health protection for emerging health risks. The Company continues to address our employees needs through J&J Flex, a hybrid model that empowers the Company's office-based employees to find the right productivity and balance of in-person and remote work.

Available information

The Company's main corporate website address is www.jnj.com. The Company makes its SEC filings available on the Company's website at www.investor.jnj.com/financials/sec-filings, as soon as reasonably practicable after having been electronically filed or furnished to the SEC. The Company's SEC filings are also available at the SEC's website at www.sec.gov.

Investors and the public should note that the Company also announces information at www.factsaboutourprescriptionopioids.com, www.factsabouttalc.com and www.LLTManagementInformation.com. We use these websites to communicate with investors and the public about our products, litigation and other matters. It is possible that the information we post to these websites could be deemed to be material information. Therefore, we encourage investors and others interested in the Company to review the information posted to these websites in conjunction with www.jnj.com, the Company's SEC filings, press releases, public conference calls and webcasts.

In addition, the Amended and Restated Certificate of Incorporation, By-Laws, the written charters of the Audit Committee, the Compensation & Benefits Committee, the Nominating & Corporate Governance Committee, the Regulatory Compliance & Sustainability Committee, the Science & Technology Committee and any special committee of the Board of Directors and the Company's Principles of Corporate Governance, Code of Business Conduct (for employees), Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers, and other corporate governance materials, are available at www.investor.jnj.com/governance/corporate-governance-overview on the Company's website and will be provided without charge to any shareholder submitting a written request, as provided above. The information on www.jnj.com, www.factsaboutourprescriptionopioids.com, www.factsabouttalc.com and www.LLTManagementInformation.com is not, and will not be deemed, a part of this Report or incorporated into any other filings the Company makes with the SEC.

Item 1A. Risk factors

An investment in the Company's common stock or debt securities involves risks and uncertainties. The Company seeks to identify, manage and mitigate risks to our business, but uncertainties and risks are difficult to predict and many are outside of the Company's control and cannot therefore be eliminated. In addition to the other information in this report and the Company's other filings with the SEC, investors should consider carefully the factors set forth below. Investors should be aware that it is not possible to predict or identify all such factors and that the following is not meant to be a complete discussion of all potential risks or uncertainties. If known or unknown risks or uncertainties materialize, the Company's business, results of operations or financial condition could be adversely affected, potentially in a material way.

Risks related to our business, industry and operations

The Company's businesses operate in highly competitive product markets and competitive pressures could adversely affect the Company's earnings.

The Company faces substantial competition in its two operating segments and in all geographic markets. The Company's businesses compete with companies of all sizes on the basis of cost-effectiveness, technological innovations, intellectual property rights, product performance, real or perceived product advantages, pricing and availability and rate of reimbursement. The Company also competes with other market participants in securing rights to acquisitions, collaborations and licensing agreements with third parties. Competition for rights to product candidates and technologies may result in significant investment and acquisition costs and onerous agreement terms for the Company. Competitors' development of more effective or less costly products, and/or their ability to secure patent and other intellectual property rights and successfully market products ahead of the Company, could negatively impact sales of the Company's existing products as well as its ability to bring new products to market despite significant prior investment in the related product development. The Company may also experience operational and financial risk in connection with acquisitions if we are unable to fully identify potential risks and liabilities associated with acquired businesses or products, successfully integrate operations and employees, and successfully identify and realize synergies with existing businesses while containing acquisition-related strain on our management, operations and financial resources.

For the Company's Innovative Medicine businesses, loss of patent exclusivity for a product often is followed by a substantial reduction in sales as competitors gain regulatory approval for generic and other competing products and enter the market. Similar competition can be triggered by the loss of exclusivity for a biological product. For the Company's MedTech businesses, technological innovation, product quality, reputation and customer service are especially important to competitiveness. Development by other companies of new or improved products, processes and technologies could threaten to make the Company's products or technologies less desirable, less economical or obsolete. The Company's business and operations will be negatively impacted if we are unable to introduce new products or technological advances that are safe, more effective, more effectively marketed or otherwise outperform those of our competitors.

Interruptions and delays in manufacturing operations could adversely affect the Company's business, sales and reputation.

The Company's manufacturing of products requires the timely delivery of sufficient amounts of complex, high-quality components and materials. The Company's subsidiaries operate 61 manufacturing facilities as well as sourcing from thousands of suppliers around the world. The Company has in the past, and may in the future, face unanticipated interruptions and delays in manufacturing through its internal or external supply chain. Manufacturing disruptions can occur for many reasons including regulatory action, production quality deviations or safety issues, labor disputes, labor shortages, site-specific incidents (such as fires), natural disasters such as hurricanes and other severe weather events, raw material shortages, political unrest, terrorist attacks and epidemics or pandemics. Such delays and difficulties in manufacturing can result in product shortages, declines in sales and reputational impact as well as significant remediation and related costs associated with addressing the shortage.

The Company relies on third parties to manufacture and supply certain of our products. Any failure by or loss of a third-party manufacturer or supplier could result in delays and increased costs, which may adversely affect our business.

The Company relies on third parties to manufacture and supply certain of our raw materials, component parts and products. We depend on these third-party manufacturers to allocate to us a portion of their manufacturing capacity sufficient to meet our needs, to produce products of acceptable quality and at acceptable manufacturing yields and to deliver those products to us on a timely basis and at acceptable prices. However, we cannot guarantee that these third-party manufacturers will be able to meet our near-term or long-term manufacturing requirements, which could result in lost sales and have an adverse effect on our business.

Other risks associated with our reliance on third parties to manufacture these products include reliance on the third party for regulatory compliance and quality assurance, misappropriation of the Company's intellectual property, limited ability to manage our inventory, possible breach of the manufacturing agreement by the third party and the possible termination or nonrenewal of the manufacturing agreement by the third party at a time that is costly or inconvenient for us. Moreover, if any of our third-party manufacturers suffers any damage to facilities, loses benefits under material agreements, experiences power outages, encounters financial difficulties, is unable to secure necessary raw materials from its suppliers or suffers any other reduction in efficiency, the Company may experience significant business disruption. In the event of any such disruption, the Company would need to seek and source other qualified third-party manufacturers, likely resulting in further delays and increased costs which could affect our business adversely.

Counterfeit versions of our products could harm our patients and have a negative impact on our revenues, earnings, reputation and business.

Our industry continues to be challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Third parties may illegally distribute and sell counterfeit versions of our products, which do not meet our rigorous manufacturing and testing standards. To distributors and patients, counterfeit products may be visually indistinguishable from the authentic version. Counterfeit medicines pose a risk to patient health and safety because of the conditions under which they are manufactured – often in unregulated, unlicensed, uninspected and unsanitary sites – as well as the lack of regulation of their contents.

The industry's failure to mitigate the threat of counterfeit medicines could adversely impact our business and reputation by impacting patient confidence in our authentic products, potentially resulting in lost sales, product recalls, and an increased threat of litigation. In addition, diversion of our products from their authorized market into other channels may result in reduced revenues and negatively affect our profitability.

Global health crises, pandemics, epidemics, or other outbreaks could adversely disrupt or impact certain aspects of the Company's business, results of operations and financial condition.

We are subject to risks associated with global health crises, epidemics, pandemics and other outbreaks (such incident(s), a health crisis or health crises). For example, the COVID-19 pandemic adversely impacted certain aspects of the Company's business, results of operations and financial condition, including lower sales and reduced customer demand and usage of certain of our products. The spread of any health crises may cause the Company to modify its business practices, and take further actions as may be required by government authorities or as the Company determines are in the best interests of our patients, customers, employees and business partners under such circumstances. While the Company has robust business continuity plans in place across our global supply chain network designed to help mitigate the impact of health crises, these efforts may not completely prevent our business from being adversely affected in the event of a health crisis. Health crises could adversely impact the Company's operations, including, among other things, our manufacturing operations, supply chain, third-party suppliers, sales and marketing, and clinical trial operations. Any of these factors could adversely affect the Company's business, financial results, and global economic conditions generally.

Risks related to government regulation and legal proceedings

Global sales in the Company's Innovative Medicine and MedTech segments may be negatively impacted by healthcare reforms and increasing pricing pressures.

Sales of the Company's Innovative Medicine and MedTech products are significantly affected by reimbursements by third-party payors such as government healthcare programs, private insurance plans and managed care organizations. As part of various efforts to contain healthcare costs, these payors are putting downward pressure on prices at which products will be reimbursed. In the U.S., increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, in part due to continued consolidation among healthcare providers, could result in further pricing pressures. In addition, recent legislation and ongoing political scrutiny on pricing, coverage and reimbursement could result in additional pricing pressures. Specifically, the Inflation Reduction Act of 2022 (IRA) may subject certain products to government-established pricing, potentially impose rebates, and subject manufacturers who fail to adhere to the government's interpretations of the law to penalties. Further, increased third-party utilization of the 340B Federal Drug Discount Program from expanded interpretations of the statute may have a negative impact on the Company's financial performance. Outside the U.S., numerous major markets, including the EU, United Kingdom, Japan and China, have pervasive government involvement in funding healthcare and, in that regard, directly or indirectly impose price controls, limit access to, or reimbursement for, the Company's products, or reduce the value of its intellectual property protection.

We are subject to an increasing number of costly and complex governmental regulations in the countries in which operations are conducted which may materially adversely affect the Company's financial condition and business operations.

As described in Item 1. Business, the Company is subject to an increasing number of extensive government laws and regulations, investigations and legal action by national, state and local government agencies in the U.S. and other countries in which it operates. For example, changes to the U.S. FDA's timing or requirements for approval or clearance of our products may have a negative impact on our ability to bring new products to market. New laws and regulations may also impose deadlines on the Company, or its third-party suppliers, manufacturers or other partners and providers, for which there may be insufficient time to implement changes to comply with such new regulations and may result in manufacturing delays or other supply chain constraints. If the Company is unable to identify ways to mitigate these delays or constraints, there may be an adverse effect on sales and access to our products.

The Company is subject to significant legal proceedings that can result in significant expenses, fines and reputational damage.

In the ordinary course of business, Johnson & Johnson and its subsidiaries are subject to numerous claims and lawsuits involving various issues such as product liability, patent disputes and claims that their product sales, marketing and pricing practices violate various antitrust, unfair trade practices and/or consumer protection laws. The Company's more significant legal proceedings are described in Note 19 Legal proceedings under Notes to the Consolidated Financial Statements included in Item 8 of this Report. Litigation, in general, and securities, derivative action, class action and multi-district litigation, in particular, can be expensive and disruptive. Some of these matters may include thousands of plaintiffs, may involve parties seeking large and/or indeterminate amounts, including punitive or exemplary damages, and may remain unresolved for several years. For example, the Company is a defendant in numerous lawsuits arising out of the use of body powders containing talc, primarily JOHNSON'S Baby Powder, and the Company's sale, manufacturing and marketing of opioids. While the Company believes it has substantial defenses in these matters, it is not feasible to predict the ultimate outcome of litigation. The Company could in the future be required to pay significant amounts as a result of settlements or judgments in these matters, potentially in excess of accruals, including matters where the Company could be held jointly and severally liable among other defendants. The resolution of, or increase in accruals for, one or more of these matters in any reporting period could have a material adverse effect on the Company's results of operations and cash flows for that period. The Company does not purchase third-party product liability insurance; however, the Company utilizes a wholly owned captive insurance company subject to certain limits.

Product reliability, safety and effectiveness concerns can have significant negative impacts on sales and results of operations, lead to litigation and cause reputational damage.

Concerns about product safety, whether raised internally or by litigants, regulators or consumer advocates, and whether or not based on scientific evidence, can result in safety alerts, product recalls, governmental investigations, regulatory action on the part of the U.S. FDA (or its counterpart in other countries), private claims and lawsuits, payment of fines and settlements, declining sales and reputational damage. These circumstances can also result in damage to brand image, brand equity and consumer trust in the Company's products. Product recalls have in the past, and could in the future, prompt government investigations and inspections, the shutdown of manufacturing facilities, continued product shortages and related sales declines, significant remediation costs, reputational damage, possible civil penalties and criminal prosecution.

The Company faces significant regulatory scrutiny, which imposes significant compliance costs and exposes the Company to government investigations, legal actions and penalties.

The rapid increase in new government laws and regulations imposes significant compliance costs to the Company and a failure of the Company to timely implement changes to comply with these new laws may expose the Company to investigations, legal actions or penalties. Regulatory issues regarding compliance with current Good Manufacturing Practices (cGMP) (and comparable quality regulations in foreign countries) by manufacturers of drugs and devices can lead to fines and penalties, product recalls, product shortages, interruptions in production, delays in new product approvals and litigation. In addition, the marketing, pricing and sale of the Company's products are subject to regulation, investigations and legal actions including under the Federal Food, Drug, and Cosmetic Act, the Medicaid Rebate Program, federal and state false claims acts, state unfair trade practices acts and consumer protection laws. Scrutiny of healthcare industry business practices by government agencies and state attorneys general in the U.S., and any resulting investigations and prosecutions, carry risk of significant civil and criminal penalties including, but not limited to, debarment from participation in government healthcare programs. Any such debarment could have a material adverse effect on the Company's business and results of operations. The most significant current investigations and litigation brought by government agencies are described in Note 19 Legal proceedings—Government proceedings under Notes to the Consolidated Financial Statements included in Item 8 of this Report.

Changes in tax laws or exposures to additional tax liabilities could negatively impact the Company's operating results.

Changes in tax laws or regulations around the world, including in the U.S. and as led by the Organization for Economic Cooperation and Development, such as the recent enactment by certain EU and non-EU countries, and the anticipated enactment by additional countries, of a global minimum tax, could negatively impact the Company's effective tax rate and results of operations. A change in statutory tax rate or certain international tax provisions in any country would result in the revaluation of the Company's deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is enacted. This change would result in an expense or benefit recorded to the Company's Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries where it operates. Changes to tax laws or regulations may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted.

See Note 8 Income taxes under Notes to the Consolidated Financial Statements included in Item 8 of this Report for additional information.

The Company conducts business and files tax returns in numerous countries and is addressing tax audits and disputes with many tax authorities. In connection with various government initiatives, companies are required to disclose more information to tax authorities on operations around the world, which may lead to greater audit scrutiny of profits earned in other countries. The Company regularly assesses the likely outcomes of its tax audits and disputes to determine the appropriateness of its tax reserves. However, any tax authority could take a position on tax treatment that is contrary to the Company's expectations, which could result in tax liabilities in excess of reserves.

Risks related to our intellectual property

The Company faces increased challenges to intellectual property rights central to its business.

The Company owns or licenses a significant number of patents and other proprietary rights relating to its products and manufacturing processes. These rights are essential to the Company's businesses and materially important to the Company's results of operations. Public policy, both within and outside the U.S., has become increasingly unfavorable toward intellectual property rights. The Company cannot be certain that it will obtain adequate patent protection for new products and technologies in the United States and other important markets or that such protections, once granted, will last as long as originally anticipated.

Competitors routinely challenge the validity or extent of the Company's owned or licensed patents and proprietary rights through litigation, interferences, oppositions and other proceedings, such as inter partes review (IPR) proceedings before the United States Patent & Trademark Office (USPTO). These proceedings absorb resources and can be protracted as well as unpredictable. In addition, challenges that the Company's products infringe the patents of third parties could result in an injunction and/or the need to pay past damages and future royalties and adversely affect the competitive position and sales of the products in question.

The Company has faced increasing patent challenges from third parties seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the U.S., manufacturers of generic versions of innovative human pharmaceutical products may challenge the validity, or claim non-infringement, of innovator products through the Abbreviated New Drug Application, or ANDA, process with the U.S. FDA and related ANDA litigation. The Biologics Price Competition and Innovation Act (BPCIA), enacted in 2010, which created a new regulatory pathway for the approval by the U.S. FDA of biosimilar alternatives to innovator-developed biological products, also created mechanisms for biosimilar applicants to challenge the patents on the innovator biologics. The IPR process with the USPTO is also being used by competitors to challenge patents asserted in litigation.

In the event the Company is not successful in defending its patents against such challenges, or upon the "at-risk" launch by the generic or biosimilar firm of its product, the Company can lose a major portion of revenues for the referenced product in a very short period of time. Current legal proceedings involving the Company's patents and other intellectual property rights are described in Note 19 Legal proceedings—Intellectual property under Notes to the Consolidated Financial Statements included in Item 8 of this Report.

Risks related to product development, regulatory approval and commercialization

Significant challenges or delays in the Company's innovation, development and implementation of new products, technologies and indications could have an adverse impact on the Company's long-term success.

The Company's continued growth and success depends on its ability to innovate and develop new and differentiated products and services that address the evolving healthcare needs of patients, providers and consumers. Development of successful products and technologies is also necessary to offset revenue losses when the Company's existing products lose market share due to various factors such as competition and loss of patent exclusivity. New products introduced within the past five years accounted for approximately 25% of 2023 sales. The Company cannot be certain when or whether it will be able to develop, license or otherwise acquire companies, products and technologies, whether particular product candidates will be granted regulatory approval, and, if approved, whether the products will be commercially successful.

The Company pursues product development through internal research and development as well as through collaborations, acquisitions, joint ventures and licensing or other arrangements with third parties. In all of these contexts, developing new products, particularly pharmaceutical and biotechnology products and medical devices, requires significant investment of resources over many years. Only a very few biopharmaceutical research and development programs result in commercially viable products. The process depends on many factors including the ability to: discern patients' and healthcare providers' future needs; develop promising new compounds, strategies and technologies; achieve successful clinical trial results; secure effective intellectual property protection; obtain regulatory approvals on a timely basis; and, if and when they reach the market, successfully differentiate the Company's products from competing products and approaches to treatment. New products or enhancements to existing products may not be accepted quickly or significantly in the marketplace due to product and price competition, changes in customer preferences or healthcare purchasing patterns, resistance by healthcare providers or uncertainty over third-party reimbursement. Even following initial regulatory approval, the success of a product can be adversely impacted by safety and efficacy findings in larger real-world patient populations, as well as market entry of competitive products.

The Company leverages the use of data science, machine learning and other forms of AI and emerging technologies across varying parts of its business and operations, and the introduction and incorporation of AI may result in unintended consequences or other new or expanded risks and liabilities. AI technology is continuously evolving, and the AI technologies we develop and adopt may become obsolete earlier than planned. Our investments in these technologies may not result in the benefits we anticipate or enable us to obtain or maintain a competitive advantage. The application of machine learning and AI in our business is emerging and evolving alongside new laws and regulations that may entail significant costs or ultimately limit our ability to continue the use of these technologies. These technologies also carry inherent risks related to data privacy and security further described below.

Risks related to financial and economic market conditions

The Company faces a variety of financial, economic, legal, social and political risks associated with conducting business internationally.

The Company's extensive operations and business activity throughout the world are accompanied by certain financial, economic, legal, social and political risks, including those listed below.

Foreign currency exchange: In fiscal 2023, approximately 45% of the Company's sales occurred outside of the U.S., with approximately 24% in Europe, 5% in the Western Hemisphere, excluding the U.S., and 16% in the Asia-Pacific and Africa region. Changes in non-U.S. currencies relative to the U.S. dollar impact the Company's revenues and expenses. While the Company uses financial instruments to mitigate the impact of fluctuations in currency exchange rates on its cash flows, unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the U.S. dollar may result in significant favorable or unfavorable translation effects when the operating results of the Company's non-U.S. business activity are translated into U.S. dollars.

Inflation and currency devaluation risks: The Company faces challenges in maintaining profitability of operations in economies experiencing high inflation rates. Specifically, the Company has accounted for operations in Argentina, Turkey and Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. While the Company strives to maintain profit margins in these areas through cost reduction programs, productivity improvements and periodic price increases, it might experience operating losses as a result of continued inflation. In addition, the impact of currency devaluations in

countries experiencing high inflation rates or significant currency exchange fluctuations could negatively impact the Company's operating results.

Illegal importation of pharmaceutical products: The illegal importation of pharmaceutical products from countries where government price controls or other market dynamics result in lower prices may adversely affect the Company's sales and profitability in the U.S. and other countries in which the Company operates. With the exception of limited quantities of prescription drugs for personal use, foreign imports of pharmaceutical products are illegal under current U.S. law. However, the volume of illegal imports continues to rise as the ability of patients and other customers to obtain the lower-priced imports has grown significantly.

Anti-bribery and other regulations: The Company is subject to various federal and foreign laws that govern its international business practices with respect to payments to government officials. Those laws include the U.S. Foreign Corrupt Practices Act (FCPA), which prohibits U.S. publicly traded companies from promising, offering, or giving anything of value to foreign officials with the corrupt intent of influencing the foreign official for the purpose of helping the Company obtain or retain business or gain any improper advantage. The Company's business is heavily regulated and therefore involves significant interaction with foreign officials. Also, in many countries outside the U.S., the healthcare providers who prescribe human pharmaceuticals are employed by the government and the purchasers of human pharmaceuticals are government entities; therefore, the Company's interactions with these prescribers and purchasers are subject to regulation under the FCPA. In addition to the U.S. application and enforcement of the FCPA, various jurisdictions in which the Company operates have laws and regulations, including the U.K. Bribery Act 2010, aimed at preventing and penalizing corrupt and anticompetitive behavior. Enforcement activities under these laws could subject the Company to additional administrative and legal proceedings and actions, which could include claims for civil penalties, criminal sanctions, and administrative remedies, including exclusion from healthcare programs.

Other financial, economic, legal, social and political risks. Other risks inherent in conducting business globally include:

- local and regional economic environments and policies in the markets that we serve, including interest rates, monetary policy, inflation, economic growth, recession, commodity prices, and currency controls or other limitations on the ability to expatriate cash;
- protective economic policies taken by governments, such as trade protection measures, increased antitrust reporting requirements and enforcement activity, and import/export licensing requirements;
- compliance with local regulations and laws including, in some countries, regulatory requirements restricting the Company's ability to manufacture or sell its products in the relevant market;
- diminished protection of intellectual property and contractual rights in certain jurisdictions;
- potential nationalization or expropriation of the Company's foreign assets;
- political or social upheavals, economic instability, repression, or human rights issues; and
- geopolitical events, including natural disasters, disruptions to markets due to war, armed conflict, terrorism, epidemics or pandemics.

Due to the international nature of the Company's business, geopolitical or economic changes or events, including global tensions and war, could adversely affect our business, results of operations or financial condition.

As described above, the Company has extensive operations and business activity throughout the world. Global tensions, conflict and/or war among any of the countries in which we conduct business or distribute our products may result in foreign currency volatility, decreased demand for our products in affected countries, and challenges to our global supply chain related to increased costs of materials and other inputs for our products and suppliers. Most recently, we have experienced, and expect to continue to experience, impacts to the Company's business resulting from the Russia-Ukraine war, rising conflict in the Middle East as well as increasing tensions between the U.S. and China. In response to heightened conflict, such as the Russia-Ukraine war, governments may impose export controls and broad financial and economic sanctions. Our business and operations may be further impacted by the imposition of trade protection measures or other policies adopted by any country that favor domestic companies and technologies over foreign competitors. Additional sanctions or other measures may be imposed by the global community, including but not limited to limitations on our ability to file, prosecute and maintain patents, trademarks and other intellectual property rights. Furthermore, in some countries, such as in Russia, action may be taken that allows companies and individuals to exploit inventions owned by patent holders from the United States and many other countries without consent or compensation and we may not be able to prevent third parties from practicing the Company's inventions in Russia or from selling or importing products in and into Russia.

Weak financial performance, failure to maintain a satisfactory credit rating or disruptions in the financial markets could adversely affect our liquidity, capital position, borrowing costs and access to capital markets.

We currently maintain investment grade credit ratings with Moody's Investors Service and Standard & Poor's Ratings Services. Rating agencies routinely evaluate us, and their ratings of our long-term and short-term debt are based on a number of factors. Any downgrade of our credit ratings by a credit rating agency, whether as a result of our actions or factors which are beyond our control, can increase the cost of borrowing under any indebtedness we may incur, reduce market capacity for our commercial paper or require the posting of additional collateral under our derivative contracts. There can be no assurance that we will be able to maintain our credit ratings, and any additional actual or anticipated changes or downgrades in our credit ratings, including any announcement that our ratings are under review for a downgrade, may have a negative impact on our liquidity, capital position and access to capital markets.

Other risks

Our business depends on our ability to recruit and retain talented, highly skilled employees and a diverse workforce.

Our continued growth requires us to recruit and retain talented employees representing diverse backgrounds, experiences, and skill sets. The market for highly skilled workers and leaders in our industry is extremely competitive and our ability to compete depends on our ability to hire, develop and motivate highly skilled personnel in all areas of our organization. Maintaining our brand and reputation, as well as a diverse, equitable and inclusive work environment enables us to attract top talent. If we are less successful in our recruiting efforts, or if we cannot retain highly skilled workers and key leaders, our ability to develop and deliver successful products and services may be adversely affected. In addition, effective succession planning is important to our long-term success. Any unsuccessful implementation of our succession plans or failure to ensure effective transfer of knowledge and smooth transitions involving key employees could adversely affect our business, financial condition, or results of operations.

Climate change or legal, regulatory or market measures to address climate change may negatively affect our business and results of operations.

Climate change resulting from increased concentrations of carbon dioxide and other greenhouse gases in the atmosphere could present risks to our operations, including an adverse impact on global temperatures, weather patterns and the frequency and severity of extreme weather and natural disasters. Natural disasters and extreme weather conditions, such as a hurricane, tornado, earthquake, wildfire or flooding, may pose physical risks to our facilities and disrupt the operation of our supply chain. The impacts of the changing climate on water resources may result in water scarcity, limiting our ability to access sufficient high-quality water in certain locations, which may increase operational costs.

Concern over climate change may also result in new or additional legal or regulatory requirements designed to reduce greenhouse gas emissions and/or mitigate the effects of climate change on the environment. If such laws or regulations are more stringent than current legal or regulatory obligations, we may experience disruption in, or an increase in the costs associated with sourcing, manufacturing and distribution of our products, which may adversely affect our business, results of operations or financial condition. Further, the impacts of climate change have an influence on customer preferences, and failure to provide climate-friendly products could potentially result in loss of market share.

An information security incident, including a cybersecurity breach, could have a negative impact on the Company's business or reputation.

To meet business objectives, the Company relies on both internal information technology (IT) systems and networks, and those of third parties and their vendors, to process and store sensitive data, including confidential research, business plans, financial information, intellectual property, and personal data that may be subject to legal protection, and ensure the continuity of the Company's supply chain and operations. The extensive information security and cybersecurity threats, which affect companies globally, pose a risk to the security and availability of these systems and networks, including customer products that are connected to or rely on such systems and networks, and the confidentiality, integrity, and availability of the Company's sensitive data. The Company assesses these threats and makes investments to increase internal protection, detection, and response capabilities, as well as ensure the Company's third-party providers have required capabilities and controls, to address this risk. Because of the frequently changing attack techniques, along with the increased volume and sophistication of the attacks, there is the potential for the Company to be adversely impacted. This impact could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action. Also, increasing use of AI could increase these risks. The Company maintains cybersecurity insurance in the event of an information security or cyber incident; however, the coverage may not be sufficient to cover all financial, legal, business or reputational losses.

As a result of increased global tensions, the Company expects there will continue to be, an increased risk of information security or cybersecurity incidents, including cyberattacks perpetrated by adversaries of countries where the Company maintains operations. Given the potential sophistication of these attacks, the Company may not be able to address the threat of information security or cybersecurity incidents proactively or implement adequate preventative measures and we may not be able to detect and address any such disruption or security breach promptly, or at all, which could adversely affect our business, results of operations or financial condition. Moreover, these threats could also impact our third-party partners resulting in compromise of the Company's IT systems, networks and data which could negatively affect the Company.

A breach of privacy laws or unauthorized access, loss or misuse of personal data could have a negative impact on the Company's business or reputation.

The Company is subject to privacy and data protection laws across the globe that impose broad compliance obligations on the collection, use, storage, access, transfer and protection of personal data. Breach of such requirements could result in substantial fines, penalties, private right of actions, claims and damage to our reputation and business. New privacy laws are expected in other territories, together with greater privacy enforcement by governmental authorities globally, particularly on data localization requirements and international data flows. The Company has established privacy compliance programs and controls that our businesses worldwide are required to comply with, but with many technology and data-driven initiatives being prioritized across the Company and involving multiple vendors and third parties, there are potential risks of controls imposed on cross border data flows, unauthorized access, and loss of personal data through internal and external threats that could impact our business operations and research activities.

The Company may be unable to achieve some or all of the anticipated strategic and financial benefits following the separation of Kenvue Inc. (Kenvue), including with respect to the Company's remaining ownership interest.

The Company incurred significant expenses in connection with the Kenvue separation (the Separation). In addition, the Company may not be able to achieve the full strategic and financial benefits that are expected to result from the Separation. The anticipated benefits of the Separation were based on a number of assumptions, some of which may prove incorrect. The Company holds a 9.5% ownership interest in Kenvue. The Company cannot predict the trading price of shares of Kenvue's common stock and the market value of the Kenvue shares are subject to market volatility and other factors outside of the Company's control. The Company intends to divest its ownership interest in Kenvue, but there can be no assurance regarding the ultimate timing of such divestiture. Unanticipated developments could delay, prevent or otherwise adversely affect the divestiture, including but not limited to financial market conditions.

The Separation could result in substantial tax liability.

The Company received a private letter ruling from the IRS as to the tax-free nature of the Separation under the U.S. Internal Revenue Code of 1986, as amended. Notwithstanding the private letter ruling and opinions of tax advisors, if the IRS determines that certain steps of the transaction did not qualify for tax-free treatment for U.S. federal income tax purposes, the resulting tax liability to the Company and its shareholders could be substantial. The Separation may also not qualify for tax-free treatment in other countries around the world, and as a result may trigger substantial tax liability to the Company.

Item 1B. Unresolved staff comments

Not applicable.

Item 1C. Cybersecurity

Risk management and strategy

The Company has documented cybersecurity policies and standards, assesses risks from cybersecurity threats, and monitors information systems for potential cybersecurity issues. To protect the Company's information systems from cybersecurity threats, the Company uses various security tools supporting protection, detection, and response capabilities. The Company maintains a cybersecurity incident response plan to help ensure a timely, consistent response to actual or attempted cybersecurity incidents impacting the Company.

The Company also identifies and assesses third-party risks within the enterprise, and through the Company's use of third-party service providers, across a range of areas including data security and supply chain through a structured third-party risk management program.

The Company maintains a formal information security training program for all employees that includes training on matters such as phishing and email security best practices. Employees are also required to complete mandatory training on data privacy.

To evaluate and enhance its cybersecurity program, the Company periodically utilizes third-party experts to undertake maturity assessments of the Company's information security program.

To date, the Company is not aware of any cybersecurity incident that has had or is reasonably likely to have a material impact on the Company's business or operations; however, because of the frequently changing attack techniques, along with the increased volume and sophistication of the attacks, there is the potential for the Company to be adversely impacted. This impact could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action. Refer to the risk factor captioned An information security incident, including a cybersecurity breach, could have a negative impact to the Company's business or reputation in Part I, Item 1A. Risk factors for additional description of cybersecurity risks and potential related impacts on the Company.

Governance - management's responsibility

The Company takes a risk-based approach to cybersecurity and has implemented cybersecurity controls designed to address cybersecurity threats and risks. The Chief Information Officer (CIO), who is a member of the Company's Executive Committee, and the Chief Information Security Officer (CISO) are responsible for assessing and managing cybersecurity risks, including the prevention, mitigation, detection, and remediation of cybersecurity incidents.

The Company's CISO, in coordination with the CIO, is responsible for leading the Company's cybersecurity program and management of cybersecurity risk. The current CISO has over twenty-five years of experience in information security, and his background includes technical experience, strategy and architecture focused roles, cyber and threat experience, and various leadership roles.

Governance - board oversight

The Company's Board of Directors oversees the overall risk management process, including cybersecurity risks, directly and through its committees. The Regulatory Compliance & Sustainability Committee (RCSC) of the board is primarily responsible for oversight of risk from cybersecurity threats and oversees compliance with applicable laws, regulations and Company policies related to, among others, privacy and cybersecurity.

RCSC meetings include discussions of specific risk areas throughout the year including, among others, those relating to cybersecurity. The CISO provides at least two updates each year to RCSC on cybersecurity matters. These reports include an overview of the cybersecurity threat landscape, key cybersecurity initiatives to improve the Company's risk posture, changes in the legal and regulatory landscape relative to cybersecurity, and overviews of certain cybersecurity incidents that have occurred within the Company and within the industry.

Item 2. Properties

The Company's subsidiaries operate 61 manufacturing facilities occupying approximately 9.8 million square feet of floor space. The manufacturing facilities are used by the industry segments of the Company's business approximately as follows:

Segment	Square Feet (in thousands)
Innovative Medicine	5,026
MedTech	4,782
Worldwide Total	9,808

Within the U.S., five facilities are used by the Innovative Medicine segment and 18 by the MedTech segment. Outside of the U.S., 13 facilities are used by the Innovative Medicine segment and 25 by the MedTech segment.

The locations of the manufacturing facilities by major geographic areas of the world are as follows:

Geographic Area	Number of Facilities	Square Feet (in thousands)
United States	23	2,973
Europe	20	4,900
Western Hemisphere, excluding U.S.	5	692
Africa, Asia and Pacific	13	1,243
Worldwide Total	61	9,808

In addition to the manufacturing facilities discussed above, the Company maintains numerous office and warehouse facilities throughout the world.

The Company's subsidiaries generally seek to own, rather than lease, their manufacturing facilities, although some, principally in non-U.S. locations, are leased. Office and warehouse facilities are often leased. The Company also engages contract manufacturers.

The Company is committed to maintaining all of its properties in good operating condition.

Segment information on additions to property, plant and equipment is contained in Note 17 Segments of business and geographic areas of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 3. Legal proceedings

The information called for by this item is incorporated herein by reference to the information set forth in Note 19 Legal proceedings of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 4. Mine safety disclosures

Not applicable.

Executive officers of the registrant

Listed below are the executive officers of the Company. There are no family relationships between any of the executive officers, and there is no arrangement or understanding between any executive officer and any other person pursuant to which the executive officer was selected. At the annual meeting of the Board of Directors, the executive officers are elected by the Board to hold office for one year and until their respective successors are elected and qualified, or until earlier resignation or removal.

Name	Age	Position
Vanessa Broadhurst	55	Member, Executive Committee; Executive Vice President, Global Corporate Affairs[(a)]
Joaquin Duato	61	Chairman of the Board; Chief Executive Officer[(b)]
Peter M. Fasolo, Ph.D.	61	Member, Executive Committee; Executive Vice President, Chief Human Resources Officer[(c)]
Elizabeth Forminard	53	Member, Executive Committee; Executive Vice President, General Counsel[(d)]
William N. Hait, M.D., Ph. D.	74	Member, Executive Committee; Executive Vice President, Chief External Innovation and Medical Officer[(e)]
John C. Reed, M.D., Ph.D.	65	Member, Executive Committee; Executive Vice President, Innovative Medicine, R&D[(f)]
Tim Schmid	54	Member, Executive Committee; Executive Vice President, Worldwide Chairman, MedTech[(g)]
James Swanson	58	Member, Executive Committee; Executive Vice President, Chief Information Officer[(h)]
Jennifer L. Taubert	60	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Innovative Medicine[(i)]
Kathryn E. Wengel	58	Member, Executive Committee; Executive Vice President, Chief Technical Operations & Risk Officer[(j)]
Joseph J. Wolk	57	Member, Executive Committee; Executive Vice President, Chief Financial Officer[(k)]

(a) Ms. V. Broadhurst was named Executive Vice President, Global Corporate Affairs and appointed to the Executive Committee in 2022. Ms. Broadhurst rejoined the Company in 2017 and was appointed Company Group Chairman, Global Commercial Strategy Organization in 2018. From 2013 to 2017, she held General Manager roles at Amgen in Inflammation & Cardiovascular, and Cardiovascular & Bone. Prior to her roles at Amgen, she served in various leadership roles at the Company from 2005-2013.

(b) Mr. J. Duato became Chairman of the Board of Directors in January 2023 subsequent to his appointments as Chief Executive Officer and Director in January 2022. Mr. Duato was appointed to the Executive Committee in 2016 when he was named Executive Vice President, Worldwide Chairman, Pharmaceuticals and subsequently served as Vice Chairman of the Executive Committee. Mr. Duato first joined the Company in 1989 with Janssen-Farmaceutica S.A. (Spain), a subsidiary of the Company, and held executive positions of increasing responsibility in all business sectors and across multiple geographies and functions.

(c) Dr. P. M. Fasolo was appointed to the Executive Committee in 2011 and was named Executive Vice President, Chief Human Resources Officer in 2016. He first joined the Company in 2004 as Worldwide Vice President, Human Resources in the MedTech segment, and subsequently served as the Company's Chief Talent Officer. He left Johnson & Johnson in 2007 to join Kohlberg Kravis Roberts & Co. as Chief Talent Officer and returned to the Company in 2010 as the Vice President, Global Human Resources.

(d) Ms. E. Forminard was appointed as Executive Vice President, General Counsel and a member of the Executive Committee in October 2022. Ms. Forminard joined the Company in 2006, serving in roles of increasing responsibility including General Counsel Medical Devices & Diagnostics, General Counsel Consumer Group & Supply Chain, Worldwide Vice President Corporate Governance, and in her immediate past role as General Counsel Pharmaceuticals.

(e) Dr. W. Hait was appointed Executive Vice President, Chief External Innovation, Medical Safety and Global Public Health Officer, and a member of the Executive Committee in 2022. He first joined the Company in 2007 and has served in a number of leadership roles including

Global Head, Janssen Research & Development from 2011 to 2018 and Global Head, Johnson & Johnson Global External Innovation from 2018 to 2022.

(f) Dr. J. C. Reed joined the Company in 2023 as Executive Vice President, Innovative Medicine, R&D and a member of the Executive Committee. Prior to joining the Company, Dr. Reed held executive leadership positions at Sanofi (2018-2022) and Roche (2013-2018), serving on their respective executive committees. He also served as CEO of Sanford-Burnham Medical Research Institute (now Sanford Burnham Prebys) where he established multiple therapeutic area-aligned research centers and platform technology centers.

(g) Mr. T. Schmid was named as Executive Vice President, Worldwide Chairman, MedTech and appointed to the Executive Committee in October 2023. He joined the Company in 1993 and has served in leadership positions throughout Johnson & Johnson MedTech, including Chief Strategic Customer Officer and President of Ethicon, and most recently served as Company Group Chairman MedTech Asia Pacific from 2018-2023.

(h) Mr. J. Swanson was appointed Executive Vice President, Chief Information Officer and a member of the Executive Committee in 2022. He rejoined the Company in 2019 as Chief Information Officer of Johnson & Johnson from Bayer Crop Science, where he served as a member of the Executive Leadership Team and as Chief Information Officer and Head of Digital Transformation. From 1996 to 2005, Mr. Swanson held positions of increasing responsibility at the Company, including Project Manager, Director IT, Sr. Director IT and Vice President, Chief Information Officer.

(i) Ms. J. L. Taubert was appointed Executive Vice President, Worldwide Chairman, Innovative Medicine (formerly Pharmaceuticals) and a member of the Executive Committee in 2018. She joined the Company in 2005 as Worldwide Vice President and held several executive positions of increasing responsibility in the Pharmaceuticals sector, including Company Group Chairman, North America, and Company Group Chairman, The Americas from 2012-2018.

(j) Ms. K. E. Wengel was appointed Executive Vice President, Chief Technical Operations & Risk Officer in 2023, subsequent to her appointment to the Executive Committee in 2018 when she was named as Executive Vice President, Chief Global Supply Chain Officer. Ms. Wengel first joined the Company in 1988 as Project Engineer and Engineering Supervisor at Janssen, a subsidiary of the Company. During her tenure with the Company, she has held a variety of strategic leadership and executive positions, including in roles within operations, quality, engineering, new products, information technology, and other technical and business functions.

(k) Mr. J. J. Wolk was appointed Executive Vice President, Chief Financial Officer and a member of the Executive Committee in July 2018. He first joined the Company in 1998 as Finance Manager, Business Development for Ortho-McNeil, a subsidiary of the Company. During his tenure at the Company, he has held a variety of senior leadership roles in several segments and functions across the Company's subsidiaries, including Vice President, Finance and Chief Financial Officer of the Janssen Pharmaceutical Companies, and Vice President, Investor Relations.

Part II

Item 5. Market for registrant's common equity, related stockholder matters and issuer purchases of equity securities

As of February 9, 2024, there were 118,772 record holders of common stock of the Company. Additional information called for by this item is incorporated herein by reference to the following sections of this Report: Note 16 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements included in Item 8; and Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters – Equity Compensation Plan Information."

Issuer purchases of equity securities

On September 14, 2022, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's Common Stock. The repurchase program was completed during the fiscal first quarter of 2023.

The following table provides information with respect to common stock purchases by the Company during the fiscal fourth quarter of 2023. Common stock purchases on the open market are made as part of a systematic plan to meet the needs of the Company's compensation programs. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal fourth quarter.

Fiscal Period	Total Number of Shares Purchased[1]	Avg. Price Paid Per Share	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
October 2, 2023 through October 29, 2023	—	—	—	—
October 30, 2023 through November 26, 2023	125,000	$147.61	—	—
November 27, 2023 through December 31, 2023	1,265,000	$156.76	—	—
Total	**1,390,000**		**—**	

[1] During the fiscal fourth quarter of 2023, the Company repurchased an aggregate of 1,390,000 shares of Johnson & Johnson Common Stock in open-market transactions, all of which were purchased as part of a systematic plan to meet the needs of the Company's compensation programs.

Item 6. Reserved

Item 7. Management's discussion and analysis of results of operations and financial condition

Organization and business segments

Description of the company and business segments

Johnson & Johnson and its subsidiaries (the Company) have approximately 131,900 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the healthcare field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The Company is organized into two business segments: Innovative Medicine and MedTech. The Innovative Medicine segment is focused on the following therapeutic areas, including Immunology, Infectious diseases, Neuroscience, Oncology, Pulmonary Hypertension, and Cardiovascular and Metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, distributors, hospitals and healthcare professionals for prescription use. The MedTech segment includes a broad portfolio of products used in the Orthopaedic, Surgery, Interventional Solutions and Vision fields. These products are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Innovative Medicine and MedTech business segments.

In all of its product lines, the Company competes with other companies both locally and globally, throughout the world. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products, as well as protecting the underlying intellectual property of the Company's product portfolio, is important to the Company's success in all areas of its business. The competitive environment requires substantial investments in continuing research.

Management's objectives

With "Our Credo" as the foundation, the Company's purpose is to blend heart, science and ingenuity to profoundly impact health for humanity. The Company, believes health is everything. The Company's strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through the Company's expertise in Innovative Medicine and MedTech, the Company is uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity.

New products introduced within the past five years accounted for approximately 25% of 2023 sales. In 2023, $15.1 billion was invested in research and development reflecting management's commitment to create life-enhancing innovations and to create value through partnerships that will profoundly impact of health for humanity.

A critical driver of the Company's success is the diversity of its 131,900 employees worldwide. Employees are empowered and inspired to lead with Our Credo and purpose as guides. This allows every employee to use the Company's reach and size to advance the Company's purpose, and to also lead with agility and urgency. Leveraging the extensive resources across the enterprise enables the Company to innovate and execute with excellence. This ensures the Company can remain focused on addressing the unmet needs of society every day and invest for an enduring impact, ultimately delivering value to its patients, consumers and healthcare professionals, employees, communities and shareholders.

*Includes acquisitions of in process research and development assets that were not accounted for as a business combination

Results of operations

Analysis of consolidated sales

For discussion on results of operations and financial condition pertaining to the fiscal years 2022 and 2021 see the Company's Annual Report on Form 10-K for the fiscal year ended January 1, 2023, Item 7. Management's discussion and analysis of results of operations and financial condition. Prior periods disclosed herein were recast to reflect the continuing operations of the Company.

In 2023, worldwide sales increased 6.5% to $85.2 billion as compared to an increase of 1.6% in 2022. These sales changes consisted of the following:

Sales increase/(decrease) due to:	2023	2022
Volume	6.8 %	8.3 %
Price	0.6	(1.8)
Currency	(0.9)	(4.9)
Total	**6.5 %**	**1.6 %**

The net impact of acquisitions and divestitures on the worldwide sales growth was a positive impact of 1.5% in 2023 and no impact in 2022.

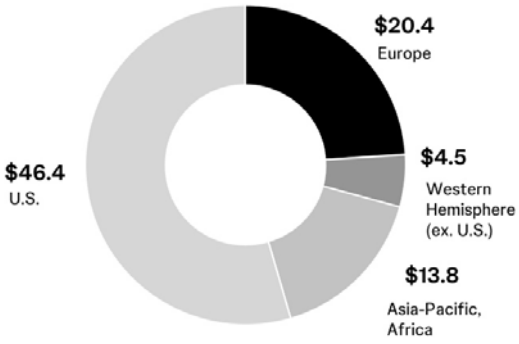
Sales by U.S. companies were $46.4 billion in 2023 and $42.0 billion in 2022. This represents increases of 10.6% in 2023 and 3.3% in 2022. Sales by international companies were $38.7 billion in 2023 and $38.0 billion in 2022. This represents an increase of 1.9% in 2023 and a decrease of 0.2% in 2022.

The five-year compound annual growth rates for worldwide, U.S. and international sales were 4.7%, 5.2% and 4.1%, respectively. The ten-year compound annual growth rates for worldwide, U.S. and international sales were 4.2%, 5.7% and 2.6%, respectively.

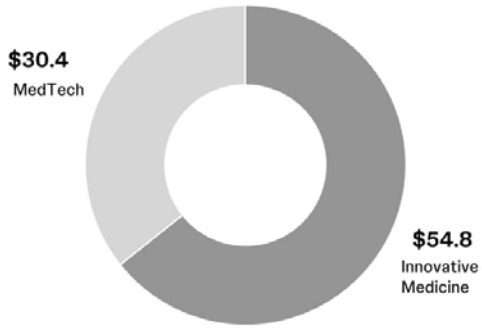
In 2023, sales by companies in Europe experienced a decline of 1.2% as compared to the prior year, which included an operational decline of 2.2% and a positive currency impact of 1.0%. In fiscal 2023, the net impact of the Covid-19 Vaccine and the loss of exclusivity of Zytiga on the European regions change in operational sales was a negative 9.8%. Sales by companies in the Western Hemisphere, excluding the U.S., achieved growth of 10.7% as compared to the prior year, which included operational growth of 15.8%, and a negative currency impact of 5.1%. Sales by companies in the Asia-Pacific, Africa region achieved growth of 3.9% as compared to the prior year, including operational growth of 9.5% and a negative currency impact of 5.6%.

In 2023, the Company utilized three wholesalers distributing products for both segments that represented approximately 18.2%, 15.1% and 14.2% of the total consolidated revenues. In 2022, the Company had three wholesalers distributing products for both segments that represented approximately 18.9%, 15.0% and 13.8% of the total consolidated revenues.

2023 Sales by geographic region (in billions)



2023 Sales by segment (in billions)



Note: values may have been rounded

Analysis of sales by business segments

Innovative Medicine segment[(1)]

Innovative Medicine segment sales in 2023 were $54.8 billion, an increase of 4.2% from 2022, which included operational growth of 4.8% and a negative currency impact of 0.6%. U.S. sales were $31.2 billion, an increase of 9.0%. International sales were $23.6 billion, a decrease of 1.5%, which included an operational decline of 0.2% and a negative currency impact of 1.3%. In 2023, acquisitions and divestitures had a net negative impact of 0.1% on the operational sales growth of the worldwide Innovative Medicine segment.

Major Innovative Medicine therapeutic area sales:

(Dollars in Millions)	2023	2022	Total Change	Operations Change	Currency Change
Total Immunology	**$18,052**	**$16,935**	**6.6 %**	**7.1 %**	**(0.5) %**
REMICADE	1,839	2,343	(21.5)	(20.7)	(0.8)
SIMPONI/SIMPONI ARIA	2,197	2,184	0.6	2.4	(1.8)
STELARA	10,858	9,723	11.7	11.9	(0.2)
TREMFYA	3,147	2,668	17.9	18.3	(0.4)
Other Immunology	11	17	(33.8)	(33.8)	—
Total Infectious Diseases	**4,418**	**5,449**	**(18.9)**	**(19.8)**	**0.9**
COVID-19 VACCINE	1,117	2,179	(48.8)	(50.1)	1.3
EDURANT/rilpivirine	1,150	1,008	14.1	11.5	2.6
PREZISTA/ PREZCOBIX/REZOLSTA/SYMTUZA	1,854	1,943	(4.6)	(4.9)	0.3
Other Infectious Diseases	297	318	(6.7)	(3.6)	(3.1)
Total Neuroscience	**7,140**	**6,893**	**3.6**	**5.4**	**(1.8)**
CONCERTA/methylphenidate	783	644	21.6	24.9	(3.3)
INVEGA SUSTENNA/XEPLION/INVEGA TRINZA/TREVICTA	4,115	4,140	(0.6)	0.0	(0.6)
SPRAVATO	689	374	84.1	84.0	0.1
Other Neuroscience[2]	1,553	1,734	(10.4)	(5.9)	(4.5)
Total Oncology	**17,661**	**15,983**	**10.5**	**11.2**	**(0.7)**
CARVYKTI	500	133	*	*	*
DARZALEX	9,744	7,977	22.2	22.9	(0.7)
ERLEADA	2,387	1,881	26.9	27.5	(0.6)
IMBRUVICA	3,264	3,784	(13.7)	(13.2)	(0.5)
ZYTIGA /abiraterone acetate	887	1,770	(49.9)	(48.4)	(1.5)
Other Oncology	879	438	*	*	*
Total Pulmonary Hypertension	**3,815**	**3,417**	**11.6**	**12.9**	**(1.3)**
OPSUMIT	1,973	1,783	10.6	11.6	(1.0)
UPTRAVI	1,582	1,322	19.7	20.4	(0.7)
Other Pulmonary Hypertension	260	313	(16.7)	(12.0)	(4.7)
Total Cardiovascular / Metabolism / Other	**3,671**	**3,887**	**(5.5)**	**(5.5)**	**0.0**
XARELTO	2,365	2,473	(4.4)	(4.4)	—
Other[3]	1,306	1,414	(7.6)	(7.4)	(0.2)
Total Innovative Medicine Sales	**$54,759**	**52,563**	**4.2 %**	**4.8 %**	**(0.6) %**

* Percentage greater than 100% or not meaningful

(1) Previously referred to as Pharmaceutical

(2) Inclusive of RISPERDAL CONSTA which was previously disclosed separately

(3) Inclusive of INVOKANA which was previously disclosed separately

Immunology products achieved sales of $18.1 billion in 2023, representing an increase of 6.6% as compared to the prior year. Increased sales of STELARA (ustekinumab) were primarily driven by patient mix, market growth, and continued strength in Inflammatory Bowel Disease. Growth of TREMFYA (guselkumab) was due to market growth, continued strength in PsO/PsA (Psoriasis and Psoriatic Arthritis) and patient mix. Additionally, SIMPONI/SIMPONI ARIA growth was driven by growth outside the U.S. Lower sales of REMICADE (infliximab) were due to biosimilar competition.

Biosimilar versions of REMICADE have been introduced in the United States and certain markets outside the United States and additional competitors continue to enter the market. Continued infliximab biosimilar competition will result in a further reduction in sales of REMICADE.

Sales of STELARA in the United States were approximately $7.0 billion in fiscal 2023. Third parties have filed abbreviated Biologics License Applications with the FDA seeking approval to market biosimilar versions of STELARA. The Company has settled certain litigation under the Biosimilar Price Competition and Innovation Act of 2009. As a result of these settlements and other agreements with separate third parties, the Company does not anticipate the launch of a biosimilar version of STELARA until January 1, 2025 in the United States.

Infectious disease products sales were $4.4 billion in 2023, a decline of 18.9% as compared to the prior year primarily driven by a decline in COVID-19 vaccine revenue and loss of exclusivity of PREZISTA.

Neuroscience products sales were $7.1 billion in 2023, representing an increase of 3.6% as compared to the prior year. The growth of SPRAVATO (esketamine) was driven by ongoing launches as well as increased physician confidence and patient demand. Growth was partially offset by declines in RISPERDAL/RISPERDAL CONSTA and the paliperidone long-acting injectables outside the U.S. due to the XEPLION loss of exclusivity in the European Union.

Oncology products achieved sales of $17.7 billion in 2023, representing an increase of 10.5% as compared to the prior year. Sales of DARZALEX (daratumumab) were driven by continued share gains in all regions and market growth. Growth of ERLEADA (apalutamide) was due to continued share gains and market growth in Metastatic Castration Resistant Prostate Cancer. Sales of CARVYKTI (ciltacabtagene autoleucel) were driven by the ongoing launch, share gains and capacity improvement. Additionally, sales from the launch of TECVAYLI (teclistamab-cqyv) and TALVEY (talquetamab-tgvs), included in Other Oncology, contributed to the growth. Growth was partially offset by ZYTIGA (abiraterone acetate) due to loss of exclusivity and IMBRUVICA (ibrutinib) due to global competitive pressures.

Pulmonary Hypertension products sales were $3.8 billion, representing an increase of 11.6% as compared to the prior year. Sales growth was due to favorable patient mix, share gains and market growth from UPTRAVI (selexipag) and OPSUMIT (macitentan) partially offset by declines in Other Pulmonary Hypertension.

Cardiovascular/Metabolism/Other products sales were $3.7 billion, a decline of 5.5% as compared to the prior year. The decline of XARELTO (rivaroxaban) sales was primarily driven by unfavorable patient mix and access changes.

The Company maintains a policy that no end customer will be permitted direct delivery of product to a location other than the billing location. This policy impacts contract pharmacy transactions involving non-grantee 340B covered entities for most of the Company's drugs, subject to multiple exceptions. Both grantee and non-grantee covered entities can maintain certain contract pharmacy arrangements under policy exceptions. The Company has been and will continue to offer 340B discounts to covered entities on all of its covered outpatient drugs, and it believes its policy will improve its ability to identify inappropriate duplicate discounts and diversion prohibited by the 340B statute. The 340B Drug Pricing Program is a U.S. federal government program requiring drug manufacturers to provide significant discounts on covered outpatient drugs to covered entities. This policy had discount implications which positively impacted sales to customers in 2023.

During 2023, the Company advanced its pipeline with several regulatory submissions and approvals for new drugs and additional indications for existing drugs as follows:

Product Name (Chemical Name)	Indication	US Approval	EU Approval	US Filing	EU Filing
AKEEGA (Niraparib and Abiraterone Acetate)	First-And-Only Dual Action Tablet for the Treatment of Patients with BRCA-Positive Metastatic Castration-Resistant Prostate Cancer (MAGNITUDE)	▯	▯		
BALVERSA (erdafitinib)	Treatment of Patients with Locally Advanced or Metastatic Urothelial Carcinoma and Selected Fibroblast Growth Factor Receptor Gene Alterations (THOR)			▯	▯
CARVYKTI (ciltacabtagene autoleucel)	Treatment for Relapsed and Refactor multiple myeloma with 1-3 PL (CARTITUDE-4)			▯	▯
EDURANT (rilpivirine)	Treatment for pediatric patients (2-12 years old) with HIV			▯	▯
ERLEADA (apalutamide)	Tablet reduction	▯	▯		
OPSUMIT (macitentan)	Treatment for pediatric pulmonary arterial hypertension				▯
OPSYNVI (mecitentan/tadalafil STCT)	Treatment for pulmonary arterial hypertension			▯	▯
RYBREVANT (amivantamab)	In Combination with Chemotherapy for the First-Line Treatment of Adult Patients with Advanced Non-Small Cell Lung Cancer with Activating EGFR Exon 20 Insertion Mutations (PAPILLON)			▯	▯
RYBREVANT / lazertinib	Treatment for Non-Small Cell Lung Cancer 2L (MARIPOSA)			▯	▯
RYBREVANT / lazertinib	Treatment for Non-Small Cell Lung Cancer 2L (MARIPOSA-2)			▯	▯
TECVAYLI (teclistamab)	Treatment of Patients with Relapsed Refractory Multiple Myeloma Biweekly Dosing		▯		
TALVEY (talquetamab)	Treatment of Patients with Relapsed and Refractory Multiple Myeloma	▯	▯		

MedTech segment

The MedTech segment sales in 2023 were $30.4 billion, an increase of 10.8% from 2022, which included operational growth of 12.4% and a negative currency impact of 1.6%. U.S. sales were $15.3 billion, an increase of 14.2% as compared to the prior year. International sales were $15.1 billion, an increase of 7.7% as compared to the prior year, which included operational growth of 10.6% and a negative currency impact of 2.9%. In 2023, the net impact of acquisitions and divestitures on the MedTech segment worldwide operational sales growth was a positive 4.6% primarily related to the Abiomed acquisition.

Major MedTech franchise sales:

(Dollars in Millions)	2023	2022	Total Change	Operations Change	Currency Change
Surgery	**$10,037**	**9,690**	**3.6 %**	**5.5 %**	**(1.9) %**
Advanced	4,671	4,569	2.2	4.2	(2.0)
General	5,366	5,121	4.8	6.8	(2.0)
Orthopaedics	**8,942**	**8,587**	**4.1**	**4.6**	**(0.5)**
Hips	1,560	1,514	3.0	3.5	(0.5)
Knees	1,456	1,359	7.1	7.5	(0.4)
Trauma	2,979	2,871	3.8	4.0	(0.2)
Spine, Sports & Other	2,947	2,843	3.7	4.5	(0.8)
Interventional Solutions	**6,350**	**4,300**	**47.7**	**49.8**	**(2.1)**
Electrophysiology	4,688	3,937	19.1	21.1	(2.0)
Abiomed	1,306	31	*	*	*
Other Interventional Solutions	356	332	7.1	9.9	(2.8)
Vision	**5,072**	**4,849**	**4.6**	**6.6**	**(2.0)**
Contact Lenses/Other	3,702	3,543	4.5	6.9	(2.4)
Surgical	1,370	1,306	4.9	5.8	(0.9)
Total MedTech Sales	**$30,400**	**27,427**	**10.8 %**	**12.4 %**	**(1.6) %**

* Percentage greater than 100% or not meaningful

The Surgery franchise sales were $10.0 billion in 2023, representing an increase of 3.6% from 2022. The growth in Advanced Surgery was primarily driven by Biosurgery global procedure growth and strength of the portfolio as well as uptake of new products in Endocutters and Energy. The growth was partially offset by competitive pressures and volume-based procurement impacts in Endocutters and Energy. The growth in General Surgery was primarily driven by increased procedures coupled with technology penetration and benefits from the differentiated Wound Closure portfolio.

The Orthopaedics franchise sales were $8.9 billion in 2023, representing an increase of 4.1% from 2022. The growth in hips reflects global procedure growth and continued strength of the portfolio partially offset by volume-based procurement impacts and Russia sanctions. The growth in knees was primarily driven by procedures, benefits from recent product additions to the ATTUNE portfolio and pull through related to the VELYS Robotic assisted solution. This was partially offset by stocking dynamics, primarily outside the U.S. The growth in Trauma was driven by global procedures and the adoption of recently launched products. This was partially offset by volume-based procurement impacts. The growth in Spine, Sports & Other was primarily driven by Digital Solutions, Shoulders, Sports and Craniomaxillofacial products partially offset by Russia sanctions and supply constraints, primarily outside the U.S.

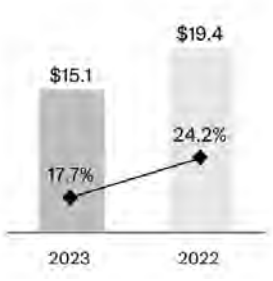
The Interventional Solutions franchise achieved sales of $6.4 billion in 2023, representing an increase of 47.7% from 2022, which includes sales from Abiomed acquired on December 22, 2022. Electrophysiology grew by double digits due to global procedure growth, new product performance and commercial execution. This was partially offset by the impacts of volume-based procurement in China. Abiomed sales reflect the strength of all commercialized regions and continued adoption of Impella 5.5 and Impella RP.

The Vision franchise achieved sales of $5.1 billion in 2023, representing an increase of 4.6% from 2022. The Contact Lenses/Other growth was primarily driven by the continued strong performance in the ACUVUE OASYS 1-Day family including recent launches and commercial execution. This was partially offset by impacts of U.S. stocking dynamics, Russia sanctions, impacts from strategic portfolio decisions and supply challenges. The Surgical operational growth was primarily driven by cataract procedure growth, continued strength of recent innovations and reduction of prior year stocking outside the U.S. This was partially offset by softer Refractive and premium IOL markets and Russia sanctions.

Analysis of consolidated earnings before provision for taxes on income

Consolidated earnings before provision for taxes on income was $15.1 billion and $19.4 billion for the years 2023 and 2022, respectively. As a percent to sales, consolidated earnings before provision for taxes on income was 17.7% and 24.2%, in 2023 and 2022, respectively.

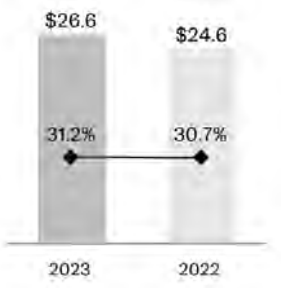
Earnings before provision for taxes



(Dollars in billions. Percentages in chart are as a percent to total sales)

Cost of products sold and selling, marketing and administrative expenses:

Cost of products sold



Selling, marketing & administrative

(Dollars in billions. Percentages in chart are as a percent to total sales)

Cost of products sold:

Cost of products sold increased as a percent to sales driven by:

- Commodity inflation, unfavorable product mix, restructuring related excess inventory costs and Abiomed amortization in the MedTech business

partially offset by

- Favorable patient mix and lower one-time COVID-19 vaccine manufacturing related exit costs in 2023 in the Innovative Medicine business

The intangible asset amortization expense included in cost of products sold was $4.5 billion and $3.9 billion for the fiscal years 2023 and 2022, respectively.

Selling, Marketing and Administrative expense:

Selling, Marketing and Administrative Expenses decreased slightly as a percent to sales driven by:

- Leveraging in Selling and Marketing expenses both the Innovative Medicine and MedTech businesses

partially offset by

- An increase in administrative costs

Research and Development Expense:

Research and development expense by segment of business was as follows:

	2023		2022	
(Dollars in Millions)	**Amount**	**% of Sales***	**Amount**	**% of Sales***
Innovative Medicine	$11,963	21.8 %	$11,642	22.1 %
MedTech	3,122	10.3	2,493	9.1
Total research and development expense	**$15,085**	**17.7 %**	**$14,135**	**17.7 %**
Percent increase/(decrease) over the prior year	6.7 %		(1.0 %)	

*As a percent to segment sales

Research and development activities represent a significant part of the Company's business. These expenditures relate to the processes of discovering, testing and developing new products, upfront payments and developmental milestones, improving existing products, as well as ensuring product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products.

Research and Development was flat as a percent to sales primarily driven by:

- Higher milestone payments in the Innovative Medicine business
- Acquired in-process research & development asset from the Laminar acquisition in the MedTech business in the fiscal year 2023

offset by

- Portfolio prioritization in the Innovative Medicine business

In-Process Research and Development Impairments (IPR&D): In the fiscal year 2023, the Company recorded a charge of approximately $0.3 billion which included $0.2 billion related to market dynamics associated with a non-strategic asset (M710) acquired as part of the acquisition of Momenta Pharmaceuticals in 2020, In the fiscal year 2022, the Company recorded an intangible asset impairment charge of approximately $0.8 billion related to an in-process research and development asset, bermekimab (JnJ-77474462), an investigational drug for the treatment of Atopic Dermatitis (AD) and Hidradenitis Suppurativa (HS). Additional information regarding efficacy of the AD indication and HS indication became available which led the Company to the decision to terminate the development of bermekimab for both AD and HS. The Company acquired all rights to bermekimab from XBiotech, Inc. in the fiscal year 2020.

Other (Income) Expense, Net: Other (income) expense, net is the account where the Company records gains and losses related to the sale and write-down of certain investments in equity securities held by Johnson & Johnson Innovation - JJDC, Inc. (JJDC), changes in the fair value of securities, investment (income)/loss related to employee benefit programs, gains and losses on divestitures, certain transactional currency gains and losses, acquisition and divestiture related costs, litigation accruals and settlements, as well as royalty income.

Other (income) expense, net for the fiscal year 2023 was unfavorable by $5.8 billion as compared to the prior year primarily due to the following:

(Dollars in Billions)(Income)/Expense	2023	2022	Change
Litigation related[1]	$6.9	0.9	6.0
Changes in the fair value of securities[2]	0.6	0.7	(0.1)
COVID-19 vaccine manufacturing exit related costs	0.4	0.7	(0.3)
Acquisition, Integration and Divestiture related[3]	0.3	0.2	0.1
Employee benefit plan related	(1.4)	(1.2)	(0.2)
Other	(0.2)	(0.5)	0.3
Total Other (Income) Expense, Net	**$6.6**	**0.8**	**5.8**

(1) 2023 was primarily related to the approximately $7.0 billion charge for talc (See Note 19 to the Consolidated Financial Statements for more details) and favorable intellectual property related litigation settlements of approximately $0.3 billion. 2022 was primarily related to pelvic mesh.

(2) The fiscal 2023 includes $0.4 billion related to the unfavorable change in the fair value of the remaining stake in Kenvue and $0.4 billion related to the partial impairment of Idorsia convertible debt and the change in the fair value of the Idorsia equity securities held.

(3) 2023 primarily related to the impairment of Ponvory and one-time integration costs related to the acquisition of Abiomed. 2022 was primarily costs related to the acquisition of Abiomed.

Interest (Income) Expense: Interest income in the fiscal year 2023 was $1.3 billion as compared to interest income of $0.5 billion in the fiscal year 2022 primarily due to higher rates of interest earned on cash balances. Interest expense in the fiscal year 2023 was $0.8 billion as compared to interest expense of $0.3 billion in the fiscal year 2022 primarily due to higher interest rates on debt balances. Cash, cash equivalents and marketable securities totaled $22.9 billion at the end of 2023, and averaged $22.6 billion as compared to the cash, cash equivalents and marketable securities total of $22.3 billion and $26.9 billion average balance in 2022. The total debt balance at the end of 2023 was $29.3 billion with an average debt balance of $34.5 billion as compared to $39.6 billion at the end of 2022 and an average debt balance of $36.7 billion. The lower average cash, cash equivalents and marketable securities was primarily due to the acquisition of Abiomed in late December of 2022. The lower average debt balance was primarily due to the repayment of commercial paper.

Income before tax by segment

Income (loss) before tax by segment of business were as follows:

	Income Before Tax		Segment Sales		Percent of Segment Sales	
(Dollars in Millions)	2023	2022	2023	2022	2023	2022
Innovative Medicine	$18,246	15,647	54,759	52,563	33.3 %	29.8
MedTech	4,669	4,447	30,400	27,427	15.4	16.2
Segment earnings before tax[1]	22,915	20,094	85,159	79,990	26.9	25.1
Less: Expenses not allocated to segments[2]	7,853	735				
Worldwide income before tax	$15,062	19,359	85,159	79,990	17.7 %	24.2

(1) See Note 17 to the Consolidated Financial Statements for more details.

(2) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense. Fiscal 2023 includes an approximately $7.0 billion charge related to talc matters and the approximately $0.4 billion unfavorable change in the fair value of the retained stake in Kenvue.

Innovative Medicine segment:

In 2023, the Innovative Medicine segment income before tax as a percent to sales was 33.3% versus 29.8% in 2022. The increase in the income before tax as a percent of sales was primarily driven by the following:

- Lower one-time COVID-19 Vaccine related exit costs of $0.7 billion in 2023 versus $1.5 billion in 2022
- Lower In-process research & development impairments of $0.2 billion in 2023 versus $0.8 billion in 2022
- Unfavorable changes in the fair value of securities in 2023 of $0.4 billion as compared to $0.7 billion in 2022
- Lower litigation related expense of $0.2 billion
- Leveraging in selling and marketing expenses
- R&D Portfolio prioritization

partially offset by

- Restructuring charges of $0.5 billion in 2023 versus $0.1 billion in 2022
- Impairment of Ponvory in 2023
- Higher milestone payments in 2023

MedTech segment:

In 2023, the MedTech segment income before tax as a percent to sales was 15.4% versus 16.2% in 2022. The decrease in the income before tax as a percent to sales was primarily driven by the following:

- Higher amortization expense of $0.5 billion in 2023 related to Abiomed
- Expense of $0.4 billion for an acquired in process research and development asset from the Laminar acquisition in 2023
- Commodity inflation in 2023

partially offset by

- Income from litigation settlements of $0.1 billion in 2023 versus expense of $0.6 billion in 2022
- Lower integration/acquisition costs related to Abiomed of $0.2 billion in 2023 versus $0.3 billion in 2022
- Leveraging in selling and marketing expenses in 2023

Restructuring: In the fiscal year 2023, the Company completed a prioritization of its research and development (R&D) investment within the Innovative Medicine segment to focus on the most promising medicines with the greatest benefit to patients. This resulted in the exit of certain programs within therapeutic areas. The R&D program exits are primarily in infectious diseases and vaccines including the discontinuation of its respiratory syncytial virus (RSV) adult vaccine program, hepatitis and HIV development. The pre-tax restructuring charge of approximately $0.5 billion in the fiscal year 2023, of which $449 million was recorded in Restructuring and $30 million was recorded in Cost of products sold on the Consolidated Statement of Earnings, included the termination of partnered and non-partnered program costs and asset impairments.

In the fiscal year 2023, the Company initiated a restructuring program of its Orthopaedics franchise within the MedTech segment to streamline operations by exiting certain markets, product lines and distribution network arrangements. The pre-tax restructuring expense of $0.3 billion in the fiscal year 2023, of which $40 million was recorded in Restructuring and $279 million was recorded in Cost of products sold on the Consolidated Statement of Earnings, primarily included inventory and instrument charges related to market and product exits.

In 2022, the Company recorded a pre-tax charge of $0.4 billion related to a restructuring program of its Global Supply Chain. The Global Supply Chain program was announced in the second quarter of 2018 and was completed in the fiscal fourth quarter of 2022.

See Note 20 to the Consolidated Financial Statements for additional details related to the restructuring programs.

Provision for Taxes on Income: The worldwide effective income tax rate from continuing operations was 11.5% in 2023 and 15.4% in 2022.

On December 15, 2022, the European Union (EU) Member States formally adopted the EU's Pillar Two Directive, which generally provides for a minimum effective tax rate of 15%, as established by the Organization for Economic Co-operation and Development (OECD) Pillar Two Framework that was supported by over 130 countries worldwide. As of December 31, 2023, several EU and non-EU countries have enacted Pillar 2 legislation with an initial effective date of January 1, 2024, with other aspects of the law effective in 2025 or later. The Company is estimating that as result of this legislation the 2024 effective tax rate will increase by approximately 1.5% or 150 basis points compared to fiscal 2023. Further legislation, guidance and regulations that may be issued in fiscal 2024, as well as other business events, may impact this estimate.

For discussion related to the fiscal 2023 provision for taxes refer to Note 8 to the Consolidated Financial Statements.

Liquidity and capital resources

Liquidity & cash flows

Cash and cash equivalents were $21.9 billion at the end of 2023 as compared to $14.1 billion at the end of 2022.

The primary sources and uses of cash that contributed to the $7.8 billion increase were:

(Dollars in billions)	
$14.1	Q4 2022 Cash and cash equivalents balance
22.8	cash generated from operating activities
0.9	net cash from investing activities
(15.8)	net cash used by financing activities
(0.1)	effect of exchange rate and rounding
$21.9	Q4 2023 Cash and cash equivalents balance

In addition, the Company had $1.1 billion in marketable securities at the end of fiscal year 2023 and $9.4 billion at the end of fiscal year 2022. See Note 1 to the Consolidated Financial Statements for additional details on cash, cash equivalents and marketable securities.

Cash flow from operations of $22.8 billion was the result of:

(Dollars In billions)	
$35.2	Net Earnings
(14.9)	gain on the Kenvue separation, net gain on sale of assets/businesses and the deferred tax provision partially offset by non-cash expenses and other adjustments primarily for depreciation and amortization, stock-based compensation, asset write-downs and charge for purchase of in process research and development assets
5.6	an increase in current and non-current liabilities
(3.5)	an increase in other current and non-current assets
2.3	an increase in accounts payable and accrued liabilities
(1.9)	an increase in accounts receivable and inventories
$22.8	Cash flow from operations

Cash flow from investing activities of $0.9 billion was primarily due to:

(Dollars in billions)	
$(4.5)	additions to property, plant and equipment
0.4	proceeds from the disposal of assets/businesses, net
(0.5)	purchases of in-process research and development assets
8.5	net sales of investments
(3.0)	credit support agreements activity, net
$0.9	Net cash from investing activities

Cash flow used for financing activities of $15.8 billion was primarily due to:

(Dollars in billions)	
$(11.8)	dividends to shareholders
(5.1)	repurchase of common stock
(10.8)	net repayment from short and long term debt
1.1	proceeds from stock options exercised/employee withholding tax on stock awards, net
(0.2)	Credit support agreements activity, net
8.0	Proceeds of short and long-term debt, net of issuance cost, related to the debt that transferred to Kenvue at separation
4.2	proceeds from Kenvue initial public offering
(1.1)	Cash transferred to Kenvue at separation
(0.1)	other and rounding
$(15.8)	Net cash used for financing activities

As of December 31, 2023, the Company's notes payable and long-term debt was in excess of cash, cash equivalents and marketable securities. As of December 31, 2023, the net debt position was $6.4 billion as compared to the prior year of $17.4 billion. The debt balance at the end of 2023 was $29.3 billion as compared to $39.6 billion in 2022. Considering recent market conditions, the Company has re-evaluated its operating cash flows and liquidity profile and does not foresee any significant incremental risk. The Company anticipates that operating cash flows, the ability to raise funds from external sources, borrowing capacity from existing committed credit facilities and access to the commercial paper markets will continue to provide sufficient resources to fund operating needs, including the Company's remaining balance to be paid on the agreement to settle opioid litigation for approximately $2.1 billion and the establishment of the approximately $9 billion reserve for talc matters (See Note 19 to the Consolidated Financial Statements for additional details). In addition, the Company monitors the global capital markets on an ongoing basis and from time to time may raise capital when market conditions are favorable.

On May 8, 2023, Kenvue, completed an initial public offering (the IPO) resulting in the issuance of 198,734,444 shares of its common stock, par value $0.01 per share (the Kenvue Common Stock), at an initial public offering of $22.00 per share for net proceeds of $4.2 billion. The excess of the net proceeds from the IPO over the net book value of the Johnson & Johnson divested interest was $2.5 billion and was recorded to additional paid-in capital. As of the closing of the IPO, Johnson & Johnson owned approximately 89.6% of the total outstanding shares of Kenvue Common Stock and at July 2, 2023, the non-controlling interest of $1.3 billion associated with Kenvue was reflected in equity attributable to non-controlling interests in the consolidated balance sheet.

On August 23, 2023, Johnson & Johnson completed the disposition of an additional 80.1% ownership of Kenvue Common Stock through an exchange offer, which resulted in Johnson & Johnson acquiring 190,955,436 shares of the Company's common stock in exchange for 1,533,830,450 shares of Kenvue Common Stock. The $31.4 billion of Johnson & Johnson common stock received in the exchange offer is recorded in Treasury stock. Following the exchange offer, the Company owns 9.5% of the total outstanding shares of Kenvue Common Stock that was recorded in other assets within continuing operations at the fair market value of $4.3 billion as of August 23, 2023 and $3.9 billion as of December 31, 2023.

Johnson & Johnson divested net assets of $11.6 billion as of August 23, 2023, and the accumulated other comprehensive loss attributable to the Consumer Health business at that date was $4.3 billion. Additionally, at the date of the exchange offer,

Johnson & Johnson decreased the non-controlling interest by $1.2 billion to record the deconsolidation of Kenvue. This resulted in a gain on the exchange offer of $21.0 billion that was recorded in Net earnings from discontinued operations, net of taxes in the consolidated statements of earnings for the fiscal third quarter of 2023. This one-time gain includes a gain of $2.8 billion on the Kenvue Common Stock retained by Johnson & Johnson. The gain on the exchange offer qualifies as a tax-free transaction for U.S. federal income tax purposes.

On September 14, 2022, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's Common Stock. In the fiscal year 2022, approximately $2.5 billion was repurchased under the program. In the fiscal year 2023, $2.5 billion has been repurchased and the repurchase program was completed.

The following table summarizes the Company's material contractual obligations and their aggregate maturities as of December 31, 2023: To satisfy these obligations, the Company intends to use cash from operations.

(Dollars in Millions)	Tax Legislation (TCJA)	Debt Obligations	Interest on Debt Obligations	Total
2024	$2,029	1,469	843	4,341
2025	2,536	1,700	789	5,025
2026	—	1,997	744	2,741
2027	—	2,320	736	3,056
2028	—	2,325	691	3,016
After 2028	—	17,539	8,706	26,245
Total	**$4,565**	**27,350**	**12,509**	**44,424**

For tax matters, see Note 8 to the Consolidated Financial Statements.

Financing and market risk

The Company uses financial instruments to manage the impact of foreign exchange rate changes on cash flows. Accordingly, the Company enters into forward foreign exchange contracts to protect the value of certain foreign currency assets and liabilities and to hedge future foreign currency transactions primarily related to product costs. Gains or losses on these contracts are offset by the gains or losses on the underlying transactions. A 10% appreciation of the U.S. Dollar from the December 31, 2023 market rates would increase the unrealized value of the Company's forward contracts by $0.1 billion. Conversely, a 10% depreciation of the U.S. Dollar from the December 31, 2023 market rates would decrease the unrealized value of the Company's forward contracts by $0.1 billion. In either scenario, the gain or loss on the forward contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated earnings and cash flows.

The Company hedges the exposure to fluctuations in currency exchange rates, and the effect on certain assets and liabilities in foreign currency, by entering into currency swap contracts. A 1% change in the spread between U.S. and foreign interest rates on the Company's interest rate sensitive financial instruments would either increase or decrease the unrealized value of the Company's swap contracts by approximately $1.6 billion. In either scenario, at maturity, the gain or loss on the swap contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated cash flows.

The Company does not enter into financial instruments for trading or speculative purposes. Further, the Company has a policy of only entering into contracts with parties that have at least an investment grade credit rating. The counterparties to these contracts are major financial institutions and there is no significant concentration of exposure with any one counterparty. Management believes the risk of loss is remote. The Company entered into credit support agreements (CSA) with certain derivative counterparties establishing collateral thresholds based on respective credit ratings and netting agreements. See Note 6 to the Consolidated Financial Statements for additional details on credit support agreements.

The Company invests in both fixed rate and floating rate interest earning securities which carry a degree of interest rate risk. The fair market value of fixed rate securities may be adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than predicted if interest rates fall. A 1% (100 basis points) change in spread on the Company's interest rate sensitive investments would either increase or decrease the unrealized value of cash equivalents and current marketable securities by less than $0.8 billion.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2023, the Company secured a new 364-day Credit Facility of $10 billion, which expires on September 5, 2024. The Company early terminated the additional 364-day revolving Credit Facility of $10 billion, which had an expiration of November 21, 2023. Interest charged on borrowings under the credit line agreement is based on either Secured Overnight Financing Rate (SOFR) Reference Rate or other applicable market rate as allowed plus applicable margins. Commitment fees under the agreement are not material.

Total borrowings at the end of 2023 and 2022 were $29.3 billion and $39.6 billion, respectively. The decrease in the debt balance was due to the repayment of commercial paper. In 2023, net debt (cash and current marketable securities, net of debt) was $6.4 billion compared to net debt of $17.4 billion in 2022. Total debt represented 30.0% of total capital (shareholders' equity and total debt) in 2023 and 34.0% of total capital in 2022. Shareholders' equity per share at the end of 2023 was $28.57 compared to $29.39 at year-end 2022.

A summary of borrowings can be found in Note 7 to the Consolidated Financial Statements.

Dividends

The Company increased its dividend in 2023 for the 61st consecutive year. Cash dividends paid were $4.70 per share in 2023 and $4.45 per share in 2022.

On January 2, 2024, the Board of Directors declared a regular cash dividend of $1.19 per share, payable on March 5, 2024 to shareholders of record as of February 20, 2024.

Other information

Critical accounting policies and estimates

Management's discussion and analysis of results of operations and financial condition are based on the Company's consolidated financial statements that have been prepared in accordance with accounting principles generally accepted in the U.S. (GAAP). The preparation of these financial statements requires that management make estimates and assumptions that affect the amounts reported for revenues, expenses, assets, liabilities and other related disclosures. Actual results may or may not differ from these estimates. The Company believes that the understanding of certain key accounting policies and estimates are essential in achieving more insight into the Company's operating results and financial condition. These key accounting policies include revenue recognition, income taxes, legal and self-insurance contingencies, valuation of long-lived assets, assumptions used to determine the amounts recorded for pensions and other employee benefit plans and accounting for stock based awards.

Revenue Recognition: The Company recognizes revenue from product sales when obligations under the terms of a contract with the customer are satisfied; generally, this occurs with the transfer of control of the goods to customers. The Company's global payment terms are typically between 30 to 90 days. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns, discounts to customers and governmental clawback provisions are accounted for as variable consideration and recorded as a reduction in sales.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including consideration of competitor pricing. Rebates are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns are estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales return accruals.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The sales returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Innovative Medicine segments are almost exclusively not resalable. Sales returns for certain franchises in the MedTech segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been less than 1.0% of annual net trade sales during the fiscal years 2023, 2022 and 2021.

Promotional programs, such as product listing allowances are recorded in the same period as related sales and include volume-based sales incentive programs. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue. The Company also earns profit-share payments through collaborative arrangements of certain products, which are included in sales to customers. Profit-share payments were less than 2.0% of the total revenues in fiscal year 2023 and less than 3.0% of the total revenues in fiscal year 2022 and 2021 are included in sales to customers.

In addition, the Company enters into collaboration arrangements that contain multiple revenue generating activities. Amounts due from collaborative partners for these arrangements are recognized as each activity is performed or delivered, based on the relative selling price. Upfront fees received as part of these arrangements are deferred and recognized over the performance period. See Note 1 to the Consolidated Financial Statements for additional disclosures on collaborations.

Reasonably likely changes to assumptions used to calculate the accruals for rebates, returns and promotions are not anticipated to have a material effect on the financial statements. The Company currently discloses the impact of changes to assumptions in the quarterly or annual filing in which there is a material financial statement impact.

Below are tables that show the progression of accrued rebates, returns, promotions, reserve for doubtful accounts and reserve for cash discounts by segment of business for the fiscal years ended December 31, 2023 and January 1, 2023.

Innovative Medicine segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/ Credits[2]	Balance at End of Period
2023				
Accrued rebates [1]	$12,289	47,523	(45,151)	14,661
Accrued returns	649	332	(347)	634
Accrued promotions	1	12	(7)	6
Subtotal	**$12,939**	**47,867**	**(45,505)**	**15,301**
Reserve for doubtful accounts	44	0	(11)	33
Reserve for cash discounts	110	1,386	(1,385)	111
Total	**$13,093**	**49,253**	**(46,901)**	**15,445**
2022				
Accrued rebates [1]	$10,331	43,026	(41,068)	12,289
Accrued returns	520	444	(315)	649
Accrued promotions	3	5	(7)	1
Subtotal	**$10,854**	**43,475**	**(41,390)**	**12,939**
Reserve for doubtful accounts	50	0	(6)	44
Reserve for cash discounts	94	1,281	(1,265)	110
Total	**$10,998**	**44,756**	**(42,661)**	**13,093**

[1] Includes reserve for customer rebates of $165 million at December 31, 2023 and $203 million at January 1, 2023, recorded as a contra asset.

[2] Includes prior period adjustments

MedTech segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/ Credits	Balance at End of Period
2023				
Accrued rebates[1]	$1,470	6,241	(6,256)	1,455
Accrued returns	134	555	(564)	125
Accrued promotions	43	74	(92)	25
Subtotal	**$1,647**	**6,870**	**(6,912)**	**1,605**
Reserve for doubtful accounts	125	33	(25)	133
Reserve for cash discounts	9	96	(100)	5
Total	**$1,781**	**6,999**	**(7,037)**	**1,743**
2022				
Accrued rebates[1]	$1,446	6,131	(6,107)	1,470
Accrued returns	134	531	(531)	134
Accrued promotions	54	102	(113)	43
Subtotal	**$1,634**	**6,764**	**(6,751)**	**1,647**
Reserve for doubtful accounts	148	6	(29)	125
Reserve for cash discounts	10	99	(100)	9
Total	**$1,792**	**6,869**	**(6,880)**	**1,781**

(1) Includes reserve for customer rebates of $740 million at December 31, 2023 and $802 million at January 1, 2023, recorded as a contra asset.

Income Taxes: Income taxes are recorded based on amounts refundable or payable for the current year and include the results of any difference between U.S. GAAP accounting and tax reporting, recorded as deferred tax assets or liabilities. The Company estimates deferred tax assets and liabilities based on enacted tax regulations and rates. Future changes in tax laws and rates may affect recorded deferred tax assets and liabilities.

The Company has unrecognized tax benefits for uncertain tax positions. The Company follows U.S. GAAP, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Management believes that changes in these estimates would not have a material effect on the Company's results of operations, cash flows or financial position.

The Company has recorded deferred tax liabilities on all undistributed earnings prior to December 31, 2017 from its international subsidiaries. The Company has not provided deferred taxes on the undistributed earnings subsequent to January 1, 2018 from certain international subsidiaries where the earnings are considered to be indefinitely reinvested. The Company intends to continue to reinvest these earnings in those international operations. If the Company decides at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company estimates that the tax effect of this repatriation would be approximately $0.5 billion under currently enacted tax laws and regulations and at current currency exchange rates. This amount does not include the possible benefit of U.S. foreign tax credits, which may substantially offset this cost.

See Note 1 and Note 8 to the Consolidated Financial Statements for further information regarding income taxes.

Legal and Self Insurance Contingencies: The Company records accruals for various contingencies, including legal proceedings and product liability claims as these arise in the normal course of business. The accruals are based on management's judgment as to the probability of losses and, where applicable, actuarially determined estimates. The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated.

The Company follows the provisions of U.S. GAAP when recording litigation related contingencies. A liability is recorded when a loss is probable and can be reasonably estimated.

See Notes 1 and 19 to the Consolidated Financial Statements for further information regarding product liability and legal proceedings.

Long-Lived and Intangible Assets: The Company assesses changes, both qualitatively and quantitatively, in economic conditions and makes assumptions regarding estimated future cash flows in evaluating the value of the Company's property, plant and equipment, goodwill and intangible assets. As these assumptions and estimates may change over time, it may or may not be necessary for the Company to record impairment charges.

Employee Benefit Plans: The Company sponsors various retirement and pension plans, including defined benefit, defined contribution and termination indemnity plans, which cover most employees worldwide. These plans are based on assumptions for the discount rate, expected return on plan assets, mortality rates, expected salary increases, healthcare cost trend rates and attrition rates. See Note 10 to the Consolidated Financial Statements for further details on these rates.

Stock Based Compensation: The Company recognizes compensation expense associated with the issuance of equity instruments to employees for their services. Based on the type of equity instrument, the fair value is estimated on the date of grant using either the Black-Scholes option valuation model or a combination of both the Black-Scholes option valuation model and Monte Carlo valuation model, and is expensed in the financial statements over the service period. The input assumptions used in determining fair value are the expected life, expected volatility, risk-free rate and expected dividend yield. For performance share units, the fair market value is calculated for the two component goals at the date of grant: adjusted operational earnings per share and relative total shareholder return. The fair values for the earnings per share goal of each performance share unit was estimated on the date of grant using the fair market value of the shares at the time of the award, discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. See Note 16 to the Consolidated Financial Statements for additional information.

New accounting pronouncements

Refer to Note 1 to the Consolidated Financial Statements for recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of December 31, 2023.

Economic and market factors

The Company is aware that its products are used in an environment where, for more than a decade, policymakers, consumers and businesses have expressed concerns about the rising cost of healthcare. In response to these concerns, the Company has a long-standing policy of pricing products responsibly. For the period 2013 - 2023, in the U.S., the weighted average compound annual growth rate of the Company's net price increases for healthcare products (prescription and over-the-counter drugs, hospital and professional products) was below the U.S. Consumer Price Index (CPI).

The Company operates in certain countries where the economic conditions continue to present significant challenges. The Company continues to monitor these situations and take appropriate actions. Inflation rates continue to have an effect on worldwide economies and, consequently, on the way companies operate. The Company has accounted for operations in Argentina, Venezuela and Turkey (beginning in the fiscal second quarter of 2022) as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. This did not have a material impact to the Company's results in the period. In the face of increasing costs, the Company strives to maintain its profit margins through cost reduction programs, productivity improvements and periodic price increases.

In December 2023, the Argentine government devalued the peso by approximately 50%. During 2023, the Company recorded a charge of approximately $130 million related to operations in Argentina due to the application of highly inflationary accounting. As of December 31, 2023, the Company's Argentine subsidiaries represented less than 1.0% of the Company's consolidated assets, liabilities, revenues and profits from continuing operations; therefore, the effect of a change in the exchange rate is not expected to have a material adverse effect on the Company's 2024 full-year results.

In July 2023, Janssen Pharmaceuticals, Inc. (Janssen) filed litigation against the U.S. Department of Health and Human Services as well as the Centers for Medicare and Medicaid Services challenging the constitutionality of the Inflation Reduction Act's (IRA) Medicare Drug Price Negotiation Program. The litigation requests a declaration that the IRA violates Janssen's rights under the First Amendment and the Fifth Amendment to the Constitution and therefore that Janssen is not subject to the IRA's mandatory pricing scheme.

Russia-Ukraine War

Although the long-term implications of Russia's invasion of Ukraine are difficult to predict at this time, the financial impact of the conflict in the fiscal year 2023, including accounts receivable or inventory reserves, was not material. As of and for each of the fiscal years ending December 31, 2023 and January 1, 2023, the business of the Company's Russian subsidiaries represented less than 1% of the Company's consolidated assets and represented 1% of revenues. The Company does not maintain Ukraine subsidiaries subsequent to the Kenvue separation.

In early March of 2022, the Company took steps to suspend all advertising, enrollment in clinical trials, and any additional investment in Russia. The Company continues to supply products relied upon by patients for healthcare purposes.

Conflict in the Middle East

Although the long-term implications of Israel's conflict are difficult to predict at this time, the financial impact of the conflict in the fiscal year 2023, including accounts receivable or inventory reserves, was not material. As of and for the fiscal year ending December 31, 2023, the business of the Company's Israel subsidiaries represented 1% of the Company's consolidated assets and represented less than 1% of revenues.

The Company is exposed to fluctuations in currency exchange rates. A 1% change in the value of the U.S. Dollar as compared to all foreign currencies in which the Company had sales, income or expense in 2023 would have increased or decreased the translation of foreign sales by approximately $0.4 billion and net income by approximately $0.2 billion.

Governments around the world consider various proposals to make changes to tax laws, which may include increasing or decreasing existing statutory tax rates. In connection with various government initiatives, companies are required to disclose more information to tax authorities on operations around the world, which may lead to greater audit scrutiny of profits earned in other countries. A change in statutory tax rate in any country would result in the revaluation of the Company's deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is enacted. This change would result in an expense or benefit recorded to the Company's Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries where it operates. Changes to the statutory tax rate may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted.

The Company faces various worldwide healthcare changes that may continue to result in pricing pressures that include healthcare cost containment and government legislation relating to sales, promotions, pricing and reimbursement of healthcare products.

Changes in the behavior and spending patterns of purchasers of healthcare products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing healthcare insurance coverage may continue to impact the Company's businesses.

The Company also operates in an environment increasingly hostile to intellectual property rights. Firms have filed Abbreviated New Drug Applications or Biosimilar Biological Product Applications with the U.S. FDA or otherwise challenged the coverage and/or validity of the Company's patents, seeking to market generic or biosimilar forms of many of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the event the Company is not successful in defending the patent claims challenged in the resulting lawsuits, generic or biosimilar versions of the products at issue will be introduced to the market, resulting in the potential for substantial market share and revenue losses for those products, and which may result in a non-cash impairment charge in any associated intangible asset. There is also a risk that one or more competitors could launch a generic or biosimilar version of the product at issue following regulatory approval even though one or more valid patents are in place.

Legal proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability, intellectual property, commercial, employment, indemnification and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of business.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of December 31, 2023, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25, Contingencies. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; ability to achieve comprehensive multi-party settlements; complexity of related cross-claims and counterclaims; and/or there are numerous parties involved. To the extent adverse awards, judgments or verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution of, or increase in accruals for, one or more of these matters in any reporting period may have a material adverse effect on the Company's results of operations and cash flows for that period.

See Note 19 to the Consolidated Financial Statements included in Item 8 of this report for further information regarding legal proceedings.

Common stock

The Company's Common Stock is listed on the New York Stock Exchange under the symbol JNJ. As of February 9, 2024, there were 118,772 record holders of Common Stock of the Company.

Item 7A. Quantitative and qualitative disclosures about market risk

The information called for by this item is incorporated herein by reference to Item 7. Management's discussion and analysis of results of operations and financial condition - Liquidity and capital resources - Financing and market risk of this Report; and Note 1 Summary of significant accounting policies - Financial instruments of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 8. Financial statements and supplementary data

Index to audited Consolidated Financial Statements

Johnson & Johnson and subsidiaries consolidated balance sheets

At December 31, 2023 and January 1, 2023
(Dollars in Millions Except Share and Per Share Amounts) (Note 1)

	2023	2022
Assets		
Current assets		
Cash and cash equivalents (Notes 1 and 2)	$21,859	12,889
Marketable securities (Notes 1 and 2)	1,068	9,392
Accounts receivable trade, less allowances $166 (2022, $169)	14,873	14,039
Inventories (Notes 1 and 3)	11,181	10,268
Prepaid expenses and other receivables	4,514	2,876
Current assets of discontinued operations (Note 21)	—	5,830
Total current assets	**53,495**	**55,294**
Property, plant and equipment, net (Notes 1 and 4)	19,898	17,982
Intangible assets, net (Notes 1 and 5)	34,175	38,489
Goodwill (Notes 1 and 5)	36,558	36,047
Deferred taxes on income (Note 8)	9,279	8,947
Other assets	14,153	9,212
Noncurrent assets of discontinued operations (Note 21)	—	21,407
Total assets	**$167,558**	**187,378**
Liabilities and Shareholders' Equity		
Current liabilities		
Loans and notes payable (Note 7)	$3,451	12,756
Accounts payable	9,632	9,889
Accrued liabilities	10,212	10,719
Accrued rebates, returns and promotions	16,001	13,579
Accrued compensation and employee related obligations	3,993	3,049
Accrued taxes on income (Note 8)	2,993	2,220
Current liabilities of discontinued operations (Note 21)	—	3,590
Total current liabilities	**46,282**	**55,802**
Long-term debt (Note 7)	25,881	26,886
Deferred taxes on income (Note 8)	3,193	3,991
Employee related obligations (Notes 9 and 10)	7,149	6,542
Long-term taxes payable (Note 1)	2,881	4,306
Other liabilities	13,398	10,146
Noncurrent liabilities of discontinued operations (Note 21)	—	2,901
Total liabilities	**98,784**	**110,574**
Commitments and Contingencies (Note 19)		
Shareholders' equity		
Preferred stock — without par value (authorized and unissued 2,000,000 shares)	—	—
Common stock — par value $1.00 per share (Note 12) (authorized 4,320,000,000 shares; issued 3,119,843,000 shares)	3,120	3,120
Accumulated other comprehensive income (loss) (Note 13)	(12,527)	(12,967)
Retained earnings and Additional-paid-in-capital	153,843	128,345
Less: common stock held in treasury, at cost (Note 12) (712,765,000 shares and 506,246,000 shares)	75,662	41,694
Total shareholders' equity	**68,774**	**76,804**
Total liabilities and shareholders' equity	**$167,558**	**187,378**

See Notes to Consolidated Financial Statements

Johnson & Johnson and subsidiaries consolidated statements of earnings

(Dollars and Shares in Millions Except Per Share Amounts) (Note 1)

	2023	2022	2021
Sales to customers	$85,159	79,990	78,740
Cost of products sold	26,553	24,596	23,402
Gross profit	58,606	55,394	55,338
Selling, marketing and administrative expenses	21,512	20,246	20,118
Research and development expense	15,085	14,135	14,277
In-process research and development impairments	313	783	900
Interest income	(1,261)	(490)	(53)
Interest expense, net of portion capitalized (Note 4)	772	276	183
Other (income) expense, net	6,634	810	526
Restructuring (Note 20)	489	275	209
Earnings before provision for taxes on income	15,062	19,359	19,178
Provision for taxes on income (Note 8)	1,736	2,989	1,377
Net earnings from continuing operations	13,326	16,370	17,801
Net earnings from discontinued operations, net of tax (Note 21)	21,827	1,571	3,077
Net earnings	**$35,153**	**17,941**	**20,878**
Net earnings per share (Notes 1 and 15)			
Continuing operations - basic	$5.26	6.23	6.76
Discontinued operations - basic	$8.62	0.60	1.17
Total net earnings per share - basic	**$13.88**	**6.83**	**7.93**
Continuing operations - diluted	$5.20	6.14	6.66
Discontinued operations - diluted	$8.52	0.59	1.15
Total net earnings per share - diluted	**$13.72**	**6.73**	**7.81**
Average shares outstanding (Notes 1 and 15)			
Basic	**2,533.5**	**2,625.2**	**2,632.1**
Diluted	**2,560.4**	**2,663.9**	**2,674.0**

See Notes to Consolidated Financial Statements

Johnson & Johnson and subsidiaries consolidated statements of comprehensive income

(Dollars in Millions) (Note 1)

	2023	2022	2021
Net earnings	$35,153	17,941	20,878
Other comprehensive income (loss), net of tax			
Foreign currency translation	(3,221)	(1,796)	(1,079)
Securities:			
Unrealized holding gain (loss) arising during period	26	(24)	(4)
Reclassifications to earnings	—	—	—
Net change	26	(24)	(4)
Employee benefit plans:			
Prior service credit (cost), net of amortization	(149)	(160)	(169)
Gain (loss), net of amortization	(1,183)	1,854	4,318
Consumer settlement/ curtailment	23	—	—
Effect of exchange rates	(90)	111	106
Net change	(1,399)	1,805	4,255
Derivatives & hedges:			
Unrealized gain (loss) arising during period	422	454	(199)
Reclassifications to earnings	(569)	(348)	(789)
Net change	(147)	106	(988)
Other comprehensive income (loss)	(4,741)	91	2,184
Comprehensive income	**$30,412**	**18,032**	**23,062**

The tax effects in other comprehensive income for the fiscal years 2023, 2022 and 2021 respectively: Foreign Currency Translation; $797 million, $460 million and $346 million; Employee Benefit Plans: $289 million, $461 million and $1,198 million, Derivatives & Hedges: $39 million, $30 million and $263 million.

See Notes to Consolidated Financial Statements

Amounts presented have not been recast to exclude discontinued operations

Johnson & Johnson and subsidiaries consolidated statements of equity

(Dollars in Millions) (Note 1)

	Total	Retained Earnings and Additional paid-in capital	Accumulated Other Comprehensive Income (Loss)	Common Stock Issued Amount	Treasury Stock Amount
Balance, January 3, 2021	**$63,278**	**113,890**	**(15,242)**	**3,120**	**(38,490)**
Net earnings	20,878	20,878			
Cash dividends paid ($4.19 per share)	(11,032)	(11,032)			
Employee compensation and stock option plans	2,171	(676)			2,847
Repurchase of common stock	(3,456)				(3,456)
Other comprehensive income (loss), net of tax	2,184		2,184		
Balance, January 2, 2022	**74,023**	**123,060**	**(13,058)**	**3,120**	**(39,099)**
Net earnings	17,941	17,941			
Cash dividends paid ($4.45 per share)	(11,682)	(11,682)			
Employee compensation and stock option plans	2,466	(974)			3,440
Repurchase of common stock	(6,035)				(6,035)
Other comprehensive income (loss), net of tax	91		91		
Balance, January 1, 2023	**76,804**	**128,345**	**(12,967)**	**3,120**	**(41,694)**
Net earnings	35,153	35,153			
Cash dividends paid ($4.70 per share)	(11,770)	(11,770)			
Employee compensation and stock option plans	2,193	(336)			2,529
Repurchase of common stock	(5,054)				(5,054)
Other	(25)				(25)
Kenvue Separation /IPO (Note 21)	(23,786)	2,451	5,181		(31,418)
Other comprehensive income (loss), net of tax	(4,741)		(4,741)		
Balance, December 31, 2023	**$68,774**	**153,843**	**(12,527)**	**3,120**	**(75,662)**

See Notes to Consolidated Financial Statements

Johnson & Johnson and subsidiaries consolidated statements of cash flows

(Dollars in Millions) (Note 1)

	2023	2022	2021
Cash flows from operating activities			
Net earnings	$35,153	17,941	20,878
Adjustments to reconcile net earnings to cash flows from operating activities:			
Depreciation and amortization of property and intangibles	7,486	6,970	7,390
Stock based compensation	1,162	1,138	1,135
Asset write-downs	1,295	1,216	989
Charge for purchase of in-process research and development assets	483	—	—
Gain on Kenvue separation	(20,984)	—	—
Net gain on sale of assets/businesses	(117)	(380)	(617)
Deferred tax provision	(4,194)	(1,663)	(2,079)
Credit losses and accounts receivable allowances	—	(17)	(48)
Changes in assets and liabilities, net of effects from acquisitions and divestitures:			
Increase in accounts receivable	(624)	(1,290)	(2,402)
Increase in inventories	(1,323)	(2,527)	(1,248)
Increase in accounts payable and accrued liabilities	2,346	1,098	2,437
(Increase)/Decrease in other current and non-current assets	(3,480)	687	(1,964)
Increase/(Decrease) in other current and non-current liabilities	5,588	(1,979)	(1,061)
Net cash flows from operating activities	**22,791**	**21,194**	**23,410**
Cash flows from investing activities			
Additions to property, plant and equipment	(4,543)	(4,009)	(3,652)
Proceeds from the disposal of assets/businesses, net	358	543	711
Acquisitions, net of cash acquired (Note 18)	—	(17,652)	(60)
Purchases of in-process research and development assets (Note 18)	(470)	—	—
Purchases of investments	(10,906)	(32,384)	(30,394)
Sales of investments	19,390	41,609	25,006
Credit support agreements activity, net	(2,963)	(249)	214
Other (including capitalized licenses and milestones)	12	(229)	(508)
Net cash from/(used) by investing activities	**878**	**(12,371)**	**(8,683)**
Cash flows from financing activities			
Dividends to shareholders	(11,770)	(11,682)	(11,032)
Repurchase of common stock	(5,054)	(6,035)	(3,456)
Proceeds from short-term debt	13,743	16,134	1,997
Repayment of short-term debt	(22,973)	(6,550)	(1,190)
Proceeds from long-term debt, net of issuance costs	—	2	5
Repayment of long-term debt	(1,551)	(2,134)	(1,802)
Proceeds from the exercise of stock options/employee withholding tax on stock awards, net	1,094	1,329	1,036
Credit support agreements activity, net	(219)	(28)	281

	2023	2022	2021
Proceeds of short and long-term debt, net of issuance cost, related to the debt that transferred to Kenvue at separation	8,047	—	—
Proceeds from Kenvue initial public offering	4,241	—	—
Cash transferred to Kenvue at separation	(1,114)	—	—
Other	(269)	93	114
Net cash used by financing activities	**(15,825)**	**(8,871)**	**(14,047)**
Effect of exchange rate changes on cash and cash equivalents	(112)	(312)	(178)
Increase/(Decrease) in cash and cash equivalents	7,732	(360)	502
Cash and cash equivalents from continuing operations, beginning of period	12,889	13,309	12,697
Cash and cash equivalents from discontinued operations, beginning of period	1,238	1,178	1,288
Cash and cash equivalents, beginning of year (Note 1)	14,127	14,487	13,985
Cash and cash equivalents from continuing operations, end of period	21,859	12,889	13,309
Cash and cash equivalents from discontinued operations, end of period	—	1,238	1,178
Cash and cash equivalents, end of year (Note 1)	**$21,859**	**14,127**	**14,487**
Supplemental cash flow data			
Cash paid during the year for:			
Interest	$1,836	982	990
Interest, net of amount capitalized	1,766	933	941
Income taxes, inclusive of discontinued operations	8,574	5,223	4,768
Supplemental schedule of non-cash investing and financing activities			
Treasury stock issued for employee compensation and stock option plans, net of cash proceeds/ employee withholding tax on stock awards	$1,435	2,114	1,811
Acquisitions			
Fair value of assets acquired	$—	18,710	61
Fair value of liabilities assumed	—	(1,058)	(1)
Net cash paid for acquisitions (Note 18)	$—	17,652	60

See Notes to Consolidated Financial Statements

Amounts presented have not been recast to exclude discontinued operations.

Notes to Consolidated Financial Statements

1. Summary of significant accounting policies

Principles of consolidation

The consolidated financial statements include the accounts of Johnson & Johnson and its subsidiaries (the Company). Intercompany accounts and transactions are eliminated. Columns and rows within tables may not add due to rounding. Percentages have been calculated using actual, non-rounded figures.

Description of the company and business segments

The Company has approximately 131,900 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the healthcare field. The Company conducts business in virtually all countries of the world and its primary focus is on products related to human health and well-being.

Kenvue IPO/separation and discontinued operations

On May 8, 2023, Kenvue, completed an initial public offering (the IPO) resulting in the issuance of 198,734,444 shares of its common stock, par value $0.01 per share (the "Kenvue Common Stock"), at an initial public offering of $22.00 per share for net proceeds of $4.2 billion. The excess of the net proceeds from the IPO over the net book value of the Johnson & Johnson divested interest was $2.5 billion and was recorded to additional paid-in capital. As of the closing of the IPO, Johnson & Johnson owned approximately 89.6% of the total outstanding shares of Kenvue Common Stock and at July 2, 2023, the non-controlling interest of $1.3 billion associated with Kenvue was reflected in equity attributable to non-controlling interests in the consolidated balance sheet in the fiscal second quarter of 2023.

On August 23, 2023, Johnson & Johnson completed the disposition of an additional 80.1% ownership of the shares of Kenvue through an exchange offer. Following the exchange offer, the Company owns 9.5% of the shares of Kenvue which are accounted for as an equity investment carried at fair value within continuing operations. The historical results of the Consumer Health business (which previously represented the Consumer Health business segment) are reflected as discontinued operations in the Company's Consolidated Financial Statements through the date of the exchange offer (see Note 21 for additional details). Unless otherwise indicated, the information in the notes to the Consolidated Financial Statements refer only to Johnson & Johnson's continuing operations.

Business segments

Following the completion of the exchange offer, the Company is organized into two business segments: Innovative Medicine and MedTech. The Innovative Medicine segment is focused on the following therapeutic areas, including Immunology, Infectious diseases, Neuroscience, Oncology, Pulmonary Hypertension, and Cardiovascular and Metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, distributors, hospitals and healthcare professionals for prescription use. The MedTech segment includes a broad portfolio of products used in the Orthopaedic, Surgery, Interventional Solutions and Vision fields. These products are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

New accounting standards

Recently adopted accounting standards

ASU 2022-04: Liabilities-Supplier Finance Programs (Topic 405-50) – Disclosure of Supplier Finance Program Obligations

The Company adopted the standard as of the beginning of fiscal year 2023, which requires that a buyer in a supplier finance program disclose additional information about the program for financial statement users.

The Company has agreements for supplier finance programs with third-party financial institutions. These programs provide participating suppliers the ability to finance payment obligations from the Company with the third-party financial institutions. The Company is not a party to the arrangements between the suppliers and the third-party financial institutions. The Company's obligations to its suppliers, including amounts due, and scheduled payment dates (which have general payment terms of 90 days), are not affected by a participating supplier's decision to participate in the program.

As of both December 31, 2023, and January 1, 2023, $0.7 billion were valid obligations under the program. The obligations are presented as Accounts payable on the Consolidated Balance Sheets.

Recently issued accounting standards

Not adopted as of December 31, 2023

ASU 2023-07: Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures
This update requires expanded annual and interim disclosures for significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss. This update will be effective for fiscal years beginning after December 15, 2023, and is to be applied retrospectively to all periods presented in the financial statements. Early adoption is permitted. As this accounting standard only impacts disclosures, it will not have a material impact on the Company's Consolidated Financial Statements.

ASU 2023-09: Income Taxes (Topic 740) - Improvements to Income Tax Disclosures
This update standardizes categories for the effective tax rate reconciliation, requires disaggregation of income taxes and additional income tax-related disclosures. This update is required to be effective for the Company for fiscal periods beginning after December 15, 2024. As this accounting standard only impacts disclosures, it will not have a material impact on the Company's Consolidated Financial Statements.

Cash equivalents

The Company classifies all highly liquid investments with stated maturities of three months or less from date of purchase as cash equivalents and all highly liquid investments with stated maturities of greater than three months from the date of purchase as current marketable securities. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating. The Company invests its cash primarily in government securities and obligations, corporate debt securities, money market funds and reverse repurchase agreements (RRAs).

RRAs are collateralized by deposits in the form of Government Securities and Obligations for an amount not less than 102% of their value. The Company does not record an asset or liability as the Company is not permitted to sell or repledge the associated collateral. The Company has a policy that the collateral has at least an A (or equivalent) credit rating. The Company utilizes a third party custodian to manage the exchange of funds and ensure that collateral received is maintained at 102% of the value of the RRAs on a daily basis. RRAs with stated maturities of greater than three months from the date of purchase are classified as marketable securities.

Investments

Investments classified as held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings. Investments classified as available-for-sale debt securities are carried at estimated fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income. Available-for-sale securities available for current operations are classified as current assets; otherwise, they are classified as long term. Management determines the appropriate classification of its investment in debt and equity securities at the time of purchase and re-evaluates such determination at each balance sheet date. The Company reviews its investments for impairment and adjusts these investments to fair value through earnings, as required.

Property, plant and equipment and depreciation

Property, plant and equipment are stated at cost. The Company utilizes the straight-line method of depreciation over the estimated useful lives of the assets:

Building and building equipment	30 years
Land and leasehold improvements	10 - 20 years
Machinery and equipment	2 - 13 years

The Company capitalizes certain computer software and development costs, included in machinery and equipment, when incurred in connection with developing or obtaining computer software for internal use. Capitalized software costs are amortized over the estimated useful lives of the software, which generally range from 3 to 8 years.

The Company reviews long-lived assets to assess recoverability using undiscounted cash flows. When certain events or changes in operating or economic conditions occur, an impairment assessment may be performed on the recoverability of the

carrying value of these assets. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows.

Revenue recognition

The Company recognizes revenue from product sales when obligations under the terms of a contract with the customer are satisfied; generally, this occurs with the transfer of control of the goods to customers. The Company's global payment terms are typically between 30 to 90 days. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns, discounts to customers and governmental clawback provisions are accounted for as variable consideration and recorded as a reduction in sales. The liability is recognized within Accrued rebates, returns, and promotions on the consolidated balance sheet.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including consideration of competitor pricing. Rebates are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. A significant portion of the liability related to rebates is from the sale of the Company's pharmaceutical products within the U.S., primarily the Managed Care, Medicare and Medicaid programs, which amounted to $11.5 billion and $9.6 billion as of December 31, 2023 and January 1, 2023, respectively. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns are estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales return accruals.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The sales returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Innovative Medicine segments are almost exclusively not resalable. Sales returns for certain franchises in the MedTech segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been less than 1.0% of annual net trade sales during each of the fiscal years 2023, 2022 and 2021.

Promotional programs, such as product listing allowances are recorded in the same period as related sales and include volume-based sales incentive programs. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue. The Company also earns profit-share payments through collaborative arrangements of certain products, which are included in sales to customers. Profit-share payments were less than 2.0% of the total revenues in fiscal year 2023 and less than 3.0% of the total revenues in the fiscal years 2022 and 2021 and are included in sales to customers.

See Note 17 to the Consolidated Financial Statements for further disaggregation of revenue.

Shipping and handling

Shipping and handling costs incurred were $0.9 billion, $0.8 billion and $0.8 billion in fiscal years 2023, 2022 and 2021, respectively, and are included in selling, marketing and administrative expense. The amount of revenue received for shipping and handling is less than 1.0% of sales to customers for all periods presented.

Inventories

Inventories are stated at the lower of cost or net realizable value determined by the first-in, first-out method.

Intangible assets and goodwill

The authoritative literature on U.S. GAAP requires that goodwill and intangible assets with indefinite lives be assessed annually for impairment. The Company completed its annual impairment test for 2023 in the fiscal fourth quarter. Future impairment

tests will be performed annually in the fiscal fourth quarter, or sooner if warranted. Purchased in-process research and development is accounted for as an indefinite lived intangible asset until the underlying project is completed, at which point the intangible asset will be accounted for as a definite lived intangible asset. If warranted the purchased in-process research and development could be written off or partially impaired depending on the underlying program.

Intangible assets that have finite useful lives continue to be amortized over their useful lives, and are reviewed for impairment when warranted by economic conditions. See Note 5 for further details on Intangible Assets and Goodwill.

Financial instruments

As required by U.S. GAAP, all derivative instruments are recorded on the balance sheet at fair value. Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value, with Level 1 having the highest priority and Level 3 having the lowest. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The Company documents all relationships between hedged items and derivatives. The overall risk management strategy includes reasons for undertaking hedge transactions and entering into derivatives. The objectives of this strategy are: (1) minimize foreign currency exposure's impact on the Company's financial performance; (2) protect the Company's cash flow from adverse movements in foreign exchange rates; (3) ensure the appropriateness of financial instruments; and (4) manage the enterprise risk associated with financial institutions. See Note 6 for additional information on Financial Instruments.

Leases

The Company determines whether an arrangement is a lease at contract inception by establishing if the contract conveys the right to control the use of identified property, plant, or equipment for a period of time in exchange for consideration. Right of Use (ROU) Assets and Lease Liabilities for operating leases are included in Other assets, Accrued liabilities, and Other liabilities on the consolidated balance sheet. The ROU Assets represent the right to use an underlying asset for the lease term and lease liabilities represent an obligation to make lease payments arising from the lease. Commitments under finance leases are not significant, and are included in Property, plant and equipment, Loans and notes payable, and Long-term debt on the consolidated balance sheet.

ROU Assets and Lease Liabilities are recognized at the lease commencement date based on the present value of all minimum lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments, when the implicit rate is not readily determinable. Lease terms may include options to extend or terminate the lease. These options are included in the lease term when it is reasonably certain that the Company will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term. The Company has elected the following policy elections on adoption: use of portfolio approach on leases of assets under master service agreements, exclusion of short term leases on the balance sheet, and not separating lease and non-lease components.

The Company primarily has operating lease for space, vehicles, manufacturing equipment and data processing equipment. The ROU asset pertaining to leases from continuing operation was $1.0 billion in both fiscal years 2023 and 2022. The lease liability from continuing operations was $1.1 billion in both fiscal years 2023 and 2022. The operating lease costs from continuing operations were $0.2 billion in fiscal years 2023, 2022 and 2021. Cash paid for amounts included in the measurement of lease liabilities from continuing operations were $0.2 billion in fiscal years 2023, 2022 and 2021.

Product liability

Accruals for product liability claims are recorded, on an undiscounted basis, when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated based on existing information and actuarially determined estimates where applicable. The accruals are adjusted periodically as additional information becomes available. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated.

Research and development

Research and development expenses are expensed as incurred in accordance with ASC 730, Research and Development. Upfront and milestone payments made to third parties in connection with research and development collaborations are expensed as incurred up to the point of regulatory approval. Payments made to third parties subsequent to regulatory approval are capitalized and amortized over the remaining useful life of the related product. Amounts capitalized for such payments are included in other intangibles, net of accumulated amortization.

The Company enters into collaborative arrangements, typically with other pharmaceutical or biotechnology companies, to develop and commercialize drug candidates or intellectual property. These arrangements typically involve two (or more) parties who are active participants in the collaboration and are exposed to significant risks and rewards dependent on the commercial success of the activities. These collaborations usually involve various activities by one or more parties, including research and development, marketing and selling and distribution. Often, these collaborations require upfront, milestone and royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development. Amounts due from collaborative partners related to development activities are generally reflected as a reduction of research and development expense because the performance of contract development services is not central to the Company's operations. In general, the income statement presentation for these collaborations is as follows:

Nature/Type of Collaboration	Statement of Earnings Presentation
Third-party sale of product & profit share payments received	Sales to customers
Royalties/milestones paid to collaborative partner (post-regulatory approval)*	Cost of products sold
Royalties received from collaborative partner	Other income (expense), net
Upfront payments & milestones paid to collaborative partner (pre-regulatory approval)	Research and development expense
Research and development payments to collaborative partner	Research and development expense
Research and development payments received from collaborative partner or government entity	Reduction of Research and development expense

* Milestones are capitalized as intangible assets and amortized to cost of products sold over the useful life.

For all years presented, there was no individual project that represented greater than 5% of the total annual consolidated research and development expense.

The Company has a number of products and compounds developed in collaboration with strategic partners including XARELTO, co-developed with Bayer HealthCare AG and IMBRUVICA, developed in collaboration and co-marketed with Pharmacyclics LLC, an AbbVie company.

Separately, the Company has a number of licensing arrangements for products and compounds including DARZALEX, licensed from Genmab A/S.

Advertising

Costs associated with advertising are expensed in the year incurred and are included in selling, marketing and administrative expenses. Advertising expenses worldwide, which comprised television, radio, print media and Internet advertising, were $0.5 billion, $0.7 billion and $1.2 billion in fiscal years 2023, 2022 and 2021, respectively.

Income taxes

Income taxes are recorded based on amounts refundable or payable for the current year and include the results of any difference between U.S. GAAP accounting and tax reporting, recorded as deferred tax assets or liabilities. The Company

estimates deferred tax assets and liabilities based on enacted tax regulations and rates. Future changes in tax laws and rates may affect recorded deferred tax assets and liabilities in the future.

The Company has unrecognized tax benefits for uncertain tax positions. The Company follows U.S. GAAP which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Management believes that changes in these estimates would not have a material effect on the Company's results of operations, cash flows or financial position.

In 2017, the United States enacted into law new U.S. tax legislation, the U.S. Tax Cuts and Jobs Act (TCJA). This law included provisions for a comprehensive overhaul of the corporate income tax code, including a reduction of the statutory corporate tax rate from 35% to 21%, effective on January 1, 2018. The TCJA included a provision for a tax on all previously undistributed earnings of U.S. companies located in foreign jurisdictions. Undistributed earnings in the form of cash and cash equivalents were taxed at a rate of 15.5% and all other earnings were taxed at a rate of 8.0%. This tax is payable over 8 years and will not accrue interest. These payments began in 2018 and will continue through 2025. The remaining balance at the end of the 2023 was approximately $4.5 billion, of which $2.5 billion is classified as noncurrent and reflected as “Long-term taxes payable” on the Company's balance sheet.

The TCJA also includes provisions for a tax on global intangible low-taxed income (GILTI). GILTI is described as the excess of a U.S. shareholder’s total net foreign income over a deemed return on tangible assets, as provided by the TCJA. In January 2018, the FASB issued guidance that allows companies to elect as an accounting policy whether to record the tax effects of GILTI in the period the tax liability is generated (i.e., “period cost”) or provide for deferred tax assets and liabilities related to basis differences that exist and are expected to effect the amount of GILTI inclusion in future years upon reversal (i.e., “deferred method”). The Company has elected to account for GILTI under the deferred method. The deferred tax amounts recorded are based on the evaluation of temporary differences that are expected to reverse as GILTI is incurred in future periods.

The Company has recorded deferred tax liabilities on all undistributed earnings prior to December 31, 2017 from its international subsidiaries. The Company has not provided deferred taxes on the undistributed earnings subsequent to January 1, 2018 from certain international subsidiaries where the earnings are considered to be indefinitely reinvested. The Company intends to continue to reinvest these earnings in those international operations. If the Company decides at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company estimates that the tax effect of this repatriation would be approximately $0.5 billion under currently enacted tax laws and regulations and at current currency exchange rates. This amount does not include the possible benefit of U.S. foreign tax credits, which may substantially offset this cost.

See Note 8 to the Consolidated Financial Statements for further information regarding income taxes.

Net earnings per share

Basic earnings per share is computed by dividing net earnings available to common shareholders by the weighted average number of common shares outstanding for the period. Diluted earnings per share reflects the potential dilution that could occur if securities were exercised or converted into common stock using the treasury stock method.

Use of estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the amounts reported. Estimates are used when accounting for sales discounts, rebates, allowances and incentives, product liabilities, income taxes, withholding taxes, depreciation, amortization, employee benefits, contingencies and intangible asset and liability valuations. Actual results may or may not differ from those estimates.

The Company follows the provisions of U.S. GAAP when recording litigation related contingencies. A liability is recorded when a loss is probable and can be reasonably estimated. The best estimate of a loss within a range is accrued; however, if no estimate in the range is better than any other, the minimum amount is accrued.

Annual closing date

The Company follows the concept of a fiscal year, which ends on the Sunday nearest to the end of the month of December. Normally each fiscal year consists of 52 weeks, but every five or six years the fiscal year consists of 53 weeks, and therefore includes additional shipping days, as was the case in fiscal year 2020, and will be the case again in fiscal year 2026.

2. Cash, cash equivalents and current marketable securities

At the end of the fiscal year 2023 and 2022, cash, cash equivalents and current marketable securities comprised:

	2023				
(Dollars in Millions)	Carrying Amount	Unrecognized Loss	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	$3,340	—	3,340	3,340	—
Non-U.S. Sovereign Securities[1]	522	—	522	174	348
U.S. Reverse repurchase agreements	4,377	—	4,377	4,377	—
Corporate debt securities[1]	338	—	338	189	149
Money market funds	4,814	—	4,814	4,814	—
Time deposits[1]	662	—	662	662	—
Subtotal	**$14,053**	**—**	**14,053**	**13,556**	**497**
U.S. Govt Securities	$8,562	—	8,562	8,259	303
U.S. Govt Agencies	71	(1)	70	—	70
Other Sovereign Securities	5	—	5	1	4
Corporate and other debt securities	237	—	237	43	194
Subtotal available for sale[2]	**$8,875**	**(1)**	**8,874**	**8,303**	**571**
Total cash, cash equivalents and current marketable securities				**$21,859**	**1,068**

	2022				
(Dollars in Millions)	Carrying Amount	Unrecognized Loss	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	$3,691	—	3,691	3,691	—
U.S. Reverse repurchase agreements	1,419	—	1,419	1,419	—
Corporate debt securities[1]	873	(1)	872	—	873
Money market funds	5,368	—	5,368	5,368	—
Time deposits[1]	443	—	443	443	—
Subtotal	**11,794**	**(1)**	**11,793**	**10,921**	**873**
U.S. Govt Securities	$9,959	(28)	9,931	1,922	8,009
U.S. Govt Agencies	210	(5)	205	—	205
Corporate and other debt securities	352	(1)	351	46	305
Subtotal available for sale[2]	**$10,521**	**(34)**	**10,487**	**1,968**	**8,519**
Total cash, cash equivalents and current marketable securities				**$12,889**	**9,392**

[1] Held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings.

[2] Available for sale debt securities are reported at fair value with unrealized gains and losses reported net of taxes in other comprehensive income.

Fair value of government securities and obligations and corporate debt securities were estimated using quoted broker prices and significant other observable inputs.

The contractual maturities of the available for sale debt securities at December 31, 2023 are as follows:

(Dollars in Millions)	Cost Basis	Fair Value
Due within one year	$8,865	8,864
Due after one year through five years	10	10
Due after five years through ten years	—	—
Total debt securities	**$8,875**	**8,874**

The Company invests its excess cash in both deposits with major banks throughout the world and other high-quality money market instruments. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating.

3. Inventories

At the end of fiscal years 2023 and 2022, inventories comprised:

(Dollars in Millions)	2023	2022
Raw materials and supplies	$2,355	1,719
Goods in process	1,952	1,577
Finished goods	6,874	6,972
Total inventories	**$11,181**	**10,268**

4. Property, plant and equipment

At the end of fiscal years 2023 and 2022, property, plant and equipment at cost and accumulated depreciation were:

(Dollars in Millions)	2023	2022
Land and land improvements	$795	784
Buildings and building equipment	12,375	11,470
Machinery and equipment	28,979	26,603
Construction in progress	5,627	4,677
Total property, plant and equipment, gross	**$47,776**	**43,534**
Less accumulated depreciation	27,878	25,552
Total property, plant and equipment, net	**$19,898**	**17,982**

The Company capitalizes interest expense as part of the cost of construction of facilities and equipment. Interest expense capitalized in fiscal years 2023, 2022 and 2021 was $70 million, $49 million and $49 million, respectively.

Depreciation expense, including the amortization of capitalized interest in fiscal years 2023, 2022 and 2021 was $2.6 billion, $2.4 billion and $2.4 billion, respectively.

Upon retirement or other disposal of property, plant and equipment, the costs and related amounts of accumulated depreciation or amortization are eliminated from the asset and accumulated depreciation accounts, respectively. The difference, if any, between the net asset value and the proceeds are recorded in earnings.

5. Intangible assets and goodwill

At the end of fiscal years 2023 and 2022, the gross and net amounts of intangible assets were:

(Dollars in Millions)	2023	2022
Intangible assets with definite lives:		
Patents and trademarks — gross	$40,417	39,388
Less accumulated amortization	(24,808)	(20,616)
Patents and trademarks — net	**$15,609**	**18,772**
Customer relationships and other intangibles — gross	$20,322	19,764
Less accumulated amortization	(12,685)	(11,363)
Customer relationships and other intangibles — net[1]	**$7,637**	**8,401**
Intangible assets with indefinite lives:		
Trademarks	$1,714	1,630
Purchased in-process research and development	9,215	9,686
Total intangible assets with indefinite lives	**$10,929**	**11,316**
Total intangible assets — net	**$34,175**	**38,489**

(1) The majority is comprised of customer relationships

Goodwill as of December 31, 2023 and January 1, 2023, as allocated by segment of business, was as follows:

(Dollars in Millions)	Innovative Medicine	MedTech	Total
Goodwill at January 2, 2022	$10,580	14,856	25,436
Goodwill, related to acquisitions	—	11,056	11,056
Goodwill, related to divestitures	—	—	—
Currency translation/other	(396)	(49)	(445)
Goodwill at January 1, 2023	10,184	25,863	36,047
Goodwill, related to acquisitions	—	—	—
Goodwill, related to divestitures	—	—	—
Currency translation/other	223	288 *	511
Goodwill at December 31, 2023	$10,407	26,151	36,558

*Includes purchase price allocation adjustments for Abiomed

The weighted average amortization period for patents and trademarks is approximately 11 years. The weighted average amortization period for customer relationships and other intangible assets is approximately 19 years. The amortization expense of amortizable assets included in Cost of products sold was $4.5 billion, $3.9 billion and $4.2 billion before tax, for the fiscal years ended December 31, 2023, January 1, 2023 and January 2, 2022, respectively. Intangible asset write-downs are included in Other (income) expense, net.

The estimated amortization expense related to intangible assets for approved products, before tax, for the five succeeding years is approximately:

(Dollars in Millions)

2024	2025	2026	2027	2028
$4,300	3,500	2,900	2,300	1,600

See Note 18 to the Consolidated Financial Statements for additional details related to acquisitions and divestitures.

6. Fair value measurements

The Company uses forward foreign exchange contracts to manage its exposure to the variability of cash flows, primarily related to the foreign exchange rate changes of future intercompany products and third-party purchases of materials denominated in a foreign currency. The Company uses cross currency interest rate swaps to manage currency risk primarily related to borrowings. Both types of derivatives are designated as cash flow hedges.

Additionally, the Company primarily uses interest rate swaps as an instrument to manage interest rate risk related to fixed rate borrowings. These derivatives are designated as fair value hedges. The Company uses cross currency interest rate swaps and forward foreign exchange contracts designated as net investment hedges. Additionally, the Company uses forward foreign exchange contracts to offset its exposure to certain foreign currency assets and liabilities. These forward foreign exchange contracts are not designated as hedges and therefore, changes in the fair values of these derivatives are recognized in earnings, thereby offsetting the current earnings effect of the related foreign currency assets and liabilities.

The Company does not enter into derivative financial instruments for trading or speculative purposes, or that contain credit risk related contingent features. The Company maintains credit support agreements (CSA) with certain derivative counterparties establishing collateral thresholds based on respective credit ratings and netting agreements. As of December 31, 2023 and January 1, 2023, the total amount of cash collateral paid by the Company under the CSA amounted to $4.0 billion and $0.8 billion net respectively, related to net investment and cash flow hedges. On an ongoing basis, the Company monitors counter-party credit ratings. The Company considers credit non-performance risk to be low, because the Company primarily enters into agreements with commercial institutions that have at least an investment grade credit rating. Refer to the table on significant financial assets and liabilities measured at fair value contained in this footnote for receivables and payables with these commercial institutions. As of December 31, 2023, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of $42.9 billion, $39.7 billion and $10.0 billion, respectively. As of January 1, 2023, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of $41.5 billion, $36.2 billion and $10.0 billion, respectively.

All derivative instruments are recorded on the balance sheet at fair value. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The designation as a cash flow hedge is made at the entrance date of the derivative contract. At inception, all derivatives are expected to be highly effective. Foreign exchange contracts designated as cash flow hedges are accounted for under the forward method and all gains/losses associated with these contracts will be recognized in the income statement when the hedged item impacts earnings. Changes in the fair value of these derivatives are recorded in accumulated other comprehensive income until the underlying transaction affects earnings, and are then reclassified to earnings in the same account as the hedged transaction.

Gains and losses associated with interest rate swaps and changes in fair value of hedged debt attributable to changes in interest rates are recorded to interest expense in the period in which they occur. Gains and losses on net investment hedges are accounted through the currency translation account within accumulated other comprehensive income. The portion excluded from effectiveness testing is recorded through interest (income) expense using the spot method. On an ongoing basis, the Company assesses whether each derivative continues to be highly effective in offsetting changes of hedged items. If and when a derivative is no longer expected to be highly effective, hedge accounting is discontinued.

The Company designated its Euro denominated notes issued in May 2016 with due dates ranging from 2022 to 2035 as a net investment hedge of the Company's investments in certain of its international subsidiaries that use the Euro as their functional currency in order to reduce the volatility caused by changes in exchange rates.

As of December 31, 2023, the balance of deferred net loss on derivatives included in accumulated other comprehensive income was $377 million after-tax. For additional information, see the Consolidated Statements of Comprehensive Income and Note 13. The Company expects that substantially all of the amounts related to forward foreign exchange contracts will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months, excluding interest rate contracts and net investment hedges. The amount ultimately realized in earnings may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity of the derivative.

The following table is a summary of the activity related to derivatives and hedges for the fiscal years ended December 31, 2023 and January 1, 2023, net of tax:

	December 31, 2023					January 1, 2023				
(Dollars in Millions)	Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense	Cost of Sales Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense
The effects of fair value, net investment and cash flow hedging:									
Gain (Loss) on fair value hedging relationship:									
Interest rate swaps contracts:									
Hedged items	$—	—	—	(930)	—	—	—	(1,098)	—
Derivatives designated as hedging instruments	—	—	—	930	—	—	—	1,098	—
Gain (Loss) on net investment hedging relationship:									
Cross currency interest rate swaps contracts:									
Amount of gain or (loss) recognized in income on derivative amount excluded from effectiveness testing	$—	—	—	130	—	—	—	140	—
Amount of gain or (loss) recognized in AOCI	—	—	—	130	—	—	—	140	—
Gain (Loss) on cash flow hedging relationship:									
Forward foreign exchange contracts:									
Amount of gain or (loss) reclassified from AOCI into income	7	186	(37)	—	8	(72)	(271)	149	—	(23)
Amount of gain or (loss) recognized in AOCI	10	447	(18)	—	9	5	319	61	—	(113)
Cross currency interest rate swaps contracts:									
Amount of gain or (loss) reclassified from AOCI into income	—	—	—	275	—	—	—	425	—
Amount of gain or (loss) recognized in AOCI	$—	—	—	(156)	—	—	—	42	—

As of December 31, 2023 and January 1, 2023, the following amounts were recorded on the consolidated balance sheet related to cumulative basis adjustment for fair value hedges

Line item in the Consolidated Balance Sheet in which the hedged item is included	Carrying Amount of the Hedged Liability		Cumulative Amount of Fair Value Hedging Adjustment Included in the Carrying Amount of the Hedged Liability	
(Dollars in Millions)	December 31, 2023	January 1, 2023	December 31, 2023	January 1, 2023
Long-term Debt	$8,862	$8,665	$(1,216)	$(1,435)

The following table is the effect of derivatives not designated as hedging instrument for the fiscal years ended December 31, 2023 and January 1, 2023:

(Dollars in Millions)	Location of Gain /(Loss) Recognized in Income on Derivative	Gain/(Loss) Recognized In Income on Derivative	
Derivatives Not Designated as Hedging Instruments		December 31, 2023	January 1, 2023
Foreign Exchange Contracts	Other (income) expense	$(60)	94

The following table is the effect of net investment hedges for the fiscal years ended December 31, 2023 and January 1, 2023:

	Gain/(Loss) Recognized In Accumulated OCI		Location of Gain or (Loss) Reclassified from Accumulated Other Comprehensive Income Into Income	Gain/(Loss) Reclassified From Accumulated OCI Into Income	
(Dollars in Millions)	December 31, 2023	January 1, 2023		December 31, 2023	January 1, 2023
Debt	$(131)	197	Interest (income) expense	—	—
Cross Currency interest rate swaps	$642	766	Interest (income) expense	—	—

The Company holds equity investments with readily determinable fair values and equity investments without readily determinable fair values. The Company measures equity investments that do not have readily determinable fair values at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer.

The following table is a summary of the activity related to equity investments for the fiscal years ended December 31, 2023 and January 1, 2023:

	January 1, 2023			December 31, 2023	
(Dollars in Millions)	Carrying Value	Changes in Fair Value Reflected in Net Income[1]	Sales/ Purchases/Other[2]	Carrying Value	Non Current Other Assets
Equity Investments with readily determinable value *	$576	(368)	4,265	4,473	4,473
Equity Investments without readily determinable value	$613	1	82	696	696

(Dollars in Millions)	January 2, 2022 Carrying Value	Changes in Fair Value Reflected in Net Income[1]	Sales/ Purchases/Other[2]	January 1, 2023 Carrying Value	Non Current Other Assets
Equity Investments with readily determinable value	$1,884	(538)	(770)	576	576
Equity Investments without readily determinable value	$413	93	107	613	613

[1] Recorded in Other Income/Expense

[2] Other includes impact of currency

* Includes the 9.5% remaining stake in Kenvue and the $0.4 billion unfavorable change in fair value of the investment between separation date and the end of the fiscal year.

For the fiscal years ended December 31, 2023 and January 1, 2023 for equity investments without readily determinable market values, $1 million and $51 million, respectively, of the changes in fair value reflected in net income were the result of impairments. There were offsetting impacts of $27 million and $142 million, respectively, of changes in the fair value reflected in net income due to changes in observable prices and gains on the disposal of investments.

Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. In accordance with ASC 820, a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described below with Level 1 having the highest priority and Level 3 having the lowest.

The fair value of a derivative financial instrument (i.e., forward foreign exchange contracts, interest rate contracts) is the aggregation by currency of all future cash flows discounted to its present value at the prevailing market interest rates and subsequently converted to the U.S. Dollar at the current spot foreign exchange rate. The Company does not believe that fair values of these derivative instruments materially differ from the amounts that could be realized upon settlement or maturity, or that the changes in fair value will have a material effect on the Company's results of operations, cash flows or financial position. The Company also holds equity investments which are classified as Level 1 and debt securities which are classified as Level 2. The Company holds acquisition related contingent liabilities based upon certain regulatory and commercial events, which are classified as Level 3, whose values are determined using discounted cash flow methodologies or similar techniques for which the determination of fair value requires significant judgment or estimations.

The following three levels of inputs are used to measure fair value:

Level 1 — Quoted prices in active markets for identical assets and liabilities.

Level 2 — Significant other observable inputs.

Level 3 — Significant unobservable inputs.

The Company's significant financial assets and liabilities measured at fair value as of the fiscal year ended December 31, 2023 and January 1, 2023 were as follows:

	2023				2022
(Dollars in Millions)	**Level 1**	**Level 2**	**Level 3**	**Total**	**Total[1]**
Derivatives designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	$—	539	—	539	629
Interest rate contracts [2]	—	988	—	988	1,534
Total	**$—**	**1,527**	**—**	**1,527**	**2,163**
Liabilities:					
Forward foreign exchange contracts	—	624	—	624	511
Interest rate contracts [2]	—	5,338	—	5,338	2,778
Total	**$—**	**5,962**	**—**	**5,962**	**3,289**
Derivatives not designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	$—	64	—	64	38
Liabilities:					
Forward foreign exchange contracts	—	75	—	75	68
Available For Sale Other Investments:					
Equity investments[3]	4,473	—	—	4,473	576
Debt securities[4]	—	8,874	—	8,874	10,487
Other Liabilities					
Contingent Consideration[5]	$		1,092	1,092	1,120

Gross to Net Derivative Reconciliation	**2023**	**2022**
(Dollars in Millions)		
Total Gross Assets	$1,591	2,201
Credit Support Agreements (CSA)	(1,575)	(2,176)
Total Net Asset	16	25
Total Gross Liabilities	6,037	3,357
Credit Support Agreements (CSA)	(5,604)	(3,023)
Total Net Liabilities	$433	334

Summarized information about changes in liabilities for contingent consideration is as follows:

	2023	2022	2021
(Dollars in Millions)			
Beginning Balance	$1,120	533	633
Changes in estimated fair value	29	(194)	(52)
Additions [6]	—	792	—
Payments/Other	(57)	(11)	(48)
Ending Balance [5]	$1,092	1,120	533

(1) 2022 assets and liabilities are all classified as Level 2 with the exception of equity investments of $576 million, which are classified as Level 1 and contingent consideration of $1,120 million, classified as Level 3.

(2) Includes cross currency interest rate swaps and interest rate swaps.

(3) Classified as non-current other assets.

(4) Classified as cash equivalents and current marketable securities.

(5) Includes $1,092 million, $1,116 million and $520 million, classified as non-current other liabilities as of December 31, 2023, January 1, 2023 and January 2, 2022, respectively. Includes $4 million and $13 million classified as current liabilities as of January 1, 2023 and January 2, 2022, respectively.

(6) In fiscal year 2022, the Company recorded $704 million of contingent consideration related to Abiomed.

See Notes 2 and 7 for financial assets and liabilities held at carrying amount on the Consolidated Balance Sheet.

7. Borrowings

The components of long-term debt are as follows:

(Dollars in Millions)	2023	Effective Rate %	2022	Effective Rate %
6.73% Debentures due 2023	$—	—%	$250	6.73 %
3.375% Notes due 2023	—	—	801	3.17
2.05% Notes due 2023	—	—	500	2.09
0.650% Notes due 2024 (750MM Euro 1.1090)[2]/(750MM Euro 1.0651)[3]	831 [2]	0.68	792 [3]	0.68
5.50% Notes due 2024 (500MM 1.2756 GBP)[2]/(500MM GBP 1.2037)[3]	637 [2]	6.75	600 [3]	6.75
2.625% Notes due 2025	750	2.63	749	2.63
0.55% Notes due 2025	950	0.57	918	0.57
2.46% Notes due 2026	1,997	2.47	1,996	2.47
2.95% Notes due 2027	900	2.96	877	2.96
0.95% Notes due 2027	1,419	0.96	1,394	0.96
1.150% Notes due 2028 (750MM Euro 1.1090)[2]/(750MM Euro 1.0651)[3]	828 [2]	1.21	794 [3]	1.21
2.90% Notes due 2028	1,497	2.91	1,496	2.91
6.95% Notes due 2029	298	7.14	298	7.14
1.30% Notes due 2030	1,630	1.30	1,607	1.30
4.95% Debentures due 2033	499	4.95	498	4.95
4.375% Notes due 2033	854	4.24	854	4.24
1.650% Notes due 2035 (1.5B Euro 1.1090)[2]/(1.5B Euro 1.0651)[3]	1,652 [2]	1.68	1,591 [3]	1.68
3.587% Notes due 2036	864	3.59	842	3.59
5.95% Notes due 2037	994	5.99	993	5.99
3.625% Notes due 2037	1,357	3.64	1,336	3.64
5.85% Debentures due 2038	697	5.85	697	5.85
3.400% Notes due 2038	993	3.42	992	3.42
4.50% Debentures due 2040	541	4.63	540	4.63
2.10% Notes due 2040	849	2.14	828	2.14
4.85% Notes due 2041	297	4.89	297	4.89
4.50% Notes due 2043	496	4.52	496	4.52
3.73% Notes due 2046	1,977	3.74	1,976	3.74
3.75% Notes due 2047	832	3.76	812	3.76
3.500% Notes due 2048	743	3.52	743	3.52
2.250% Notes due 2050	826	2.29	808	2.29
2.450% Notes due 2060	1,073	2.49	1,055	2.49
Other	69	—	7	—
Subtotal	**27,350** [4]	**2.98 %** [1]	**28,437** [4]	**3.04 %** [1]
Less current portion	1,469		1,551	
Total long-term debt	**$25,881**		**$26,886**	

[1] Weighted average effective rate.

(2) Translation rate at December 31, 2023.

(3) Translation rate at January 1, 2023.

(4) The excess of the carrying value over the fair value of debt was $1.0 billion and $1.6 billion at the end of fiscal year 2023 and fiscal year 2022, respectively.

Fair value of the long-term debt was estimated using market prices, which were corroborated by quoted broker prices and significant other observable inputs.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2023, the Company secured a new 364-day Credit Facility of $10 billion, which expires on September 5, 2024. The Company early terminated the additional 364-day revolving Credit Facility of $10 billion, which had an expiration of November 21, 2023. Interest charged on borrowings under the credit line agreement is based on either the Term SOFR Reference Rate or other applicable market rates as allowed under the terms of the agreement, plus applicable margins. Commitment fees under the agreements are not material.

Throughout fiscal years 2023 and 2022, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $3.5 billion and $12.8 billion at the end of fiscal years 2023 and 2022, respectively. The current portion of the long term debt was $1.5 billion and $1.6 billion in 2023 and 2022, respectively, and the remainder is commercial paper and local borrowing by international subsidiaries.

The current debt balance as of December 31, 2023 includes $2.0 billion of commercial paper which has a weighted average interest rate of 5.37% and a weighted average maturity of approximately two months. The current debt balance as of January 1, 2023 includes $11.2 billion of commercial paper which has a weighted average interest rate of 4.23% and a weighted average maturity of approximately two months.

Aggregate maturities of long-term debt obligations commencing in 2024 are:

(Dollars in Millions)					
2024	**2025**	**2026**	**2027**	**2028**	**After 2028**
$1,469	1,700	1,997	2,320	2,325	17,539

8. Income taxes

The provision for taxes on income consists of:

(Dollars in Millions)	2023	2022	2021
Currently payable:			
U.S. taxes	$2,705	2,274	1,338
International taxes	3,090	2,295	2,069
Total currently payable	5,795	4,569	3,407
Deferred:			
U.S. taxes	(3,440)	(1,990)	565
International taxes	(619)	410	(2,595)
Total deferred	(4,059)	(1,580)	(2,030)
Provision for taxes on income	**$1,736**	**2,989**	**1,377**

A comparison of income tax expense at the U.S. statutory rate of 21% in fiscal years 2023, 2022 and 2021, to the Company's effective tax rate is as follows:

(Dollars in Millions)	2023	2022	2021
U.S.	$(2,033)	4,606	4,275
International	17,095	14,753	14,903
Earnings before taxes on income:	$15,062	19,359	19,178
Tax rates:			
U.S. statutory rate	21.0 %	21.0	21.0
International operations[1]	(8.1)	(5.0)	(19.1)
U.S. Tax Settlements	(3.0)	—	—
U.S. taxes on international income[2]	(0.3)	(1.1)	8.9
Tax benefits from loss on capital assets	—	—	(1.6)
Tax benefits on share-based compensation	(0.8)	(1.4)	(1.2)
All other	2.7	1.9	(0.8)
Effective Rate	11.5 %	15.4	7.2

(1) International operations reflect the impacts of operations in jurisdictions with statutory tax rates different than the U.S., particularly Ireland, Switzerland, Belgium and Puerto Rico, which is a favorable impact on the effective tax rate as compared with the U.S. statutory rate.

(2) Includes the impact of the GILTI tax, the Foreign-Derived Intangible Income deduction and other foreign income that is taxable under the U.S. tax code. The 2023 and 2022 amount includes the impact of certain provisions of the 2017 TCJA that became effective in fiscal 2022. The 2023 amount includes the impact of certain foreign subsidiaries deferred tax remeasurements for legislative elections and the 2021 amounts include the reorganization of international subsidiaries further described below.

The fiscal year 2023 effective tax rate decreased 3.9% as compared to the fiscal year 2022 effective tax rate as the Company recorded certain non-recurring favorable tax items in fiscal year 2023 when compared to the prior fiscal year.

In the fiscal fourth quarter of 2023, the Company settled the U.S. Internal Revenue Service audit for tax years 2013 through 2016 which resulted in a favorable impact to the rate of 3.0%. This settlement was partially offset by the Company recording a $0.4 billion decrease in expected U.S. foreign tax credits, an unfavorable effective rate impact of 2.6%, which has been reflected as a current tax expense in U.S. taxes on international income on the Company's effective tax rate reconciliation.

In the fiscal year 2023, the Company had certain non-recurring impacts as a result of legislative tax elections made in certain international subsidiaries which resulted in a change in the Company's tax basis in certain assets resulting in deferred tax re-measurements. The net impact of these non-recurring items is a net benefit of 3.4% to the Company's annual effective tax rate, comprised of the following items:

- approximately $0.3 billion of tax benefit on local deferred tax assets to record the remeasurement of the increased tax basis, this benefit has been reflected as International operations on the Company's effective tax rate reconciliation. This benefit was offset by approximately $0.1 billion of U.S. deferred tax expense on the GILTI deferred tax liability resulting from the remeasurement of these deferred tax assets. This has been reflected in the "U.S. tax on international income" on the Company's effective tax rate reconciliation.
- approximately $0.3 billion of U.S. deferred tax benefit on the GILTI deferred tax as a result of an international subsidiary making an election to change the treatment of a local deferred tax asset to a refundable tax credit. This has been reflected in the U.S. taxes on international income on the Company's effective tax rate reconciliation.

The Company's 2023 and 2022 tax rates benefited from certain provisions of the Tax Cuts and Jobs Act of 2017 that became effective in fiscal 2022. The Company also had lower income in higher tax jurisdictions vs. fiscal year 2022, primarily in the U.S. where the Company recorded an approximately $7.0 billion charge related to talc matters in the United States at an effective tax rate of 21.1% (for further information see Note 19 to the Consolidated Financial Statements).

The fiscal year 2022 effective tax rate increased 8.2% as compared to the fiscal year 2021 effective tax rate as the Company recorded certain non-recurring favorable tax items in fiscal year 2021 which resulted in an unfavorable impact to the Company's fiscal 2022 effective tax rate when compared to the prior fiscal year. These items are described below. The Company's 2022 tax rate also benefited from the impairment of bermekimab for AD IPR&D and changes in the fair value of securities in the Company's investment portfolio, both recorded at the U.S. statutory rate.

In the fiscal year 2021, the Company reorganized the ownership structure of certain wholly-owned international subsidiaries. As part of this reorganization, the Company increased the tax basis of certain assets to fair value in accordance with applicable local regulations. The net impact of this restructuring was approximately $0.6 billion net benefit or 3.2% benefit to the Company's annual effective tax rate, comprised of the following items:

- approximately $2.3 billion of local deferred tax assets to record the remeasurement of the tax basis of these assets to fair value, this benefit has been reflected as International operations on the Company's effective tax rate reconciliation.
- approximately $1.7 billion of U.S. deferred tax expense relating to the GILTI deferred tax liability resulting from the remeasurement of these deferred tax assets. This expense has been reflected as U.S. taxes on international income on the Company's effective tax rate reconciliation.

Also, in the fiscal fourth quarter of 2021, the Company recognized a loss on certain U.S. affiliates related to the previously impaired book value of certain intangibles, which reduced the 2021 effective tax rate by approximately 1.6% which is reflected as a Tax benefits from loss on capital assets on the effective tax rate reconciliation. Additionally other fiscal 2021 impacts to the rate were primarily driven by litigation and acquisition related items as follows:

- the Company accrued additional legal expenses, of approximately $1.6 billion for talc at an effective tax rate of 23.5% and $0.8 billion for Risperdal Gynecomastia settlements at an effective tax rate of 16.4% (See Note 19 to the Consolidated Financial Statements for more details).
- the Company recorded a partial IPR&D charge of $0.9 billion for the Ottava intangible asset (acquired with the Auris Health acquisition in 2019) at an effective rate of 22.4%.

Temporary differences and carryforwards at the end of fiscal years 2023 and 2022 were as follows:

	2023 Deferred Tax		2022 Deferred Tax	
(Dollars in Millions)	**Asset**	**Liability**	**Asset**	**Liability**
Employee related obligations	$586		685	
Stock based compensation	686		632	
Depreciation of property, plant and equipment		(902)		(845)
Goodwill and intangibles		(1,252)		(1,737)
R&D capitalized for tax	3,595		2,611	
Reserves & liabilities	3,816		2,733	
Income reported for tax purposes[1]	359		2,026	
Net realizable operating loss carryforwards[2]	996		1,319	
Undistributed foreign earnings	1,801	(1,695)	1,517	(1,604)
Global intangible low-taxed income		(2,731)		(3,628)
Miscellaneous international	831		861	(66)
Miscellaneous U.S.		(4)	452	
Total deferred income taxes	**$12,670**	**(6,584)**	**12,836**	**(7,880)**

(1) In fiscal 2023, the Company changed the presentation of income taxes accrued on intercompany profits on inventory still owned by the Company as part of "Prepaid expenses and other" on the Consolidated Balance Sheet.

(2) Net of valuation allowances of $1.1 billion and $0.8 billion in 2023 and 2022. The change in the valuation allowance from 2022 to 2023 was driven by approximately $0.1 billion from acquisition related activity and the remainder was due to normal operations during the fiscal year.

The Company has wholly-owned international subsidiaries that have cumulative net losses. The Company believes that it is more likely than not that these subsidiaries will generate future taxable income sufficient to utilize these deferred tax assets. However, in certain jurisdictions, valuation allowances have been recorded against deferred tax assets for loss carryforwards that are not more likely than not to be realized.

The following table summarizes the activity related to unrecognized tax benefits for continuing operations:

(Dollars in Millions)	2023	2022	2021
Beginning of year	$3,716	3,210	3,260
Increases related to current year tax positions	239	523	242
Increases related to prior period tax positions	244	143	23
Decreases related to prior period tax positions	(781)	(148)	(128)
Settlements	(880)	(1)	(187)
Lapse of statute of limitations	(53)	(11)	—
End of year	**$2,485**	**3,716**	**3,210**

As of December 31, 2023 the Company had approximately $2.5 billion of unrecognized tax benefits. The Company conducts business and files tax returns in numerous countries and currently has tax audits in progress with a number of tax authorities. With respect to the United States the Internal Revenue Service has completed its audit for all tax years through 2016.

In other major jurisdictions where the Company conducts business, the years that remain open to tax audits go back to the year 2008. The Company believes it is possible that some tax audits may be completed over the next twelve months by taxing authorities in some jurisdictions, including in the United States. However, the Company is not able to provide a reasonably reliable estimate of the timing of any other future tax payments or change in uncertain tax positions, if any.

The Company classifies liabilities for unrecognized tax benefits and related interest and penalties as long-term liabilities. Interest expense and penalties related to unrecognized tax benefits are classified as income tax expense. The Company recognized after tax interest expense of $99 million, $136 million and $42 million in fiscal years 2023, 2022 and 2021, respectively. The total amount of accrued interest was $264 million and $637 million in fiscal years 2023 and 2022, respectively.

9. Employee related obligations

At the end of fiscal 2023 and fiscal 2022, employee related obligations recorded on the Consolidated Balance Sheets were:

ollars in Millions)	2023	2022
nsion benefits	$3,129	2,475
stretirement benefits	1,963	1,728
stemployment benefits	2,527	2,832
ferred compensation	68	100
tal employee obligations	7,687	7,135
ss current benefits payable	538	593
nployee related obligations — non-current	**$7,149**	**6,542**

Prepaid employee related obligations of $4,992 million and $4,581 million for 2023 and 2022, respectively, are included in Other assets on the Consolidated Balance Sheets.

10. Pensions and other benefit plans

The Company sponsors various retirement and pension plans, including defined benefit, defined contribution and termination indemnity plans, which cover most employees worldwide. The Company also provides post-retirement benefits, primarily healthcare, to all eligible U.S. retired employees and their dependents.

Many international employees are covered by government-sponsored programs and the cost to the Company is not significant.

In the U.S, non-union pension benefits for employees hired before January 1, 2015 are primarily based on the employee's compensation during the last five years before retirement and the number of years of service (the Final Average Pay formula). U.S. pension benefits for employees hired after 2014, are calculated using a different formula based on employee compensation over total years of service (the Retirement Value formula).

In January 2021, the Company announced that, effective on January 1, 2026, all eligible U.S. non-union employees, regardless of hire date, will earn benefits under the Retirement Value formula. This amendment does not affect the benefits accrued under the Final Average Pay formula for service before January 1, 2026.

International subsidiaries have plans under which funds are deposited with trustees, annuities are purchased under group contracts, or reserves are provided.

The Company does not fund retiree healthcare benefits in advance and has the right to modify these plans in the future.

In 2023 and 2022 the Company used December 31, 2023 and December 31, 2022, respectively, as the measurement date for all U.S. and international retirement and other benefit plans.

Net periodic benefit costs for the Company's defined benefit retirement plans and other benefit plans for 2023, 2022 and 2021 include the following components:

	Retirement Plans			Other Benefit Plans		
(Dollars in Millions)	**2023**	**2022**	**2021**	**2023**	**2022**	**2021**
Service cost	$893	1,319	1,412	264	320	309
Interest cost	1,437	908	768	214	104	80
Expected return on plan assets	(2,716)	(2,756)	(2,644)	(7)	(8)	(7)
Amortization of prior service cost	(184)	(184)	(181)	(2)	(5)	(31)
Recognized actuarial losses (gains)	(199)	650	1,251	23	122	151
Curtailments and settlements	93	1	1	(5)	—	—
Net periodic benefit cost (credit)	**$(676)**	**(62)**	**607**	**487**	**533**	**502**

The service cost component of net periodic benefit cost is presented in the same line items on the Consolidated Statement of Earnings where other employee compensation costs are reported, including Cost of products sold, Research and development expense, Selling, marketing and administrative expenses, and Net earnings from discontinued operations, net of taxes if related to the separation of Kenvue. All other components of net periodic benefit cost are presented as part of Other (income) expense, net on the Consolidated Statement of Earnings, with the exception of certain amounts for curtailments and settlements, which are reported in Net earnings from discontinued operations, net of taxes if related to the separation of Kenvue (as noted above).

Unrecognized gains and losses for the U.S. pension plans are amortized over the average remaining future service for each plan. For plans with no active employees, they are amortized over the average life expectancy. The amortization of gains and losses for the other U.S. benefit plans is determined by using a 10% corridor of the greater of the market value of assets or the accumulated postretirement benefit obligation. Total unamortized gains and losses in excess of the corridor are amortized over the average remaining future service.

Prior service costs/benefits for the U.S. pension plans are amortized over the average remaining future service of plan participants at the time of the plan amendment. Prior service cost/benefit for the other U.S. benefit plans is amortized over the average remaining service to full eligibility age of plan participants at the time of the plan amendment.

The following table represents the weighted-average actuarial assumptions:

	Retirement Plans			Other Benefit Plans		
Worldwide Benefit Plans	**2023**	**2022**	**2021**	**2023**	**2022**	**2021**
Net Periodic Benefit Cost						
Service cost discount rate	4.85 %	2.46	2.14	5.40	2.59	2.09
Interest cost discount rate	5.25 %	2.80	2.34	5.43	2.64	2.33
Rate of increase in compensation levels	3.71 %	4.02	4.01	4.22	4.21	4.25
Expected long-term rate of return on plan assets	7.21 %	7.25	7.71			
Benefit Obligation						
Discount rate	4.58 %	5.01	2.49	5.11	5.42	2.68
Rate of increase in compensation levels	3.69 %	4.00	4.01	4.22	4.21	4.21

The Company's discount rates are determined by considering current yield curves representing high quality, long-term fixed income instruments. The resulting discount rates are consistent with the duration of plan liabilities. The Company's methodology in determining service and interest cost uses duration specific spot rates along that yield curve to the plans' liability cash flows.

The expected rates of return on plan asset assumptions represent the Company's assessment of long-term returns on diversified investment portfolios globally. The assessment is determined using projections from external financial sources, long-term historical averages, actual returns by asset class and the various asset class allocations by market.

The following table displays the assumed healthcare cost trend rates, for all individuals:

Healthcare Plans	**2023**		**2022**
Healthcare cost trend rate assumed for next year	13.90 %	*	5.96 %
Rate to which the cost trend rate is assumed to decline (ultimate trend)	4.00 %		3.99 %
Year the rate reaches the ultimate trend rate	2048		2047

*excludes ongoing negotiations regarding healthcare cost with service providers

The following table sets forth information related to the benefit obligation and the fair value of plan assets at fiscal year-end 2023 and 2022 for the Company's defined benefit retirement plans and other post-retirement plans:

	Retirement Plans		Other Benefit Plans	
(Dollars in Millions)	**2023**	**2022**	**2023**	**2022**
Change in Benefit Obligation				
Projected benefit obligation — beginning of year	$29,390	41,272	4,192	4,874
Service cost	893	1,319	264	320
Interest cost	1,437	908	214	104
Plan participant contributions	73	67	—	—
Amendments	(6)	7	—	—
Actuarial (gains) losses[1]	2,068	(12,159)	469	(704)
Divestitures & acquisitions[2]	(352)	—	1	—
Curtailments, settlements & restructuring	(238)	(7)	(332)	—
Benefits paid from plan[3]	(2,122)	(1,220)	(702)	(393)
Effect of exchange rates	601	(797)	2	(9)
Projected benefit obligation — end of year	**$31,744**	**29,390**	**4,108**	**4,192**

Change in Plan Assets				
Plan assets at fair value — beginning of year	$31,496	41,909	78	102
Actual return (loss) on plan assets	3,951	(8,663)	16	(17)
Company contributions	268	261	694	386
Plan participant contributions	73	67	—	—
Settlements	(176)	(5)	—	—
Divestitures & acquisitions[2]	(509)	—	—	—
Benefits paid from plan assets[3]	(2,122)	(1,220)	(702)	(393)
Effect of exchange rates	626	(853)	—	—
Plan assets at fair value — end of year	**$33,607**	**31,496**	**86**	**78**
Funded status — end of year	**$1,863**	**2,106**	**(4,022)**	**(4,114)**
Amounts Recognized in the Company's Balance Sheet consist of the following:				
Non-current assets	$4,992	4,581	—	—
Current liabilities	(119)	(127)	(416)	(461)
Non-current liabilities	(3,010)	(2,348)	(3,606)	(3,653)
Total recognized in the consolidated balance sheet — end of year	**$1,863**	**2,106**	**(4,022)**	**(4,114)**
Amounts Recognized in Accumulated Other Comprehensive Income consist of the following:				
Net actuarial loss	$4,962	3,948	354	239
Prior service cost (credit)	(1,236)	(1,417)	(6)	(7)
Unrecognized net transition obligation	—	—	—	
Total before tax effects	**$3,726**	**2,531**	**348**	**232**
Accumulated Benefit Obligations — end of year	**$30,139**	**27,797**		

[1] The actuarial (gains)/losses for retirement plans in 2023 and 2022 were primarily driven by changes in the discount rates.

[2] Primarily driven by the Kenvue separation.

[3] Includes approximately $800 million transferred to a group annuity contract issued by a third-party insurer for the U.S. Salaried Pension Plan.

	Retirement Plans		Other Benefit Plans	
(Dollars in Millions)	**2023**	**2022**	**2023**	**2022**
Amounts Recognized in Net Periodic Benefit Cost and Other Comprehensive Income				
Net periodic benefit cost (credit)	$(676)	(62)	487	533
Net actuarial (gain) loss	711	(793)	136	(751)
Amortization of net actuarial loss	199	(655)	(22)	(121)
Prior service cost (credit)	(2)	7	—	—
Amortization of prior service (cost) credit	185	183	2	5
Effect of exchange rates	103	(140)	—	(1)
Total loss/(income) recognized in other comprehensive income, before tax	**$1,195**	**(1,398)**	**116**	**(868)**
Total recognized in net periodic benefit cost and other comprehensive income	**$519**	**(1,460)**	**603**	**(335)**

The Company plans to continue to fund its U.S. Qualified Plans to comply with the Pension Protection Act of 2006. International Plans are funded in accordance with local regulations. Additional discretionary contributions are made when deemed appropriate to meet the long-term obligations of the plans. For certain plans, funding is not a common practice, as funding provides no economic benefit. Consequently, the Company has several pension plans that are not funded.

In 2023, the Company contributed $135 million and $133 million to its U.S. and international pension plans, respectively.

The following table displays the funded status of the Company's U.S. Qualified & Non-Qualified pension plans and international funded and unfunded pension plans at December 31, 2023 and December 31, 2022, respectively:

	U.S. Plans				International Plans			
	Qualified Plans		Non-Qualified Plans		Funded Plans		Unfunded Plans	
(Dollars in Millions)	**2023**	**2022**	**2023**	**2022**	**2023**	**2022**	**2023**	**2022**
Plan Assets	$22,298	20,937	—	—	11,309	10,559	—	—
Projected Benefit Obligation	19,152	18,394	2,037	1,937	10,431	8,982	124	77
Accumulated Benefit Obligation	18,557	17,696	1,982	1,872	9,498	8,166	102	63
Over (Under) Funded Status								
Projected Benefit Obligation	$3,146	2,543	(2,037)	(1,937)	878	1,577	(124)	(77)
Accumulated Benefit Obligation	3,741	3,241	(1,982)	(1,872)	1,811	2,393	(102)	(63)

Plans with accumulated benefit obligations in excess of plan assets have an accumulated benefit obligation, projected benefit obligation and plan assets of $5.8 billion, $6.1 billion and $3.1 billion, respectively, at the end of 2023, and $2.7 billion, $2.7 billion and $0.3 billion, respectively, at the end of 2022.

The following table displays the projected future benefit payments from the Company's retirement and other benefit plans:

(Dollars in Millions)	**2024**	**2025**	**2026**	**2027**	**2028**	**2029-2033**
Projected future benefit payments						
Retirement plans	$1,481	1,473	1,549	1,647	1,745	10,133
Other benefit plans	$427	438	396	411	428	2,360

The following table displays the projected future minimum contributions to the unfunded retirement plans. These amounts do not include any discretionary contributions that the Company may elect to make in the future.

(Dollars in Millions)	**2024**	**2025**	**2026**	**2027**	**2028**	**2029-2033**
Projected future contributions	$122	126	133	139	145	787

Each pension plan is overseen by a local committee or board that is responsible for the overall administration and investment of the pension plans. In determining investment policies, strategies and goals, each committee or board considers factors including, local pension rules and regulations; local tax regulations; availability of investment vehicles (separate accounts, commingled accounts, insurance funds, etc.); funded status of the plans; ratio of actives to retirees; duration of liabilities; and other relevant factors including: diversification, liquidity of local markets and liquidity of base currency. A majority of the Company's pension funds are open to new entrants and are expected to be on-going plans. Permitted investments are primarily liquid and/or listed, with little reliance on illiquid and non-traditional investments such as hedge funds.

The Company's retirement plan asset allocation at the end of 2023 and 2022 and target allocations for 2024 are as follows:

	Percent of Plan Assets		Target Allocation
	2023	2022	2024
Worldwide Retirement Plans			
Equity securities	58 %	62 %	58 %
Debt securities	42	38	42
Total plan assets	**100 %**	**100 %**	**100 %**

Determination of fair value of plan assets

The Plan has an established and well-documented process for determining fair values. Fair value is based upon quoted market prices, where available. If listed prices or quotes are not available, fair value is based upon models that primarily use, as inputs, market-based or independently sourced market parameters, including yield curves, interest rates, volatilities, equity or debt prices, foreign exchange rates and credit curves.

While the Plan believes its valuation methods are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

Valuation hierarchy

The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described in the table below with Level 1 having the highest priority and Level 3 having the lowest.

The Net Asset Value (NAV) is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Following is a description of the valuation methodologies used for the investments measured at fair value.

- *Short-term investment funds* — Cash and quoted short-term instruments are valued at the closing price or the amount held on deposit by the custodian bank. Other investments are through investment vehicles valued using the NAV provided by the administrator of the fund. The NAV is a quoted price in a market that is not active and classified as Level 2.
- *Government and agency securities* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified within Level 1 of the valuation hierarchy. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows. When quoted market prices for a security are not available in an active market, they are classified as Level 2.
- *Debt instruments* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified as Level 1. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows and are classified as Level 2. Level 3 debt instruments are priced based on unobservable inputs.
- *Equity securities* — Equity securities are valued at the closing price reported on the major market on which the individual securities are traded. Substantially all equity securities are classified within Level 1 of the valuation hierarchy.
- *Commingled funds* — These investment vehicles are valued using the NAV provided by the fund administrator. Assets in the Level 2 category have a quoted market price.
- *Other assets* — Other assets are represented primarily by limited partnerships. These investment vehicles are valued using the NAV provided by the fund administrator. Other assets that are exchange listed and actively traded are classified as Level 1, while inactively traded assets are classified as Level 2.

The following table sets forth the Retirement Plans' investments measured at fair value as of December 31, 2023 and December 31, 2022:

	Quoted Prices in Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs[1] (Level 3)		Investments Measured at Net Asset Value		Total Assets	
(Dollars in Millions)	**2023**	**2022**	**2023**	**2022**	**2023**	**2022**	**2023**	**2022**	**2023**	**2022**
Short-term investment funds	$12	26	829	13	—	—	—	—	841	39
Government and agency securities	—	—	5,985	5,863	—	—	—	—	5,985	5,863
Debt instruments	—	—	3,899	3,681	—	—	—	—	3,899	3,681
Equity securities	7,764	8,846	—	2	—	—	—	—	7,764	8,848
Commingled funds	—	—	4,967	4,362	43	56	6,672	6,096	11,682	10,514
Other assets	—	—	49	33	92	12	3,295	2,506	3,436	2,551
Investments at fair value	**$7,776**	**8,872**	**15,729**	**13,954**	**135**	**68**	**9,967**	**8,602**	**33,607**	**31,496**

[1] The activity for the Level 3 assets is not significant for all years presented.

The Company's Other Benefit Plans are unfunded except for U.S. commingled funds (Level 2) of $86 million and $78 million at December 31, 2023 and December 31, 2022, respectively.

The fair value of Johnson & Johnson Common Stock directly held in plan assets was $14 million (0.0% of total plan assets) at December 31, 2023 and $21 million (0.1% of total plan assets) at December 31, 2022.

11. Savings plan

The Company has voluntary 401(k) savings plans designed to enhance the existing retirement programs covering eligible employees. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which the employee is eligible. Total Company matching contributions to the plans were $263 million, $257 million and $239 million in fiscal years 2023, 2022 and 2021, respectively.

12. Capital and treasury stock

Changes in treasury stock were:

	Treasury Stock	
(Amounts in Millions Except Treasury Stock Shares in Thousands)	**Shares**	**Amount**
Balance at January 3, 2021	487,331	$38,490
Employee compensation and stock option plans	(17,399)	(2,847)
Repurchase of common stock	20,946	3,456
Balance at January 2, 2022	490,878	39,099
Employee compensation and stock option plans	(20,007)	(3,440)
Repurchase of common stock	35,375	6,035
Balance at January 1, 2023	506,246	41,694
Employee compensation and stock option plans	(15,521)	(2,529)
Repurchase of common stock	31,085	5,079
Kenvue share exchange (Note 21)	190,955	31,418
Balance at December 31, 2023	712,765	$75,662

Aggregate shares of common stock issued were approximately 3,119,843,000 shares at the end of fiscal years 2023, 2022 and 2021.

Cash dividends paid were $4.70 per share in fiscal year 2023, compared with dividends of $4.45 per share in fiscal year 2022, and $4.19 per share in fiscal year 2021.

On January 2, 2024, the Board of Directors declared a regular cash dividend of $1.19 per share, payable on March 5, 2024 to shareholders of record as of February 20, 2024.

On September 14, 2022, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's shares of common stock. The repurchase program was completed during the fiscal first quarter of 2023.

13. Accumulated other comprehensive income (loss)

Components of other comprehensive income (loss) consist of the following:

(Dollars in Millions)	Foreign Currency Translation	Gain/ (Loss) On Securities	Employee Benefit Plans	Gain/ (Loss) On Derivatives & Hedges	Total Accumulated Other Comprehensive Income (Loss)
January 3, 2021	$(8,938)	1	(6,957)	652	(15,242)
Net 2021 changes	(1,079)	(4)	4,255	(988)	2,184
January 2, 2022	(10,017)	(3)	(2,702)	(336)	(13,058)
Net 2022 changes	(1,796)	(24)	1,805	106	91
January 1, 2023	(11,813)	(27)	(897)	(230)	(12,967)
Net 2023 changes	(3,221)	26	(1,399)	(147)	(4,741)
Kenvue Separation/IPO	4,885		296 *		5,181
December 31, 2023	$(10,149)	(1)	(2,000)	(377)	(12,527)

Amounts in accumulated other comprehensive income are presented net of the related tax impact. Foreign currency translation is not adjusted for income taxes where it relates to permanent investments in international subsidiaries. For additional details on comprehensive income see the Consolidated Statements of Comprehensive Income.

Details on reclassifications out of Accumulated Other Comprehensive Income:

Gain/(Loss) On Securities - reclassifications released to Other (income) expense, net.

Employee Benefit Plans - reclassifications are included in net periodic benefit cost. See Note 10 for additional details.

Gain/(Loss) On Derivatives & Hedges - reclassifications to earnings are recorded in the same account as the hedged transaction. See Note 6 for additional details.

* Includes impact of curtailments and settlements in connection with separation from Kenvue.

14. International currency translation

For translation of its subsidiaries operating in non-U.S. Dollar currencies, the Company has determined that the local currencies of its international subsidiaries are the functional currencies except those in highly inflationary economies, which are defined as those which have had compound cumulative rates of inflation of 100% or more during the past three years, or where a substantial portion of its cash flows are not in the local currency. For the majority of the Company's subsidiaries the local currency is the functional currency.

In consolidating international subsidiaries, balance sheet currency effects are recorded as a component of accumulated other comprehensive income. The other current and non-current assets line within the Statement of Cash flows includes the impact of foreign currency translation. This equity account includes the results of translating certain balance sheet assets and liabilities at current exchange rates and some accounts at historical rates, except for those located in highly inflationary economies (Argentina and Venezuela). Beginning in the fiscal second quarter of 2022, the Company also accounted for operations in Turkey as highly inflationary. The translation of balance sheet accounts for highly inflationary economies are reflected in the operating results.

A rollforward of the changes during fiscal years 2023, 2022 and 2021 for foreign currency translation adjustments is included in Note 13.

Net currency transaction gains and losses included in Other (income) expense were losses of $366 million, $286 million and $216 million in fiscal years 2023, 2022 and 2021, respectively.

15. Earnings per share

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal years ended December 31, 2023, January 1, 2023 and January 2, 2022:

(In Millions Except Per Share Amounts)	2023	2022	2021
Basic net earnings per share from continuing operations	$5.26	6.23	6.76
Basic net earnings per share from discontinued operations	8.62	0.60	1.17
Total net earnings per share - basic	13.88	6.83	7.93
Average shares outstanding — basic	2,533.5	2,625.2	2,632.1
Potential shares exercisable under stock option plans	94.1	140.1	138.0
Less: shares repurchased under treasury stock method	(67.2)	(101.4)	(96.1)
Adjusted average shares outstanding — diluted	2,560.4	2,663.9	2,674.0
Diluted net earnings per share from continuing operations	5.20	6.14	6.66
Diluted net earnings per share from discontinuing operations	8.52	0.59	1.15
Total net earnings per share - diluted	$13.72	6.73	7.81

The diluted net earnings per share calculation for fiscal year 2023 excluded 43 million shares related to stock options, as the exercise price of these options was greater than the average market value of the Company's stock.

The diluted net earnings per share calculation for the fiscal years 2022 and 2021 included all shares related to stock options, as the exercise price of these options was less than the average market value of the Company's stock.

16. Common stock, stock option plans and stock compensation agreements

At December 31, 2023, the Company had one stock-based compensation plan. The shares outstanding are for contracts under the Company's 2012 Long-Term Incentive Plan and the 2022 Long-Term Incentive Plan. The 2012 Long-Term Incentive Plan expired on April 26, 2022. All awards (stock options, restricted shares units and performance share units) granted subsequent to that date were under the 2022 Long-Term Incentive Plan. Under the 2022 Long-Term Incentive Plan, the Company may issue up to 150 million shares of common stock, of which up to 110 million shares of common stock may be issued subject to stock options or stock appreciation rights and up to 40 million shares of common stock may be issued subject to full value awards. Awards will generally be counted on a 1-for-1 basis against the share reserve, provided that if more than 40 million full value awards are granted, each full value award in excess of 40 million will be counted on a 5-for-1 basis against the share reserve. Shares available for future grants under the 2022 Long-Term Incentive Plan were 130 million at the end of fiscal year 2023.

The compensation cost that has been charged against income for these plans was $1,087 million, $1,028 million and $1,038 million for fiscal years 2023, 2022 and 2021, respectively. The total income tax benefit recognized in the income statement for share-based compensation costs was $221 million, $177 million and $199 million for fiscal years 2023, 2022 and 2021, respectively. The Company also recognized additional income tax benefits of $126 million, $267 million and $213 million for fiscal years 2023, 2022 and 2021, respectively, for which options were exercised or restricted shares were vested. The total unrecognized compensation cost was $907 million, $866 million and $775 million for fiscal years 2023, 2022 and 2021, respectively. The weighted average period for this cost to be recognized was 1.80 years, 1.80 years and 1.78 years for fiscal years 2023, 2022, and 2021, respectively. Share-based compensation costs capitalized as part of inventory were insignificant in all periods.

The Company settles employee benefit equity issuances with treasury shares. Treasury shares are replenished through market purchases throughout the year for the number of shares used to settle employee benefit equity issuances.

Stock options

Stock options expire 10 years from the date of grant and vest over service periods that range from 6 months to 4 years.
Options granted under the 2012 Long-Term Incentive Plan were granted at the average of the high and low prices of the Company's Common Stock on the New York Stock Exchange on the date of grant. Options granted under the 2022 Long-Term incentive Plan were granted at the closing price of the Company's Common Stock on the New York Stock Exchange on the date of grant.

The fair value of each option award was estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the following table. For 2023, 2022, and 2021 grants, expected volatility represents a blended rate of 10-year weekly historical overall volatility rate, and a 5-week average implied volatility rate based on at-the-money traded Johnson & Johnson options with a life of 2 years. For all grants, historical data is used to determine the expected life of the option. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant.

The average fair value of options granted was $27.85, $23.23 and $20.86, in fiscal years 2023, 2022 and 2021, respectively. The fair value was estimated based on the weighted average assumptions of:

	2023	2022	2021
Risk-free rate	3.74 %	1.98 %	0.83 %
Expected volatility	17.69 %	18.00 %	18.59 %
Expected life (in years)	7.0	7.0	7.0
Expected dividend yield	2.90 %	2.70 %	2.50 %

A summary of option activity under the Plan as of December 31, 2023, is presented below:

(Shares in Thousands)	Outstanding Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (Dollars in Millions)
Shares at January 1, 2023	118,672	$134.95	$4,949
Options granted	16,320	162.75	
Options exercised	(12,386)	109.48	
Options canceled/forfeited*	(10,368)	155.62	
Shares at December 31, 2023	**112,238**	**$139.88**	**$2,239**

The total intrinsic value of options exercised was $729 million, $1,228 million and $919 million in fiscal years 2023, 2022 and 2021, respectively.

*includes 7,689 shares of options cancelled as a result of the conversion of Johnson & Johnson stock options held by Kenvue employees into Kenvue stock options

The following table summarizes stock options outstanding and exercisable at December 31, 2023:

(Shares in Thousands)	Outstanding			Exercisable	
Exercise Price Range	Options	Average Life[1]	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
$90.44 - $101.87	20,774	1.4	$99.21	20,774	$99.21
$115.67 - $129.51	19,368	3.6	122.49	19,368	122.49
$131.94 - $151.41	27,391	5.6	142.84	26,676	142.61
$162.70 - $162.75	13,928	9.1	162.75	6	162.75
$164.62 - $165.89	30,777	7.6	165.29	174	165.12
	112,238	**5.5**	**$139.88**	**66,998**	**$123.39**

[1] Average contractual life remaining in years.

Stock options outstanding at January 1, 2023 and January 2, 2022 were 118,672 and an average life of 5.8 years and 117,361 and an average life of 5.8 years, respectively. Stock options exercisable at January 1, 2023 and January 2, 2022 were 63,661 at an average price of $113.06 and 62,742 at an average price of $104.42, respectively.

Restricted share units and performance share units

The Company grants restricted share units which vest over service periods that range from 6 months to 3 years. The Company also grants performance share units, which are paid in shares of Johnson & Johnson Common Stock after the end of a three-year performance period. Performance shares were granted with two equally-weighted goals that directly align with or help drive long-term total shareholder return: adjusted operational earnings per share and relative total shareholder return. The number of shares actually earned at the end of the three-year period will vary, based only on actual performance, from 0% to 200% of the target number of performance share units granted.

A summary of the restricted share units and performance share units activity under the Plans as of December 31, 2023 is presented below:

(Shares in Thousands)	Outstanding Restricted Share Units	Outstanding Performance Share Units
Shares at January 1, 2023	13,616	2,357
Granted	5,910	828
Issued	(4,329)	(785)
Canceled/forfeited/adjusted*	(2,259)	(363)
Shares at December 31, 2023	12,938	2,037

*includes 1,421 shares of restricted share units and 264 shares of performance share units cancelled as a result of the conversion of Johnson & Johnson restricted share units and performance share units held by Kenvue employees into Kenvue restricted share units

The average fair value of the restricted share units granted was $152.63, $153.67 and $152.62 in fiscal years 2023, 2022 and 2021, respectively, using the fair market value at the date of grant. The fair value of restricted share units was discounted for dividends, which are not paid on the restricted share units during the vesting period. The fair value of restricted share units issued was $605 million, $591 million and $611 million in 2023, 2022 and 2021, respectively.

The weighted average fair value of the performance share units granted was $145.17, $170.46 and $179.35 in fiscal years 2023, 2022 and 2021, calculated using the weighted average fair market value for each of the component goals at the date of grant.

The fair values for the earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. The fair value of performance share units issued was $140 million, $94 million and $83 million in fiscal years 2023, 2022 and 2021, respectively.

17. Segments of business and geographic areas

Following the separation of the Consumer Health business in the fiscal third quarter of 2023, the Company is now organized into two business segments: Innovative Medicine (formerly referred to as Pharmaceutical) and MedTech. The segment results have been recast for all periods to reflect the continuing operations of the Company.

	Sales to Customers			% Change	
(Dollars in Millions)	2023	2022	2021	'23 vs. '22	'22 vs. '21
INNOVATIVE MEDICINE[1]					
Immunology					
U.S.	$11,539	11,036	10,843	4.6 %	1.8
International	6,513	5,899	5,907	10.4	(0.1)
Worldwide	18,052	16,935	16,750	6.6	1.1
REMICADE					
U.S.	1,143	1,417	2,019	(19.3)	(29.8)
U.S. Exports	147	204	236	(28.0)	(13.6)
International	549	722	935	(23.9)	(22.8)
Worldwide	1,839	2,343	3,190	(21.5)	(26.6)
SIMPONI / SIMPONI ARIA					
U.S.	1,124	1,166	1,127	(3.6)	3.5
International	1,073	1,017	1,148	5.4	(11.4)
Worldwide	2,197	2,184	2,276	0.6	(4.0)
STELARA					
U.S.	6,966	6,388	5,938	9.0	7.6
International	3,892	3,335	3,196	16.7	4.4
Worldwide	10,858	9,723	9,134	11.7	6.5
TREMFYA					
U.S.	2,147	1,844	1,503	16.5	22.7
International	999	824	624	21.2	32.0
Worldwide	3,147	2,668	2,127	17.9	25.4
OTHER IMMUNOLOGY					
U.S.	11	17	21	(33.8)	(18.4)
International	0	0	3	—	*
Worldwide	11	17	24	(33.8)	(28.2)
Infectious Diseases					
U.S.	1,500	1,680	2,249	(10.7)	(25.3)
International	2,918	3,769	3,576	(22.6)	5.4
Worldwide	4,418	5,449	5,825	(18.9)	(6.5)
COVID-19 VACCINE					
U.S.	0	120	634	*	(81.1)
International	1,117	2,059	1,751	(45.8)	17.6
Worldwide	1,117	2,179	2,385	(48.8)	(8.6)

(Dollars in Millions)	Sales to Customers 2023	2022	2021	% Change '23 vs. '22	'22 vs. '21
EDURANT / rilpivirine					
U.S.	35	36	41	(3.7)	(10.8)
International	1,115	972	953	14.8	2.0
Worldwide	1,150	1,008	994	14.1	1.5
PREZISTA / PREZCOBIX / REZOLSTA / SYMTUZA					
U.S.	1,446	1,494	1,508	(3.2)	(1.0)
International	408	449	575	(9.2)	(21.9)
Worldwide	1,854	1,943	2,083	(4.6)	(6.7)
OTHER INFECTIOUS DISEASES					
U.S.	19	30	66	(34.5)	(55.5)
International	278	289	297	(3.8)	(2.6)
Worldwide	297	318	363	(6.7)	(12.3)
Neuroscience					
U.S.	4,065	3,570	3,347	13.9	6.7
International	3,076	3,323	3,641	(7.5)	(8.7)
Worldwide	7,140	6,893	6,988	3.6	(1.4)
CONCERTA / methylphenidate					
U.S.	230	151	172	52.5	(12.5)
International	554	493	495	12.2	(0.4)
Worldwide	783	644	667	21.6	(3.5)
INVEGA SUSTENNA / XEPLION / INVEGA TRINZA / TREVICTA					
U.S.	2,897	2,714	2,550	6.7	6.5
International	1,218	1,426	1,472	(14.6)	(3.1)
Worldwide	4,115	4,140	4,022	(0.6)	3.0
SPRAVATO					
U.S.	589	328	198	79.7	65.7
International	100	46	26	*	76.9
Worldwide	689	374	224	84.1	67.0
OTHER NEUROSCIENCE[2]					
U.S.	349	376	427	(7.3)	(11.9)
International	1,204	1,358	1,647	(11.3)	(17.5)
Worldwide	1,553	1,734	2,074	(10.4)	(16.4)
Oncology					
U.S.	8,462	6,930	5,958	22.1	16.3
International	9,199	9,052	8,590	1.6	5.4
Worldwide	17,661	15,983	14,548	10.5	9.9

(Dollars in Millions)	Sales to Customers 2023	2022	2021	% Change '23 vs. '22	'22 vs. '21
CARVYKTI					
U.S.	469	133	—	*	*
International	30	—	—	*	*
Worldwide	500	133	—	*	*
DARZALEX					
U.S.	5,277	4,210	3,169	25.4	32.8
International	4,467	3,767	2,854	18.6	32.0
Worldwide	9,744	7,977	6,023	22.2	32.4
ERLEADA					
U.S.	1,065	968	813	10.0	19.2
International	1,322	913	478	44.8	*
Worldwide	2,387	1,881	1,291	26.9	45.7
IMBRUVICA					
U.S.	1,051	1,390	1,747	(24.4)	(20.4)
International	2,214	2,394	2,622	(7.5)	(8.7)
Worldwide	3,264	3,784	4,369	(13.7)	(13.4)
ZYTIGA/abiraterone acetate					
U.S.	50	74	119	(32.1)	(37.8)
International	837	1,696	2,178	(50.7)	(22.1)
Worldwide	887	1,770	2,297	(49.9)	(22.9)
OTHER ONCOLOGY					
U.S.	549	156	110	*	41.8
International	330	283	458	16.9	(38.2)
Worldwide	879	438	568	*	(22.9)
Pulmonary Hypertension					
U.S.	2,697	2,346	2,365	15.0	(0.8)
International	1,117	1,071	1,085	4.3	(1.3)
Worldwide	3,815	3,417	3,450	11.6	(1.0)
OPSUMIT					
U.S.	1,292	1,132	1,147	14.1	(1.3)
International	681	651	672	4.6	(3.2)
Worldwide	1,973	1,783	1,819	10.6	(2.0)
UPTRAVI					
U.S.	1,326	1,104	1,056	20.1	4.5
International	255	218	181	17.3	20.4
Worldwide	1,582	1,322	1,237	19.7	6.9
OTHER PULMONARY HYPERTENSION					
U.S.	79	110	163	(28.6)	(32.3)
International	182	202	232	(10.3)	(12.8)
Worldwide	260	313	395	(16.7)	(20.8)

(Dollars in Millions)	Sales to Customers 2023	2022	2021	% Change '23 vs. '22	'22 vs. '21
Cardiovascular / Metabolism / Other					
U.S.	2,906	3,042	3,192	(4.5)	(4.7)
International	765	845	927	(9.4)	(8.9)
Worldwide	3,671	3,887	4,119	(5.5)	(5.6)
XARELTO					
U.S.	2,365	2,473	2,438	(4.4)	1.4
International	—	—	—	—	—
Worldwide	2,365	2,473	2,438	(4.4)	1.4
OTHER[3]					
U.S.	541	569	754	(5.0)	(24.5)
International	765	845	927	(9.4)	(8.8)
Worldwide	1,306	1,414	1,682	(7.6)	(15.9)
TOTAL INNOVATIVE MEDICINE					
U.S.	31,169	28,604	27,954	9.0	2.3
International	23,590	23,959	23,726	(1.5)	1.0
Worldwide	54,759	52,563	51,680	4.2	1.7
MEDTECH					
Interventional Solutions					
U.S.	3,633	2,169	1,836	67.5	18.2
International	2,717	2,131	2,135	27.5	(0.2)
Worldwide	6,350	4,300	3,971	47.7	8.3
ELECTROPHYSIOLOGY					
U.S.	2,458	2,036	1,730	20.7	17.7
International	2,230	1,901	1,893	17.3	0.4
Worldwide	4,688	3,937	3,623	19.1	8.7
ABIOMED[4]					
U.S.	1,066	31	—	*	*
International	240	—	—	*	*
Worldwide	1,306	31	—	*	*
OTHER INTERVENTIONAL SOLUTIONS					
U.S.	109	102	106	6.7	(3.8)
International	247	230	242	7.3	(5.0)
Worldwide	356	332	348	7.1	(4.6)
Orthopaedics					
U.S.	5,525	5,321	5,126	3.8	3.8
International	3,417	3,267	3,462	4.6	(5.6)
Worldwide	8,942	8,587	8,588	4.1	0.0
HIPS					
U.S.	996	943	878	5.6	7.3
International	564	571	602	(1.2)	(5.1)
Worldwide	1,560	1,514	1,480	3.0	2.3

(Dollars in Millions)	Sales to Customers 2023	2022	2021	% Change '23 vs. '22	'22 vs. '21
KNEES					
U.S.	896	851	787	5.3	8.2
International	559	508	538	10.2	(5.7)
Worldwide	1,456	1,359	1,325	7.1	2.6
TRAUMA					
U.S.	1,949	1,882	1,819	3.6	3.5
International	1,030	989	1,066	4.1	(7.2)
Worldwide	2,979	2,871	2,885	3.8	(0.5)
SPINE, SPORTS & OTHER					
U.S.	1,684	1,645	1,642	2.4	0.2
International	1,263	1,198	1,256	5.4	(4.6)
Worldwide	2,947	2,843	2,898	3.7	(1.9)
Surgery					
U.S.	4,031	3,897	3,867	3.4	0.8
International	6,006	5,793	5,945	3.7	(2.6)
Worldwide	10,037	9,690	9,812	3.6	(1.2)
ADVANCED					
U.S.	1,833	1,784	1,761	2.8	1.3
International	2,837	2,785	2,861	1.9	(2.6)
Worldwide	4,671	4,569	4,622	2.2	(1.1)
GENERAL					
U.S.	2,198	2,113	2,105	4.0	0.4
International	3,168	3,008	3,085	5.3	(2.5)
Worldwide	5,366	5,121	5,190	4.8	(1.3)
Vision					
U.S.	2,086	1,990	1,857	4.8	7.2
International	2,986	2,859	2,831	4.5	1.0
Worldwide	5,072	4,849	4,688	4.6	3.4
CONTACT LENSES / OTHER					
U.S.	1,626	1,522	1,398	6.8	8.9
International	2,076	2,022	2,043	2.7	(1.0)
Worldwide	3,702	3,543	3,440	4.5	3.0
SURGICAL					
U.S.	460	468	459	(1.8)	2.0
International	910	837	788	8.6	6.2
Worldwide	1,370	1,306	1,248	4.9	4.6
TOTAL MEDTECH					
U.S.	15,275	13,377	12,686	14.2	5.4
International	15,125	14,050	14,374	7.7	(2.3)
Worldwide	30,400	27,427	27,060	10.8	1.4

(Dollars in Millions)	Sales to Customers 2023	2022	2021	% Change '23 vs. '22	'22 vs. '21
WORLDWIDE					
U.S.	46,444	41,981	40,640	10.6	3.3
International	38,715	38,009	38,100	1.9	(0.2)
Worldwide	$85,159	79,990	78,740	6.5 %	1.6

*Percentage greater than 100% or not meaningful

(1) Previously referred to as Pharmaceutical

(2) Inclusive of RISPERDAL CONSTA which was previously disclosed separately

(3) Inclusive of INVOKANA which was previously disclosed separately

(4) Acquired on December 22, 2022

(Dollars in Millions)	Income Before Tax 2023 (3)	2022 (4)	2021 (5)	Identifiable Assets 2023	2022
Innovative Medicine	$18,246	15,647	17,750	$58,324	58,436
MedTech	4,669	4,447	4,208	74,710	70,956
Total	**22,915**	**20,094**	**21,958**	**133,034**	**129,392**
Less: Expense not allocated to segments (1)	7,853	735	2,780		
Discontinued operations				—	27,237
General corporate (2)				34,524	30,749
Worldwide total	**$15,062**	**19,359**	**19,178**	**$167,558**	**187,378**

(Dollars in Millions)	Additions to Property, Plant & Equipment 2023	2022	2021	Depreciation and Amortization 2023	2022	2021
Innovative Medicine	$1,653	1,374	1,198	$3,847	3,687	4,029
MedTech	2,372	2,120	1,933	2,943	2,302	2,286
Segments total	4,025	3,494	3,131	6,790	5,989	6,315
Discontinued operations	162	303	314	383	641	739
General corporate	356	212	207	313	340	336
Worldwide total	**$4,543**	**4,009**	**3,652**	**$7,486**	**6,970**	**7,390**

(Dollars in Millions)	Sales to Customers 2023	2022	2021	Long-Lived Assets (6) 2023	2022
United States	$46,444	41,981	40,640	$54,832	58,750
Europe	20,410	20,664	20,595	31,616	29,878
Western Hemisphere excluding U.S.	4,549	4,108	3,927	1,491	1,289
Asia-Pacific, Africa	13,756	13,237	13,578	1,500	1,520
Segments total	85,159	79,990	78,740	89,439	91,437
Discontinued operations				—	27,237
General corporate				1,192	1,081
Other non long-lived assets				76,927	67,623
Worldwide total	**$85,159**	**79,990**	**78,740**	**$167,558**	**187,378**

See Note 1 for a description of the segments in which the Company operates.

Export sales are not significant. In fiscal year 2023, the Company utilized three wholesalers distributing products for both segments that represented approximately 18.2%, 15.1% and 14.2% of the total consolidated revenues. In fiscal year 2022, the Company had three wholesalers distributing products for both segments that represented approximately 18.9%, 15.0% and 13.8% of the total consolidated revenues. In fiscal year 2021, the Company had three wholesalers distributing products for all three segments that represented approximately 16.6%, 12.6%, and 12.6% of the total consolidated revenues.

(1) Amounts not allocated to segments include interest (income)/expense and general corporate (income)/expense. Fiscal 2023 includes an approximately $7 billion charge related to talc matters (See Note 19, Legal proceedings, for additional details) and $0.4 billion related to the unfavorable change in the fair value of the retained stake in Kenvue.

(2) General corporate includes cash, cash equivalents and marketable securities.

(3) Innovative Medicine includes:

- One-time COVID-19 Vaccine manufacturing exit related costs of $0.7 billion
- A restructuring related charge of $0.5 billion
- Unfavorable changes in the fair value of securities of $0.4 billion
- Favorable litigation related items of $0.1 billion
- Loss on divestiture $0.2 billion.
- An intangible asset impairment charge of approximately $0.2 billion related to market dynamics associated with a non-strategic asset (M710) acquired as part of the acquisition of Momenta Pharmaceuticals in 2020.

MedTech includes:

- Acquired in process research and development asset of $0.4 billion related to the Laminar acquisition in 2023
- A restructuring related charge of $0.3 billion
- Acquisition and integration related costs of $0.2 billion primarily related to the acquisition of Abiomed
- A Medical Device Regulation charge of $0.3 billion
- Income from litigation settlements of $0.1 billion

(4) Innovative Medicine includes:

- One-time COVID-19 Vaccine manufacturing exit related costs of $1.5 billion
- An intangible asset impairment charge of approximately $0.8 billion related to an in-process research and development asset, bermekimab (JnJ-77474462), an investigational drug for the treatment of Atopic Dermatitis (AD) and Hidradenitis Suppurativa (HS) acquired with the acquisition of XBiotech, Inc. in the fiscal year 2020. Additional information regarding efficacy of the AD and HS indications became available which led the Company to the decision to terminate the development of bermekimab for AD and HS
- Litigation expense of $0.1 billion
- Unfavorable changes in the fair value of securities of $0.7 billion
- A restructuring related charge of $0.1 billion

MedTech includes:

- Litigation expense of $0.6 billion primarily for pelvic mesh related costs
- A restructuring related charge of $0.3 billion
- Acquisition and integration related costs of $0.3 billion primarily related to the acquisition of Abiomed
- A Medical Device Regulation charge of $0.3 billion

(5) Innovative Medicine includes:

- Litigation expense of $0.6 billion, primarily related to Risperdal Gynecomastia
- Divestiture gains of $0.6 billion
- Gains of $0.5 billion related to the change in the fair value of securities
- A restructuring related charge of $0.1 billion

MedTech includes:

- An in-process research and development expense of $0.9 billion related to Ottava
- A restructuring related charge of $0.3 billion
- A Medical Device Regulation charge of $0.2 billion

- Litigation expense of $0.1 billion

(6) Long-lived assets include property, plant and equipment, net for fiscal years 2023, and 2022 of $19,898 and $17,982, respectively, and intangible assets and goodwill, net for fiscal years 2023 and 2022 of $70,733 and $74,536, respectively.

18. Acquisitions and divestitures

In the fiscal first quarter of 2024, the Company announced it has entered into a definitive agreement to acquire Ambrx Biopharma, Inc., or Ambrx (Nasdaq: AMAM), a clinical-stage biopharmaceutical company with a proprietary synthetic biology technology platform to design and develop next-generation antibody drug conjugates (ADCs), in an all-cash merger transaction for a total equity value of approximately $2.0 billion, or $1.9 billion net of estimated cash acquired. The Company will acquire all of the outstanding shares of Ambrx's common stock for $28.00 per share through a merger of Ambrx with a subsidiary of the Company. The closing of the transaction is expected to occur in the first half of 2024, subject to receipt of Ambrx shareholder approval, as well as clearance under the Hart-Scott-Rodino Antitrust Improvements Act and other customary closing conditions. The Company expects that the transaction will be accounted for as a business combination and the results of operations will be included in the Innovative Medicine segment as of the acquisition date.

During the fiscal year 2023, the Company did not make any acquisitions that qualified as a business combination.

During the fiscal year 2023, there were asset acquisitions of in-process research and development of approximately $0.5 billion in cash, primarily consisting of the acquisition of Laminar Inc. for $0.4 billion which was closed on November 30, 2023. Laminar Inc. is a privately-held medical device company focused on eliminating the left atrial appendage (LAA) in patients with non-valvular atrial fibrillation (AFib).

During the fiscal year 2022, certain businesses were acquired for $17.7 billion in cash and $1.1 billion of liabilities assumed. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $17.3 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

The fiscal year 2022 acquisitions primarily included Abiomed, Inc. (Abiomed). The remaining acquisitions were not material.

On December 22, 2022, the Company completed the acquisition of Abiomed, a leading, first-to-market provider of cardiovascular medical technology with a first-in-kind portfolio for the treatment of coronary artery disease and heart failure which also has an extensive innovation pipeline of life-saving technologies. The transaction broadens the Company's position as a growing cardiovascular innovator, advancing the standard of care in heart failure and recovery, one of healthcare's largest areas of unmet need. The transaction was accounted for as a business combination and the results of operations were included in the MedTech segment as of the date of the acquisition. The acquisition was completed through a tender offer for all outstanding shares. The consideration paid in the acquisition consisted of an upfront payment of $380.00 per share in cash, amounting to $17.1 billion, net of cash acquired, as well as a non-tradeable contingent value right ("CVR") entitling the holder to receive up to $35.00 per share in cash (which with respect to the CVRs total approximately $1.6 billion in the aggregate) if certain commercial and clinical milestones are achieved. The corresponding enterprise value (without taking into account the CVRs) of approximately $16.5 billion includes cash, cash equivalents and marketable securities acquired.

The milestones of the CVR consist of:

a. $17.50 per share, payable if net sales for Abiomed products exceeds $3.7 billion during Johnson & Johnson's fiscal second quarter of 2027 through fiscal first quarter of 2028, or if this threshold is not met during this period and is subsequently met during any rolling four quarter period up to the end of Johnson & Johnson's fiscal first quarter of 2029, $8.75 per share;

b. $7.50 per share payable upon FDA premarket application approval of the use of Impella® products in ST-elevated myocardial infarction (STEMI) patients without cardiogenic shock by January 1, 2028; and

c. $10.00 per share payable upon the first publication of a Class I recommendation for the use of Impella® products in high risk PCI or STEMI with or without cardiogenic shock within four years from their respective clinical endpoint publication dates, but in all cases no later than December 31, 2029.

During the fiscal fourth quarter of 2023, the Company finalized the purchase price allocation. In the fiscal 2023, there were purchase price allocation adjustments netting to approximately $0.2 billion with an offsetting increase to goodwill. The fair value of the acquisition was allocated to assets acquired of $20.1 billion (net of $0.3 billion cash acquired), primarily to goodwill for $11.1 billion, amortizable intangible assets for $6.6 billion, IPR&D for $1.1 billion, marketable securities of $0.6 billion and

liabilities assumed of $3.0 billion, which includes the fair value of the contingent consideration mentioned above for $0.7 billion and deferred taxes of $2.0 billion. The goodwill is primarily attributable to the commercial acceleration and expansion of the portfolio and is not expected to be deductible for tax purposes. The contingent consideration was recorded in Other Liabilities and adjusted to fair value through the fiscal year end 2023 on the Consolidated Balance Sheet.

The amortizable intangible assets were primarily comprised of already in-market products of the Impella® platform with an average weighted life of 14 years. The IPR&D assets were valued for technology programs for unapproved products. The value of the IPR&D was calculated using probability-adjusted cash flow projections discounted for the risk inherent in such projects. The probability of success factor ranged from 52% to 70%. The discount rate applied was 9.5%.

In 2023, the Company recorded acquisition related costs before tax of approximately $0.2 billion, which was primarily recorded in Other (income)/expense. In 2022, the Company recorded acquisition related costs before tax of approximately $0.3 billion, which was recorded in Other (income)/expense.

During fiscal year 2021, the Company did not make any material acquisitions that qualified as a business combination.

In accordance with U.S. GAAP standards related to business combinations, and goodwill and other intangible assets, supplemental pro forma information for fiscal years 2023, 2022 and 2021 is not provided, as the impact of the aforementioned acquisitions did not have a material effect on the Company's results of operations.

Divestitures

During the fiscal year 2023, the Company executed divestitures resulting in approximately $0.2 billion in proceeds resulting in gains or losses that were not material. At fiscal year end 2023, the Company held assets, primarily intangibles, on its Consolidated Balance Sheet that it expects to divest of approximately $0.3 billion primarily related to Acclarent and Ponvory.

During fiscal year 2022, the Company did not make any material divestitures.

During fiscal year 2021, in separate transactions, the Company divested two brands outside the U.S. within the Innovative Medicine segment. The Company recognized a pre-tax gain recorded in Other (income) expense, net, of approximately $0.6 billion.

19. Legal proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability; intellectual property; commercial; indemnification and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of their business.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred, and the amount of the loss can be reasonably estimated. As of December 31, 2023, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25, Contingencies. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; ability to achieve comprehensive multi-party settlements; complexity of related cross-claims and counterclaims; and/or there are numerous parties involved. To the extent adverse awards, judgments or verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution of, or increase in accruals for, one or more of these matters in any reporting period may have a material adverse effect on the Company's results of operations and cash flows for that period.

Matters concerning talc

A significant number of personal injury claims alleging that talc causes cancer have been asserted against Johnson & Johnson Consumer Inc., its successor LTL Management LLC (now known as LLT Management LLC) and the Company arising out of the use of body powders containing talc, primarily JOHNSON'S Baby Powder.

In talc cases that previously have gone to trial, the Company has obtained a number of defense verdicts, but there also have been verdicts against the Company, many of which have been reversed on appeal. In June 2020, the Missouri Court of Appeals reversed in part and affirmed in part a July 2018 verdict of $4.7 billion in Ingham v. Johnson & Johnson, et al., No. ED 207476 (Mo. App.), reducing the overall award to $2.1 billion. An application for transfer of the case to the Missouri Supreme Court was subsequently denied and in June 2021, a petition for certiorari, seeking a review of the Ingham decision by the United States Supreme Court, was denied. In June 2021, the Company paid the award, which, including interest, totaled approximately $2.5 billion. The facts and circumstances, including the terms of the award, were unique to the Ingham decision and not representative of other claims brought against the Company. The Company continues to believe that it has strong legal grounds to contest the other talc verdicts that it has appealed. Notwithstanding the Company's confidence in the safety of its talc products, in certain circumstances the Company has settled cases.

In October 2021, Johnson & Johnson Consumer Inc. (Old JJCI) implemented a corporate restructuring (the 2021 Corporate Restructuring). As a result of that restructuring, Old JJCI ceased to exist and three new entities were created: (a) LTL Management LLC, a North Carolina limited liability company (LTL or Debtor); (b) Royalty A&M LLC, a North Carolina limited liability company and a direct subsidiary of LTL (RAM); and (c) the Debtor's direct parent, Johnson & Johnson Consumer Inc., a New Jersey company (New JJCI). The Debtor received certain of Old JJCI's assets and became solely responsible for the talc-related liabilities of Old JJCI, including all liabilities related in any way to injury or damage, or alleged injury or damage, sustained or incurred in the purchase or use of, or exposure to, talc, including talc contained in any product, or to the risk of, or responsibility for, any such damage or injury, except for any liabilities for which the exclusive remedy is provided under a workers' compensation statute or act (the Talc-Related Liabilities).

In October 2021, notwithstanding the Company's confidence in the safety of its talc products, the Debtor filed a voluntary petition with the United States Bankruptcy Court for the Western District of North Carolina, Charlotte Division, seeking relief under chapter 11 of the Bankruptcy Code (the LTL Bankruptcy Case). All litigation against LTL, Old JJCI, New JJCI, the Company, other of their corporate affiliates, identified retailers, insurance companies, and certain other parties (the Protected Parties) was stayed, although LTL did agree to lift the stay on a small number of appeals where appeal bonds had been filed. The LTL Bankruptcy Case was transferred to the United States Bankruptcy Court for the District of New Jersey. Claimants filed motions to dismiss the LTL Bankruptcy Case and, following a multiple day hearing, the New Jersey Bankruptcy Court denied those motions in March 2022.

The claimants subsequently filed notices of appeal as to the denial of the motions to dismiss the LTL Bankruptcy Case and the extension of the stay to the Protected Parties. On January 30, 2023, the Third Circuit reversed the Bankruptcy Court's ruling and remanded to the Bankruptcy Court to dismiss the LTL bankruptcy.

LTL filed a petition for rehearing of the Third Circuit's decision, which was denied in March 2023. LTL subsequently filed a motion in the Third Circuit to stay the mandate directing the New Jersey Bankruptcy Court to dismiss the LTL bankruptcy pending filing and disposition of a petition for writ of certiorari to the United States Supreme Court. The Third Circuit denied the motion to stay the mandate and issued the mandate.

In April 2023, the New Jersey Bankruptcy Court dismissed the LTL Bankruptcy Case, effectively lifting the stay as to all parties and returning the talc litigation to the tort system. LTL re-filed in the United States Bankruptcy Court for the District of New Jersey seeking relief under chapter 11 of the Bankruptcy Code (the LTL 2 Bankruptcy Case). As a result of the new filing, all talc claims against LTL were again automatically stayed pursuant to section 362 of the Bankruptcy Code. Additionally, the New Jersey Bankruptcy Court issued a temporary restraining order staying all litigation as to LTL, Old JJCI, New JJCI, the Company, identified retailers, and certain other parties (the New Protected Parties).

Also in April 2023, the New Jersey Bankruptcy Court issued a decision that granted limited injunctive relief to the Company and the New Protected Parties (the LTL 2 Preliminary Injunction). The LTL 2 Preliminary Injunction remained in force until late August 2023, following the Bankruptcy Court's extension of the initial LTL 2 Preliminary Injunction in June 2023. Under the LTL 2 Preliminary Injunction, except for in those cases filed in the federal court ovarian cancer multi-district litigation, discovery in all personal injury and wrongful death matters was permitted to proceed.

Furthermore, in April 2023, the Talc Claimants' Committee filed a motion to dismiss the LTL 2 Bankruptcy followed by similar motions from other claimants. Hearings on the motions to dismiss occurred in June 2023. On July 28, 2023, the court dismissed the LTL 2 Bankruptcy case and, the same day, the Company stated its intent to appeal the decision and to continue its efforts to obtain a resolution of the talc claims. In September 2023, the Bankruptcy Court entered an order granting LTL leave to seek a direct appeal to the Third Circuit Court of Appeals. In October 2023, the Third Circuit granted LTL's petition for a direct appeal. Briefing is ongoing.

Following the dismissal of LTL 2, new lawsuits were filed and cases across the country that had been stayed were reactivated. The majority of the cases are pending in federal court, organized in a multi-district litigation (MDL) in the United States District Court for the District of New Jersey. In the MDL, case-specific discovery is proceeding with an expectation that a trial will occur in early 2025. Separately, discovery and pre-trial activity is underway in various individually filed and set cases around the country, with most activity for such cases centralized in New Jersey and California.

In the original bankruptcy case, the Company agreed to provide funding to LTL for the payment of amounts the New Jersey Bankruptcy Court determines are owed by LTL and the establishment of a $2 billion trust in furtherance of this purpose. The Company established a reserve for approximately $2 billion in connection with the aforementioned trust. During the bankruptcy proceedings LTL had been de-consolidated by the Company. In the LTL 2 Bankruptcy Case, the Company had agreed to contribute an additional amount which, when added to the prior $2 billion, would be a total reserve of approximately $9 billion payable over 25 years (nominal value approximately $12 billion discounted at a rate of 4.41%), to resolve all the current and future talc claims. The approximate $9 billion reserve encompasses actual and contemplated settlements, of which approximately one-third is recorded as a current liability. The recorded amount remains the Company's best estimate of probable loss after the dismissal.

The parties have not yet reached a resolution of all talc matters and the Company is unable to estimate the possible loss or range of loss beyond the amount accrued.

A class action advancing claims relating to industrial talc was filed against the Company and others in New Jersey state court in May 2022 (the Edley Class Action). The Edley Class Action asserts, among other things, that the Company fraudulently defended past asbestos personal injury lawsuits arising from exposure to industrial talc mined, milled, and manufactured before January 6, 1989 by the Company's then wholly owned subsidiary, Windsor Minerals, Inc., which is currently a debtor in the Imerys Bankruptcy described hereafter. The Company removed the Edley Class Action to federal court in the District of New Jersey. In October 2022, the Company filed motions to dismiss and to deny certification of a class to pursue the Edley Class Action in the New Jersey District Court. Argument on the motions was heard in November 2023. Thereafter, the Company resolved this matter.

In February 2019, the Company's talc supplier, Imerys Talc America, Inc. and two of its affiliates, Imerys Talc Vermont, Inc. and Imerys Talc Canada, Inc. (collectively, Imerys) filed a voluntary petition for relief under chapter 11 of the United States Code (the Bankruptcy Code) in the United States Bankruptcy Court for the District of Delaware (Imerys Bankruptcy). The Imerys Bankruptcy relates to Imerys's potential liability for personal injury from exposure to talcum powder sold by Imerys. In its bankruptcy, Imerys alleges it has claims against the Company for indemnification and rights to joint insurance proceeds. In its bankruptcy, Imerys proposed a chapter 11 plan (the Imerys Plan) that contemplated all talc-related claims against it being channeled to a trust along with its alleged indemnification rights against the Company. Following confirmation and consummation of the plan, the trust would pay talc claims pursuant to proposed trust distribution procedures (the TDP) and then seek indemnification from the Company.

In February 2021, Cyprus Mines Corporation (Cyprus), which had owned certain Imerys talc mines, filed a voluntary petition for relief under chapter 11 of the Bankruptcy Code and filed its Disclosure Statement and Plan (the Cyprus Plan). The Cyprus Plan contemplates a settlement with Imerys and talc claimants where Cyprus would make a monetary contribution to a trust established under the Imerys Plan in exchange for an injunction against talc claims asserted against it and certain affiliated parties.

The Imerys Plan proceeded to solicitation in early 2021. However, the Imerys Plan did not receive the requisite number of votes to be confirmed after the Bankruptcy Court ruled certain votes cast in favor of the Imerys Plan should be disregarded. Imerys subsequently canceled its confirmation hearing.

Imerys, the Imerys Tort Claimants' Committee, and the Imerys Future Claimants' Representative, along with Cyprus, the Cyprus Tort Claimants' Committee, and the Cyprus Future Claimants' Representative (collectively the Mediation Parties) have been engaged in mediation since shortly after the confirmation hearing was canceled in October 2021. In September 2023, the Bankruptcy Court entered an order extending the term of the mediation among the Mediation Parties through the end of December 2023. The Bankruptcy Court also authorized Imerys and Cyprus to proceed with mediation with certain of their insurers through the end of December 2023.

In September 2023, Imerys and Cyprus filed amended plans of reorganization. The amended plans contemplate a similar construct as the prior Imerys and Cyprus Plans, including all talc claims against Imerys and Cyprus (and certain other protected parties) being channeled to a trust along with Imerys's and Cyprus's alleged indemnification rights against the Company. In January 2024, Imerys and Cyprus filed revised TDP. In February 2024, Imerys and Cyprus filed certain motions related to their Disclosure Statement.

In February 2018, a securities class action lawsuit was filed against the Company and certain named officers in the United States District Court for the District of New Jersey, alleging that the Company violated the federal securities laws by failing to disclose alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S Baby Powder, and that purchasers of the Company's shares suffered losses as a result. In April 2019, the Company moved to dismiss the complaint. In

December 2019, the Court denied, in part, the motion to dismiss. In April 2021, briefing on Plaintiff's motion for class certification was completed. The case was stayed in May 2022 pursuant to the LTL Bankruptcy Case and was reopened in May 2023. In December 2023, the Court granted Plaintiff's motion for class certification. In January 2024, Defendants filed a petition with the Third Circuit under Federal Rule of Civil Procedure 23(f) for permission to appeal the Court's order granting class certification. Fact discovery is proceeding.

A lawsuit was brought against the Company in the Superior Court of California for the County of San Diego alleging violations of California's Consumer Legal Remedies Act (CLRA) relating to JOHNSON'S Baby Powder. In that lawsuit, the plaintiffs allege that the Company violated the CLRA by failing to provide required Proposition 65 warnings. In July 2019, the Company filed a notice of removal to the United States District Court for the Southern District of California and plaintiffs filed a second amended complaint shortly thereafter. In October 2019, the Company moved to dismiss the second amended complaint for failure to state a claim upon which relief may be granted. In response to those motions, plaintiffs filed a third amended complaint. In December 2019, the Company moved to dismiss the third amended complaint for failure to state a claim upon which relief may be granted. In April 2020, the Court granted the motion to dismiss but granted leave to amend. In May 2020, plaintiffs filed a Fourth Amended Complaint but indicated that they would be filing a motion for leave to file a fifth amended complaint. Plaintiffs filed a Fifth Amended Complaint in August 2020. The Company moved to dismiss the Fifth Amended Complaint for failure to state a claim upon which relief may be granted. In January 2021, the Court issued an Order and opinion ruling in the Company's favor and granting the motion to dismiss with prejudice. In February 2021, Plaintiffs filed a Notice of Appeal with the Ninth Circuit. Plaintiffs filed their opening brief in July 2021. The company filed its responsive brief in October 2021. After the Notice of Suggestion of Bankruptcy was filed with the Ninth Circuit, a stay was imposed, and the Court held the reply deadline in abeyance. In September 2023, the stay lifted. With briefing complete, the Court is expected to either schedule oral argument or issue its decision at any time.

In June 2014, the Mississippi Attorney General filed a complaint in Chancery Court of The First Judicial District of Hinds County, Mississippi against the Company and Johnson & Johnson Consumer Companies, Inc. (now known as Johnson & Johnson Consumer Inc.) (collectively, JJCI). The complaint alleges that JJCI violated the Mississippi Consumer Protection Act by failing to disclose alleged health risks associated with female consumers' use of talc contained in JOHNSON'S Baby Powder and JOHNSON'S Shower to Shower (a product divested in 2012) and seeks injunctive and monetary relief. In February 2022, the trial court set the case for trial to begin in February 2023. However, in October 2022, the LTL bankruptcy court issued an order staying the case. In March 2023, the Third Circuit issued the mandate to dismiss the LTL Bankruptcy Case and in April 2023, the New Jersey Bankruptcy Court dismissed the LTL Bankruptcy Case, effectively lifting the stay as to this matter. The State requested a new trial setting. Later in April 2023, the trial court set a new trial date for April 2024. The Company filed summary judgment and Daubert motions. The State filed a limited Daubert motion. The parties agreed to the Court's request for mediation. A pretrial conference is set for February 2024 and trial is scheduled for April 2024. However, the Company is actively engaged in resolution discussions concerning this matter.

In January 2020, the State of New Mexico filed a consumer protection case alleging that the Company deceptively marketed and sold its talcum powder products by making misrepresentations about the safety of the products and the presence of carcinogens, including asbestos. In March 2022, the New Mexico court denied the Company's motion to compel the State of New Mexico to engage in discovery of state agencies and denied the Company's request for interlocutory appeal of that decision. The Company then filed a Petition for Writ of Superintending Control and a Request for a Stay to the New Mexico Supreme Court on the issue of the State of New Mexico's discovery obligations. In April 2022, in view of the efforts to resolve talc-related claims in the LTL Bankruptcy Case, the Company and the State agreed to a 60-day stay of all matters except for the pending writ before the New Mexico Supreme Court, which expired in June 2022. Thereafter, the Company moved to enjoin prosecution of the case in the LTL Bankruptcy Case. In October 2022, the bankruptcy court issued an order staying the case. In December 2022, the State filed an appeal to the Third Circuit concerning the stay order. Separately, in September 2022, the New Mexico Supreme Court granted the Company's request for a stay pending further briefing on the scope of the State of New Mexico's discovery obligations. In March 2023, the Third Circuit issued the mandate to dismiss the LTL Bankruptcy Case and in April 2023, the New Jersey Bankruptcy Court dismissed the LTL Bankruptcy Case, effectively lifting the stay as to this matter. While the State notified the New Mexico Supreme Court of the lifted stay of litigation in April 2023, the Court has not taken any action since being notified of the lifting of the stay and it remains in effect.

Forty-two states and the District of Columbia (including Mississippi and New Mexico) have commenced a joint investigation into the Company's marketing of its talcum powder products. At this time, the multi-state group has not asserted any claims against the Company. Five states have issued Civil Investigative Demands seeking documents and other information. The Company has produced documents to Arizona, North Carolina, Texas, and Washington and entered into confidentiality agreements. The Company has not received any follow up requests from those states. In March 2022, each of the forty-two states agreed to mediation of their claims in the LTL Bankruptcy Case. In July 2022, New Mexico and Mississippi indicated they would no longer voluntarily submit to further mediation in the LTL Bankruptcy and would proceed with their respective cases in state court. In March 2023, the mediation was terminated. In January 2024, the Company reached an agreement in principle with the multi-state group of state Attorneys General, subject to ongoing negotiation of non-monetary terms. The unique procedural history and status of the New Mexico and Mississippi matters specifically have been discussed above.

In addition, the Company has received inquiries, subpoenas, and requests to produce documents regarding talc matters and the LTL Bankruptcy Case from various governmental authorities. The Company has produced documents and responded to inquiries, and will continue to cooperate with government inquiries.

Matters concerning opioids

Beginning in 2014 and continuing to the present, the Company and Janssen Pharmaceuticals, Inc. (JPI), along with other pharmaceutical companies, have been named in close to 3,500 lawsuits related to the marketing of opioids, including DURAGESIC, NUCYNTA and NUCYNTA ER. The majority of the cases have been filed by state and local governments. Similar lawsuits have also been filed by private plaintiffs and organizations, including but not limited to the following: individual plaintiffs on behalf of children born with Neonatal Abstinence Syndrome (NAS); hospitals; and health insurers/payors.

To date, the Company and JPI have litigated two of the cases to judgment and have prevailed in both, either at trial or on appeal.

In October 2019, the Company announced a proposed agreement in principle with a negotiating committee of state Attorneys General to settle all remaining government opioid litigation claims nationwide. Under the final national settlement agreement, which was announced in July 2021, the Company agreed to pay up to $5.0 billion to resolve all opioid lawsuits and future opioid claims by states, cities, counties, local school districts and other special districts, and tribal governments, contingent on sufficient participation by eligible government entities, and with credits back for entities that declined or were ineligible to participate. In July 2021, the Company announced that the terms of the agreement to settle the state and subdivision claims had been finalized and approximately 60% of the all-in settlement was paid by the end of fiscal 2023. The expected payment schedule provides that approximately $0.7 billion of payments are to be paid by the end of fiscal 2024. The agreement is not an admission of liability or wrongdoing, and it provides for the release of all opioid-related claims against the Company, JPI, and their affiliates (including the Company's former subsidiaries Tasmanian Alkaloids Pty, Ltd. and Noramco, Inc.). As of January 2024, the Company and JPI have settled or otherwise resolved the opioid claims advanced by all government entity claimants except the City of Baltimore, a number of school districts and other claimants.

The Company and JPI continue to defend the cases brought by the remaining government entity litigants as well as the cases brought by private litigants, including NAS claimants, hospitals, and health insurers/payors. Counting the private litigant cases, there are approximately 35 remaining opioid cases against the Company and JPI in various state courts, 430 remaining cases in the Ohio MDL, and 4 additional cases in other federal courts. Some of these cases have been dismissed and are being appealed by the plaintiffs and certain others are scheduled for trial in 2024 or 2025.

In addition, the Province of British Columbia filed suit against the Company and its Canadian affiliate Janssen Inc., and many other industry members, in Canada, and is seeking to have that action certified as an opt in class action on behalf of other provincial/territorial and the federal governments in Canada. Additional proposed class actions have been filed in Canada against the Company and Janssen Inc., and many other industry members, by and on behalf of people who used opioids (for personal injuries), municipalities and First Nations bands. These actions allege a variety of claims related to opioid marketing practices, including false advertising, unfair competition, public nuisance, consumer fraud violations, deceptive acts and practices, false claims and unjust enrichment. An adverse judgment in any of these lawsuits could result in the imposition of large monetary penalties and significant damages including, punitive damages, cost of abatement, substantial fines, equitable remedies and other sanctions.

From June 2017 through December 2019, the Company's Board of Directors received a series of shareholder demand letters alleging breaches of fiduciary duties related to the marketing of opioids. The Board retained independent counsel to investigate the allegations in the demands, and in April 2020, independent counsel delivered a report to the Board recommending that the Company reject the shareholder demands and take the steps that are necessary or appropriate to secure dismissal of related derivative litigation. The Board unanimously adopted the recommendations of the independent counsel's report.

In November 2019, one of the shareholders who sent a demand filed a derivative complaint against the Company as the nominal defendant and certain current and former directors and officers as defendants in the Superior Court of New Jersey. The complaint alleges breaches of fiduciary duties related to the marketing of opioids, and that the Company has suffered damages as a result of those alleged breaches. A series of additional derivative complaints making similar allegations against the same and similar defendants were filed in New Jersey state and federal courts in 2019 and 2020. By 2022, all but two state court cases had been voluntarily dismissed. In February 2022, the state court granted the Company's motion to dismiss one of the two cases, and the shareholder that brought the second case filed a notice of dismissal. The shareholder whose complaint was dismissed filed a motion for reconsideration. In May 2022, the state court held oral argument on the motion for reconsideration and subsequently denied the motion. The shareholder has appealed the state court's dismissal order.

Product liability

The Company and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While the Company believes it has substantial defenses, it is not feasible to predict the ultimate outcome of litigation. From time to time, even if it has substantial defenses, the Company considers isolated settlements based on a variety of circumstances. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25, Contingencies. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

The table below contains the most significant of these cases and provides the approximate number of plaintiffs in the United States with direct claims in pending lawsuits regarding injuries allegedly due to the relevant product or product category as of December 31, 2023:

Product or product category	Number of plaintiffs
Body powders containing talc, primarily JOHNSON'S Baby Powder	59,140
DePuy ASR XL Acetabular System and DePuy ASR Hip Resurfacing System	160
PINNACLE Acetabular Cup System	920
Pelvic meshes	6,720
ETHICON PHYSIOMESH Flexible Composite Mesh	370
RISPERDAL	200
ELMIRON	2,150

The number of pending lawsuits is expected to fluctuate as certain lawsuits are settled or dismissed and additional lawsuits are filed. There may be additional claims that have not yet been filed.

MedTech

DePuy ASR XL Acetabular System and ASR Hip Resurfacing System

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR XL Acetabular System and DePuy ASR Hip Resurfacing System (ASR Hip) used in hip replacement surgery. Claims for personal injury have been made against DePuy and the Company. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada, Australia, Ireland, Germany, India and Italy. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR Hip plaintiffs to establish a program to settle claims with eligible ASR Hip patients in the United States who had surgery to replace their ASR Hips, known as revision surgery, as of August 2013. DePuy reached additional agreements in February 2015 and March 2017, which further extended the settlement program to include ASR Hip patients who had revision surgeries after August 2013 and prior to February 15, 2017. This settlement program has resolved more than 10,000 claims, thereby bringing to resolution significant ASR Hip litigation activity in the United States. However, lawsuits in the United States remain, and the settlement program does not address litigation outside of the United States. In Australia, a class action settlement was reached that resolved the claims of the majority of ASR Hip patients in that country. In Canada, the Company has reached agreements to settle the class actions filed in that country. The Company continues to receive information with respect to potential additional costs associated with this recall on a worldwide basis. The Company has established accruals for the costs associated with the United States settlement program and ASR Hip-related product liability litigation.

DePuy PINNACLE Acetabular Cup System

Claims for personal injury have also been made against DePuy Orthopaedics, Inc. and the Company (collectively, DePuy) relating to the PINNACLE Acetabular Cup System used in hip replacement surgery. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Most cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States

District Court for the Northern District of Texas (Texas MDL). Beginning on June 1, 2022, the Judicial Panel on Multidistrict Litigation ceased transfer of new cases into the Texas MDL, and there are now cases pending in federal court outside the Texas MDL. Litigation also has been filed in state courts and in countries outside of the United States. During the first quarter of 2019, DePuy established a United States settlement program to resolve these cases. As part of the settlement program, adverse verdicts have been settled. The Company has established an accrual for product liability litigation associated with the PINNACLE Acetabular Cup System and the related settlement program.

Ethicon Pelvic Mesh

Claims for personal injury have been made against Ethicon, Inc. (Ethicon) and the Company arising out of Ethicon's pelvic mesh devices used to treat stress urinary incontinence and pelvic organ prolapse. The Company continues to receive information with respect to potential costs and additional cases. Cases filed in federal courts in the United States had been organized as a multi-district litigation (MDL) in the United States District Court for the Southern District of West Virginia. In March 2021, the MDL Court entered an order closing the MDL. The MDL Court has remanded cases for trial to the jurisdictions where the case was originally filed and additional pelvic mesh lawsuits have been filed, and remain, outside of the MDL. The Company has settled or otherwise resolved the majority of the United States cases and the estimated costs associated with these settlements and the remaining cases are reflected in the Company's accruals. In addition, class actions and individual personal injury cases or claims seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices have been commenced in various countries outside of the United States, including claims and cases in the United Kingdom, the Netherlands, Belgium, France, Ireland, Italy, Spain and Slovenia and class actions in Israel, Australia, Canada and South Africa. In November 2019, the Federal Court of Australia issued a judgment regarding its findings with respect to liability in relation to the three Lead Applicants and generally in relation to the design, manufacture, pre and post-market assessments and testing, and supply and promotion of the devices in Australia used to treat stress urinary incontinence and pelvic organ prolapse. In September 2022, after exhausting its appeals, the Company reached an in-principle agreement to resolve the two pelvic mesh class actions in Australia and in March 2023 the Federal Court approved the settlement. The class actions in Canada were discontinued in 2020 as a result of a settlement of a group of cases and an agreement to resolve the Israeli class action was reached in May 2021. The parties in the Israeli class action are currently finalizing the terms of the settlement. A motion to approve the settlement was filed with the Court. The Company has established accruals with respect to product liability litigation associated with Ethicon's pelvic mesh products.

Ethicon Physiomesh

Following a June 2016 worldwide market withdrawal of Ethicon Physiomesh Flexible Composite Mesh (Physiomesh), claims for personal injury have been made against Ethicon, Inc. (Ethicon) and the Company alleging personal injury arising out of the use of this hernia mesh device. Cases filed in federal courts in the United States have been organized as a multi-district litigation (MDL) in the United States District Court for the Northern District of Georgia. A multi-county litigation (MCL) also has been formed in New Jersey state court and assigned to Atlantic County for cases pending in New Jersey. In addition to the matters in the MDL and MCL, there are additional lawsuits pending in the United States District Court for the Southern District of Ohio, which are part of the MDL for polypropylene mesh devices manufactured by C.R. Bard, Inc., and lawsuits pending in two New Jersey MCLs formed for Proceed/Proceed Ventral Patch and Prolene Hernia systems, and lawsuits pending outside the United States. In May 2021, Ethicon and lead counsel for the plaintiffs entered into a term sheet to resolve approximately 3,600 Physiomesh cases (covering approximately 4,300 plaintiffs) pending in the MDL and MCL at that time. A master settlement agreement (MSA) was entered into in September 2021 and includes 3,729 cases in the MDL and MCL. All deadlines and trial settings in those proceedings are currently stayed pending the completion of the settlement agreement. Of the cases subject to the MSA, 3,390 have been dismissed with prejudice. Ethicon has received releases from 3,584 plaintiffs, and releases continue to be submitted as part of the settlement process. Post-settlement cases in the Physiomesh MDL and MCL are subject to docket control orders requiring early expert reports and discovery requirements. In May 2023, Ethicon entered an additional settlement to resolve the claims of 292 Physiomesh claimants. That settlement is proceeding, and releases are being returned. As of December 31, 2023, there were 5 Physiomesh cases in the MDL and 3 in the New Jersey MCL which are not included in either settlement and which remain subject to the docket control orders.

Claims have also been filed against Ethicon and the Company alleging personal injuries arising from the PROCEED Mesh and PROCEED Ventral Patch hernia mesh products. In March 2019, the New Jersey Supreme Court entered an order consolidating these cases pending in New Jersey as an MCL in Atlantic County Superior Court. Additional cases have been filed in various federal and state courts in the United States, and in jurisdictions outside the United States.

Ethicon and the Company also have been subject to claims for personal injuries arising from the PROLENE Polypropylene Hernia System. In January 2020, the New Jersey Supreme Court created an MCL in Atlantic County Superior Court to handle such cases. Cases involving this product have also been filed in other federal and state courts in the United States.

In October 2022, an agreement in principle, subject to various conditions, was reached to settle the majority of the pending cases involving Proceed, Proceed Ventral Patch, Prolene Hernia System and related multi-layered mesh products, as well as a number of unfiled claims. All litigation activities in the two New Jersey MCLs are stayed pending effectuation of the proposed settlement. Future cases that are filed in the New Jersey MCLs will be subject to docket control orders requiring early expert reports and discovery requirements.

The Company has established accruals with respect to product liability litigation associated with Ethicon Physiomesh Flexible Composite Mesh, PROCEED Mesh and PROCEED Ventral Patch, and PROLENE Polypropylene Hernia System products.

Innovative Medicine

RISPERDAL

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and the Company arising out of the use of RISPERDAL, and related compounds, indicated for the treatment of schizophrenia, acute manic or mixed episodes associated with bipolar I disorder and irritability associated with autism. Lawsuits primarily have been filed in state courts in Pennsylvania, California, and Missouri. Other actions are pending in various courts in the United States and Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has successfully defended a number of these cases but there have been verdicts against the Company, including a verdict in October 2019 of $8.0 billion of punitive damages related to one plaintiff, which the trial judge reduced to $6.8 million in January 2020. In September 2021, the Company entered into a settlement in principle with the counsel representing plaintiffs in this matter and in substantially all of the outstanding cases in the United States. The costs associated with this and other settlements are reflected in the Company's accruals.

ELMIRON

Claims for personal injury have been made against a number of Johnson & Johnson companies, including Janssen Pharmaceuticals, Inc. and the Company, arising out of the use of ELMIRON, a prescription medication indicated for the relief of bladder pain or discomfort associated with interstitial cystitis. These lawsuits, which allege that ELMIRON contributes to the development of permanent retinal injury and vision loss, have been filed in both state and federal courts across the United States. In December 2020, lawsuits filed in federal courts in the United States, including putative class action cases seeking medical monitoring, were organized as a multi-district litigation in the United States District Court for the District of New Jersey. All cases in the multi-district litigation are in active discussions regarding resolution, and as a result, all activity is stayed. In addition, cases have been filed in various state courts of New Jersey, which have been coordinated in a multi-county litigation in Bergen County, as well as the Court of Common Pleas in Philadelphia, which have been coordinated and granted mass tort designation. No activity has taken place in the New Jersey state court litigation; however, three bellwether trials have been set in Philadelphia for March, April and May 2024. In addition, three class action lawsuits have been filed in Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has established accruals for defense and indemnity costs associated with ELMIRON related product liability litigation.

Intellectual property

Certain subsidiaries of the Company are subject, from time to time, to legal proceedings and claims related to patent, trademark and other intellectual property matters arising out of their businesses. Many of these matters involve challenges to the coverage and/or validity of the patents on various products and allegations that certain of the Company's products infringe the patents of third parties. Although these subsidiaries believe that they have substantial defenses to these challenges and allegations with respect to all significant patents, there can be no assurance as to the outcome of these matters. A loss in any of these cases could adversely affect the ability of these subsidiaries to sell their products, result in loss of sales due to loss of market exclusivity, require the payment of past damages and future royalties, and may result in a non-cash impairment charge for any associated intangible asset.

Innovative Medicine - litigation against filers of abbreviated new drug applications (ANDAs)

The Company's subsidiaries have brought lawsuits against generic companies that have filed ANDAs with the U.S. FDA (or similar lawsuits outside of the United States) seeking to market generic versions of products sold by various subsidiaries of the Company prior to expiration of the applicable patents covering those products. These lawsuits typically include allegations of non-infringement and/or invalidity of patents listed in FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the Orange Book). In each of these lawsuits, the Company's subsidiaries are seeking an order enjoining the defendant from marketing a generic version of a product before the expiration of the relevant patents (Orange Book Listed Patents). In the event the Company's subsidiaries are not successful in an action, or any automatic statutory stay expires before the court rulings are obtained, the generic companies involved would have the ability, upon regulatory approval, to introduce generic versions of their products to the market, resulting in the potential for substantial market share and revenue losses for the applicable products, and which may result in a non-cash impairment charge in any associated intangible asset. In addition, from time to time, the Company's subsidiaries may settle these types of actions

and such settlements can involve the introduction of generic versions of the products at issue to the market prior to the expiration of the relevant patents.

The Inter Partes Review (IPR) process with the United States Patent and Trademark Office (USPTO), created under the 2011 America Invents Act, is also being used at times by generic companies in conjunction with ANDAs and lawsuits to challenge the applicable patents.

XARELTO

Beginning in March 2021, Janssen Pharmaceuticals, Inc.; Bayer Pharma AG; Bayer AG; and Bayer Intellectual Property GmbH filed patent infringement lawsuits in United States district courts against generic manufacturers who have filed ANDAs seeking approval to market generic versions of XARELTO before expiration of certain Orange Book Listed Patents. The following entities are named defendants: Dr. Reddy's Laboratories, Inc.; Dr. Reddy's Laboratories, Ltd.; Lupin Limited; Lupin Pharmaceuticals, Inc.; Taro Pharmaceutical Industries Ltd.; Taro Pharmaceuticals U.S.A., Inc.; Teva Pharmaceuticals USA, Inc.; Mylan Pharmaceuticals Inc.; Mylan Inc.; Mankind Pharma Limited; Apotex Inc.; Apotex Corp.; Auson Pharmaceuticals Inc.; Macleods Pharmaceuticals Ltd; Macleods Pharma USA, Inc.; Indoco Remedies Limited; FPP Holding Company LLC; Umedica Laboratories Pvt. Ltd.; Aurobindo Pharma Limited; Aurobindo Pharma USA, Inc.; Cipla Ltd.; Cipla USA Inc.; and InvaGen Pharmaceuticals, Inc. The following U.S. patents are included in one or more cases: 9,539,218 and 10,828,310.

U.S. Patent No. 10,828,310 was also under consideration by the USPTO in an IPR proceeding. In July 2023, the USPTO issued a final written decision finding the claims of the patent invalid. In September 2023, Bayer Pharma AG filed an appeal to the U.S. Court of Appeals for the Federal Circuit.

OPSUMIT

Beginning in January 2023 Actelion Pharmaceuticals Ltd and Actelion Pharmaceuticals US, Inc. filed patent infringement lawsuits in United States district courts against generic manufacturers who have filed ANDAs seeking approval to market generic versions of OPSUMIT before expiration of certain Orange Book Listed Patents. The following entities are named defendants: Sun Pharmaceutical Industries Limited; Sun Pharmaceutical Industries, Inc.; MSN Laboratories Private Limited; MSN Pharmaceuticals Inc.; and Mylan Pharmaceuticals Inc. The following U.S. patents are included in one or more cases: 7,094,781; and 10,946,015. In November 2023, the Company entered into a confidential settlement agreement with MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. In December 2023, the Company entered into a confidential settlement agreement with Sun Pharmaceutical Industries Limited and Sun Pharmaceuticals Industries, Inc.

INVEGA SUSTENNA

Beginning in January 2018, Janssen Pharmaceutica NV and Janssen Pharmaceuticals, Inc. filed patent infringement lawsuits in United States district courts against generic manufacturers who have filed ANDAs seeking approval to market generic versions of INVEGA SUSTENNA before expiration of the Orange Book Listed Patent. The following entities are named defendants: Teva Pharmaceuticals USA, Inc.; Mylan Laboratories Limited; Pharmascience Inc.; Mallinckrodt PLC; Specgx LLC; Tolmar, Inc.; and Accord Healthcare, Inc. The following U.S. patent is included in one or more cases: 9,439,906.

Beginning in February 2018, Janssen Inc. and Janssen Pharmaceutica NV initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against generic manufacturers who have filed ANDSs seeking approval to market generic versions of INVEGA SUSTENNA before expiration of the listed patent. The following entities are named defendants: Pharmascience Inc. and Apotex Inc. The following Canadian patent is included in one or more cases: 2,655,335.

INVEGA TRINZA

Beginning in September 2020, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV, and Janssen Research & Development, LLC filed patent infringement lawsuits in United States district courts against generic manufacturers who have filed ANDAs seeking approval to market generic versions of INVEGA TRINZA before expiration of the Orange Book Listed Patent. The following entities are named defendants: Mylan Laboratories Limited; Mylan Pharmaceuticals Inc.; and Mylan Institutional LLC. The following U.S. patent is included in one or more cases: 10,143,693. In May 2023, the District Court issued a decision finding that Mylan's proposed generic product infringes the asserted patent and that the patent is not invalid. Mylan has appealed the verdict.

SYMTUZA

Beginning in November 2021, Janssen Products, L.P., Janssen Sciences Ireland Unlimited Company, Gilead Sciences, Inc. and Gilead Sciences Ireland UC filed patent infringement lawsuits in United States district courts against generic manufacturers who have filed ANDAs seeking approval to market generic versions of SYMTUZA before expiration of certain Orange Book Listed Patents. The following entities are named defendants: Lupin Limited; Lupin Pharmaceuticals, Inc.; MSN Laboratories

Private Ltd.; MSN Life Sciences Private Ltd.; MSN Pharmaceuticals Inc.; Apotex Inc.; and Apotex Corp. The following U.S. patents are included in one or more cases: 10,039,718 and 10,786,518.

ERLEADA

Beginning in May 2022, Aragon Pharmaceuticals, Inc., Janssen Biotech, Inc. (collectively, Janssen), Sloan Kettering Institute for Cancer Research (SKI) and The Regents of the University of California filed patent infringement lawsuits in United States district courts against generic manufacturers who have filed ANDAs seeking approval to market generic versions of ERLEADA before expiration of certain Orange Book Listed Patents. The following entities are named defendants: Lupin Limited; Lupin Pharmaceuticals, Inc.; Zydus Worldwide DMCC; Zydus Pharmaceuticals (USA), Inc.; Zydus Lifesciences Limited; Sandoz Inc.; Eugia Pharma Specialities Limited; Aurobindo Pharma USA, Inc.; Auromedics Pharma LLC; Hetero Labs Limited Unit V; and Hetero USA, Inc. The following U.S. patents are included in one or more cases: 9,481,663; 9,884,054; 10,052,314 (which reissued as RE49,353); 10,702,508; 10,849,888; 8,445,507; 8,802,689; 9,388,159; 9,987,261; and RE49,353. In December 2023, Janssen and SKI voluntarily dismissed their case against Lupin Limited and Lupin Pharmaceuticals, Inc.

UPTRAVI

Beginning in November 2022, Actelion Pharmaceuticals US Inc., Actelion Pharmaceuticals Ltd and Nippon Shinyaku Co., Ltd. filed patent infringement lawsuits in United States district courts against generic manufacturers who have filed ANDAs seeking approval to market generic versions of UPTRAVI intravenous before expiration of certain Orange Book Listed Patents. The following entities are named defendants: Alembic Pharmaceuticals Limited, Alembic Pharmaceuticals Inc.; Lupin Ltd.; Lupin Pharmaceuticals, Inc.; Cipla Limited; Cipla USA Inc.; MSN Laboratories Private Ltd.; and MSN Pharmaceuticals Inc. The following U.S. patents are included in one or more cases: 8,791,122 and 9,284,280. In November 2023, the Company entered into a confidential settlement agreement with Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals Inc.

SPRAVATO

Beginning in May 2023, Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV filed patent infringement lawsuits in United States district courts against generic manufacturers who have filed ANDAs seeking approval to market generic versions of SPRAVATO before expiration of certain Orange Book Listed Patents. The following entities are named defendants: Sandoz Inc.; Hikma Pharmaceuticals Inc. USA; Hikma Pharmaceuticals PLC; and Alkem Laboratories Ltd. The following U.S. patents are included in one or more cases: 10,869,844; 11,173,134; 11,311,500; and 11,446,260.

STELARA

In November 2023, Biocon Biologics Inc. filed a Petition for Inter Partes Review with the USPTO seeking review of U.S. Patent No. 10,961,307 related to methods of treating ulcerative colitis with ustekinumab.

MedTech

In March 2016, Abiomed, Inc. (Abiomed) filed a declaratory judgment action against Maquet Cardiovascular LLC (Maquet) in U.S. District Court for the District of Massachusetts seeking a declaration that the Impella does not infringe certain Maquet patents, currently U.S. Patent Nos. 7,022,100 ('100); 8,888,728; 9,327,068; 9,545,468; 9,561,314; and 9,597,437. Maquet counterclaimed for infringement of each of those patents. After claim construction, Maquet alleged infringement of only the '100 patent. In September 2021, the court granted Abiomed's motion for summary judgment of non-infringement of the '100 patent, and in September 2023, the district court entered final judgment in favor of Abiomed on all patents-in-suit. Maquet appealed.

Government proceedings

Like other companies in the pharmaceutical and medical technologies industries, the Company and certain of its subsidiaries are subject to extensive regulation by national, state and local government agencies in the United States and other countries in which they operate. Such regulation has been the basis of government investigations and litigations. The most significant litigation brought by, and investigations conducted by, government agencies are listed below. It is possible that criminal charges and substantial fines and/or civil penalties or damages could result from government investigations or litigation.

MedTech

In July 2018, the Public Prosecution Service in Rio de Janeiro and representatives from the Brazilian antitrust authority CADE inspected the offices of more than 30 companies including Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda. The authorities appear to be investigating allegations of possible anti-competitive behavior and possible improper payments in the medical device industry. The Company continues to respond to inquiries regarding the Foreign

Corrupt Practices Act from the United States Department of Justice and the United States Securities and Exchange Commission.

In July 2023, the U.S. Department of Justice ("DOJ") issued Civil Investigative Demands to the Company, Johnson & Johnson Surgical Vision, Inc., and Johnson & Johnson Vision Care, Inc. (collectively, "J&J Vision") in connection with a civil investigation under the False Claims Act relating to free or discounted intraocular lenses and equipment used in eye surgery, such as phacoemulsification and laser systems. J&J Vision has begun producing documents and information responsive to the Civil Investigative Demands. J&J Vision is in ongoing discussions with the DOJ regarding its inquiry.

Innovative Medicine

In July 2016, the Company and Janssen Products, LP were served with a qui tam complaint pursuant to the False Claims Act filed in the United States District Court for the District of New Jersey alleging the off-label promotion of two HIV products, PREZISTA and INTELENCE, and anti-kickback violations in connection with the promotion of these products. The complaint was filed under seal in December 2012. The federal and state governments have declined to intervene, and the lawsuit is being prosecuted by the relators. The Court denied summary judgment on all claims in December 2021. Daubert motions were granted in part and denied in part in January 2022, and the case is proceeding to trial. Trial is scheduled for May 2024.

In March 2017, Janssen Biotech, Inc. (JBI) received a Civil Investigative Demand from the United States Department of Justice regarding a False Claims Act investigation concerning management and advisory services provided to rheumatology and gastroenterology practices that purchased REMICADE or SIMPONI ARIA. In August 2019, the United States Department of Justice notified JBI that it was closing the investigation. Subsequently, the United States District Court for the District of Massachusetts unsealed a qui tam False Claims Act complaint, which was served on the Company. The Department of Justice had declined to intervene in the qui tam lawsuit in August 2019. The Company filed a motion to dismiss, which was granted in part and denied in part. Discovery is underway.

From time to time, the Company has received requests from a variety of United States Congressional Committees to produce information relevant to ongoing congressional inquiries. It is the policy of Johnson & Johnson to cooperate with these inquiries by producing the requested information.

General litigation

The Company or its subsidiaries are also parties to various proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the Company's agreement to implement remediation activities at designated hazardous waste sites or to reimburse the government or third parties for the costs they have incurred in performing remediation as such sites.

In October 2017, certain United States service members and their families brought a complaint against a number of pharmaceutical and medical devices companies, including Johnson & Johnson and certain of its subsidiaries in United States District Court for the District of Columbia, alleging that the defendants violated the United States Anti-Terrorism Act. The complaint alleges that the defendants provided funding for terrorist organizations through their sales practices pursuant to pharmaceutical and medical device contracts with the Iraqi Ministry of Health. In July 2020, the District Court dismissed the complaint. In January 2022, the United States Court of Appeals for the District of Columbia Circuit reversed the District Court's decision. In June 2023, defendants filed a petition for a writ of certiorari to the United States Supreme Court.

In February 2024, a putative class action was filed against the Company, the Pension & Benefits Committee of Johnson & Johnson, and certain named officers and employees, in United States District Court for the District of New Jersey. The complaint alleges that defendants breached fiduciary duties under the Employee Retirement Income Security Act (ERISA) by allegedly mismanaging the Company's prescription-drug benefits program. The complaint seeks damages and other relief.

MedTech

In October 2020, Fortis Advisors LLC (Fortis), in its capacity as representative of the former stockholders of Auris Health Inc. (Auris), filed a complaint against the Company, Ethicon Inc., and certain named officers and employees (collectively, Ethicon) in the Court of Chancery of the State of Delaware. The complaint alleges breach of contract, fraud, and other causes of action against Ethicon in connection with Ethicon's acquisition of Auris in 2019. The complaint seeks damages and other relief. In December 2021, the Court granted in part and denied in part defendants' motion to dismiss certain causes of action. All claims against the individual defendants were dismissed. The trial was held in January 2024 and the decision is pending.

Innovative Medicine

In June 2019, the United States Federal Trade Commission (FTC) issued a Civil Investigative Demand to the Company and Janssen Biotech, Inc. (collectively, Janssen) in connection with its investigation of whether Janssen's REMICADE contracting practices violate federal antitrust laws. The Company has produced documents and information responsive to the Civil Investigative Demand. Janssen is in ongoing discussions with the FTC staff regarding its inquiry.

In February 2022, the United States Federal Trade Commission (FTC) issued Civil Investigative Demands to Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) in connection with its investigation of whether advertising practices for REMICADE violate federal law. Janssen has produced documents and information responsive to the Civil Investigative Demands. Janssen is in ongoing discussions with the FTC staff regarding the inquiry.

In June 2022, Genmab A/S filed a Notice for Arbitration with International Institute for Conflict Prevention and Resolution (CPR) against Janssen Biotech, Inc. seeking milestones and an extended royalty term for Darzalex FASPRO. In April 2023, the Arbitration Panel ruled in Janssen's favor and dismissed Genmab's claims. In January 2024, Genmab's appeal of this dismissal was denied.

In October 2018, two separate putative class actions were filed against Actelion Pharmaceutical Ltd., Actelion Pharmaceuticals U.S., Inc., and Actelion Clinical Research, Inc. (collectively Actelion) in United States District Court for the District of Maryland and United States District Court for the District of Columbia. The complaints allege that Actelion violated state and federal antitrust and unfair competition laws by allegedly refusing to supply generic pharmaceutical manufacturers with samples of TRACLEER. TRACLEER is subject to a Risk Evaluation and Mitigation Strategy required by the U.S. Food and Drug Administration, which imposes restrictions on distribution of the product. In January 2019, the plaintiffs dismissed the District of Columbia case and filed a consolidated complaint in the United States District Court for the District of Maryland.

In December 2023, a putative class action lawsuit was filed against the Company and Janssen Biotech Inc. (collectively "Janssen") in the United States District Court for the Eastern District of Virginia. The complaint alleges that Janssen violated federal and state antitrust laws and other state laws by delaying biosimilar competition with STELARA through the Janssen's enforcement of patent rights covering STELARA. The complaint seeks damages and other relief.

In June 2022, Janssen Pharmaceuticals, Inc. filed a Demand for Arbitration against Emergent Biosolutions Inc. et al. (EBSI) with the American Arbitration Association, alleging that EBSI breached the parties' Manufacturing Services Agreement for the Company's COVID-19 vaccine. In July 2022, Emergent filed its answering statement and counterclaims. The hearing is scheduled for July 2024.

20. Restructuring

In fiscal 2023, the Company commenced restructuring actions within its Innovative Medicine and MedTech segments. The amounts and details of the current year programs are included below.

In fiscal 2023, the Company completed a prioritization of its research and development (R&D) investment within its Innovative Medicine segment to focus on the most promising medicines with the greatest benefit to patients. This resulted in the exit of certain programs within certain therapeutic areas. The R&D program exits are primarily in infectious diseases and vaccines including the discontinuation of its respiratory syncytial virus (RSV) adult vaccine program, hepatitis and HIV development. Pre-tax Restructuring expenses of $479 million in the fiscal year 2023, included the termination of partnered and non-partnered development program costs and asset impairments. The estimated costs of these total activities is between $500 million - $600 million and is expected to be completed by the end of fiscal year 2024.

In fiscal 2023, the Company initiated a restructuring program of its Orthopaedics franchise within the MedTech segment to streamline operations by exiting certain markets, product lines and distribution network arrangements. The pre-tax restructuring expense of $319 million in the fiscal year 2023 primarily included inventory and instrument charges related to market and product exits. The estimated costs of the total program are between $700 million - $800 million and is expected to be completed by the end of fiscal year 2025.

The following table summarizes the restructuring expenses for the fiscal year 2023:

(Pre-tax Dollars in Millions)	**2023**
Innovative Medicine Segment[1]	$479
MedTech Segment[2]	319
Total Programs	$798

[1] Included $449 million in Restructuring and $30 million in Cost of products sold on the Consolidated Statement of Earnings

[2] Included $40 million in Restructuring and $279 million in Cost of products sold on the Consolidated Statement of Earnings

Restructuring reserves as of December 31, 2023 and January 1, 2023 were insignificant.

21. Kenvue separation and discontinued operations

On May 8, 2023, Kenvue, completed an initial public offering (the IPO) resulting in the issuance of 198,734,444 shares of its common stock, par value $0.01 per share (the "Kenvue Common Stock"), at an initial public offering of $22.00 per share for net proceeds of $4.2 billion. The excess of the net proceeds from the IPO over the net book value of the Johnson & Johnson divested interest was $2.5 billion and was recorded to additional paid-in capital. As of the closing of the IPO, Johnson & Johnson owned approximately 89.6% of the total outstanding shares of Kenvue Common Stock and at July 2, 2023, the non-controlling interest of $1.3 billion associated with Kenvue was reflected in equity attributable to non-controlling interests in the consolidated balance sheet in the fiscal second quarter of 2023.

On August 23, 2023, Johnson & Johnson completed the disposition of an additional 80.1% ownership of Kenvue Common Stock through an exchange offer, which resulted in Johnson & Johnson acquiring 190,955,436 shares of the Company's common stock in exchange for 1,533,830,450 shares of Kenvue Common Stock. The $31.4 billion of Johnson & Johnson common stock received in the exchange offer is recorded in Treasury stock. Following the exchange offer, the Company owns 9.5% of the total outstanding shares of Kenvue Common Stock that was recorded in other assets within continuing operations at the fair market value of $4.3 billion as of August 23, 2023. Subsequent changes are reflected in other income/expense and amounted to $0.4 billion expense through December 31, 2023.

Johnson & Johnson divested net assets of $11.6 billion as of August 23, 2023, and the accumulated other comprehensive loss attributable to the Consumer Health business at that date was $4.3 billion. Additionally, at the date of the exchange offer, Johnson & Johnson decreased the non-controlling interest by $1.2 billion to record the deconsolidation of Kenvue. This resulted in a non-cash gain on the exchange offer of $21.0 billion that was recorded in Net earnings from discontinued operations, net of taxes in the consolidated statements of earnings for the fiscal third quarter of 2023. This one-time gain includes a gain of $2.8 billion on the Kenvue Common Stock retained by Johnson & Johnson. The gain on the exchange offer qualifies as a tax-free transaction for U.S. federal income tax purposes.

Also in connection with the separation, Johnson & Johnson and Kenvue entered into a separation agreement and also entered into various other agreements that provide for certain transactions to effect the transfer of the assets and liabilities of the Consumer Health business to Kenvue and to govern various interim and ongoing relationships between Kenvue and Johnson & Johnson following the completion of the Kenvue IPO, including transition services agreements (TSAs), transition manufacturing agreements (TMAs), trademark agreements, intellectual property agreements, an employee matters agreement, and a tax matters agreement. Under the TSAs, Johnson & Johnson will provide Kenvue various services and, similarly, Kenvue will provide Johnson & Johnson various services. The provision of services under the TSAs generally will terminate within 24 months following the Kenvue IPO. Additionally, Johnson & Johnson and Kenvue entered into TMAs pursuant to which Johnson & Johnson will manufacture and supply to Kenvue certain products and, similarly, Kenvue will manufacture and supply to Johnson & Johnson certain products. The terms of the TMAs range in initial duration from 3 months to 5 years.

Amounts related to the TSAs and TMAs included in the consolidated statements of earnings were immaterial for the fiscal year 2023. Additionally, the amounts due to and from Kenvue for the above agreements was not material as of December 31, 2023.

The results of the Consumer Health business (previously reported as a separate business segment), as well as the associated gain, have been reflected as discontinued operations in the Company's consolidated statements of earnings as Net earnings from discontinued operations, net of taxes. Prior periods have been recast to reflect this presentation. As a result of the separation of Kenvue, Johnson & Johnson incurred separation costs of $986 million, $1,089 million and $67 million in the fiscal years 2023, 2022 and 2021, respectively, which are also included in Net earnings from discontinued operations, net of taxes. These costs were primarily related to external advisory, legal, accounting, contractor and other incremental costs directly related to separation activities. In the fiscal 2022, as part of the planned separation of the Company's Consumer Health business, the Company recognized approximately $0.5 billion in net incremental tax costs. As of January 1, 2023, the assets and liabilities associated with the Consumer Health business were classified as assets and liabilities of discontinued operations in the consolidated balance sheets.

Details of Net Earnings from Discontinued Operations, net of taxes are as follows:

(Dollars in Millions)	2023[1]	2022	2021
Sales to customers	$10,036	14,953	15,035
Cost of products sold	4,369	6,494	6,452
Gross profit	5,667	8,459	8,583
Selling, marketing and administrative expenses	3,085	4,519	4,542
Research and development expense	258	468	437
Interest Income	(117)	—	—
Interest expense, net of portion capitalized	199	—	—
Other (income) expense, net	1,092	1,060	(37)
(Gain) on separation of Kenvue	(20,984)	—	—
Restructuring	—	46	43
Earnings from Discontinued Operations Before Provision for Taxes on Income	22,134	2,366	3,598
Provision for taxes on income	307	795	521
Net earnings from Discontinued Operations	**$21,827**	**1,571**	**3,077**

[1] The Company ceased consolidating the results of the Consumer Health business on August 23, 2023, the date of the exchange offer, but continued to reflect any separation costs incurred as part of discontinued operations through the end of the fiscal fourth quarter.

The following table presents depreciation, amortization and capital expenditures of the discontinued operations related to Kenvue:

(Dollars in Millions)	2023[1]	2022	2021
Depreciation and Amortization	$383	641	739
Capital expenditures	$162	303	314

Details of assets and liabilities of discontinued operations were as follows:

	January 1, 2023
Assets	
Cash and cash equivalents	$1,238
Accounts receivable trade, less allowances for doubtful accounts	2,121
Inventories	2,215
Prepaid expenses and other receivables	256
Total current assets of discontinued operations	**5,830**
Property, plant and equipment, net	1,821
Intangible assets, net	9,836
Goodwill	9,184
Deferred taxes on income	176
Other assets	390
Total noncurrent assets of discontinued operations	**$21,407**
Liabilities	
Loans and notes payable	$15
Accounts payable	1,814
Accrued liabilities including accrued taxes on income	644
Accrued rebates, returns and promotions	838
Accrued compensation and employee related obligations	279
Total current liabilities of discontinued operations	**3,590**
Long-term debt	2
Deferred taxes on income	2,383
Employee related obligations	225
Other liabilities	291
Total noncurrent liabilities of discontinued operations	**$2,901**

22. Selected quarterly financial data (unaudited)

Selected unaudited quarterly financial data has been recast for discontinued operations for the years 2023 and 2022 and is summarized below:

	2023				2022			
(Dollars in Millions Except Per Share Data)	First Quarter[1]	Second Quarter	Third Quarter[2]	Fourth Quarter[3]	First Quarter[4]	Second Quarter	Third Quarter	Fourth Quarter[5]
Segment sales to customers								
Innovative Medicine	$13,413	13,731	13,893	13,722	12,869	13,317	13,214	13,163
MedTech	7,481	7,788	7,458	7,673	6,971	6,898	6,782	6,776
Total sales	20,894	21,519	21,351	21,395	19,840	20,215	19,996	19,939
Gross profit	14,207	15,057	14,745	14,597	13,822	13,893	13,824	13,855
Earnings (Loss) before provision for taxes on income	(1,287)	6,306	5,217	4,826	5,203	5,144	5,172	3,840
Net earnings (loss) from continuing operations	(491)	5,376	4,309	4,132	4,571	4,262	4,310	3,227
Net earnings (loss) from discontinued operations, net of tax	423	(232)	21,719	(83)	578	552	148	293
Net earnings (loss)	(68)	5,144	26,028	4,049	5,149	4,814	4,458	3,520
Basic net earnings(loss) per share:								
Basic net earnings (loss) per share from continuing operations	(0.19)	2.07	1.71	1.71	1.74	1.62	1.64	1.24
Basic net earnings (loss) per share from discontinued operations	0.16	(0.09)	8.61	(0.03)	0.22	0.21	0.06	0.11
Basic net earnings (loss) per share	(0.03)	1.98	10.32	1.68	1.96	1.83	1.70	1.35
Diluted net earnings (loss) per share:								
Diluted net earnings (loss) per share from continuing operations	(0.19)	2.05	1.69	1.70	1.71	1.60	1.62	1.22
Diluted net earnings (loss) per share from discontinued operations	0.16	(0.09)	8.52	(0.03)	0.22	0.20	0.06	0.11
Diluted net earnings (loss) per share	(0.03)	1.96	10.21	1.67	1.93	1.80	1.68	1.33

(1) The fiscal first quarter of 2023 includes a $6.9 billion charge related to talc matters.

(2) The fiscal third quarter of 2023 includes; a non-cash gain on the exchange offer of $21.0 billion that was recorded in Net earnings from discontinued operations, net of taxes; $0.6 billion related to the unfavorable change in the fair value of the retained stake in Kenvue and $0.4 billion related to the partial impairment of Idorsia convertible debt and the change in the fair value of the Idorsia equity securities held.

(3) The fourth quarter of 2023 includes favorable changes in the fair value of securities of $0.4 billion

(4) In the fiscal first quarter of 2022, the Company recorded an intangible asset impairment charge of approximately $0.6 billion related to an in-process research and development asset, bermekimab (JnJ-77474462).

(5) The fiscal fourth quarter of 2022 includes one-time COVID-19 Vaccine related exit costs of $0.8 billion.

Report of independent registered public accounting firm

To the Board of Directors and Shareholders of Johnson & Johnson

Opinions on the financial statements and internal control over financial reporting

We have audited the accompanying consolidated balance sheets of Johnson & Johnson and its subsidiaries (the "Company") as of December 31, 2023 and January 1, 2023, and the related consolidated statements of earnings, of comprehensive income, of equity and of cash flows for each of the three fiscal years in the period ended December 31, 2023, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and January 1, 2023, and the results of its operations and its cash flows for each of the three fiscal years in the period ended December 31, 2023 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Basis for opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and limitations of internal control over financial reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical audit matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

U.S. pharmaceutical rebate reserves – managed care, medicare and medicaid

As described in Note 1 to the consolidated financial statements, the Company recognizes revenue from product sales when obligations under the terms of a contract with the customer are satisfied. Rebates and discounts provided to customers are accounted for as variable consideration and recorded as a reduction in sales. The liability for such rebates and discounts is recognized within Accrued Rebates, Returns, and Promotions on the consolidated balance sheet. A significant portion of the liability related to rebates is from the sale of pharmaceutical goods within the U.S., primarily the Managed Care, Medicare and Medicaid programs, which amounted to $11.5 billion as of December 31, 2023. For significant rebate programs, which include the U.S. Managed Care, Medicare and Medicaid rebate programs, rebates and discounts estimated by management are based on contractual terms, historical experience, patient outcomes, trend analysis, and projected market conditions in the U.S. pharmaceutical market.

The principal considerations for our determination that performing procedures relating to U.S. pharmaceutical rebate reserves - Managed Care, Medicare and Medicaid is a critical audit matter are the significant judgment by management due to the significant measurement uncertainty involved in developing these reserves and the high degree of auditor judgment, subjectivity and audit effort in performing procedures and evaluating the assumptions related to contractual terms, historical experience, patient outcomes, trend analysis, and projected market conditions in the U.S. pharmaceutical market.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to U.S. pharmaceutical rebate reserves - Managed Care, Medicare and Medicaid, including controls over the assumptions used to estimate these rebates. These procedures also included, among others, (i) developing an independent estimate of the rebates by utilizing third party information on price and market conditions in the U.S. pharmaceutical market, the terms of the specific rebate programs, and the historical experience and trend analysis of actual rebate claims paid; (ii) testing rebate claims processed by the Company, including evaluating those claims for consistency with the contractual and mandated terms of the Company's rebate arrangements; and (iii) comparing the independent estimates to management's estimates.

Litigation contingencies – talc

As described in Notes 1 and 19 to the consolidated financial statements, the Company records accruals for loss contingencies associated with legal matters, including talc, when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. To the extent adverse awards, judgments, or verdicts have been rendered against the Company, management does not record an accrual until a loss is determined to be probable and can be reasonably estimated. For these matters, management is unable to estimate the possible loss or range of loss beyond the amounts accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors, including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; ability to achieve comprehensive multi-party settlements; complexity of related cross-claims and counterclaims; and/or there are numerous parties involved. Management continues to believe that the Company has strong legal grounds to contest the talc verdicts it has appealed. Notwithstanding management's confidence in the safety of the Company's talc products, in certain circumstances the Company has settled cases. The Company has recognized a total provision of approximately $9 billion, of which approximately one-third is recorded as a current liability and which encompasses actual and contemplated settlements. The recorded amount remains the Company's best estimate of probable loss after the dismissal. The parties have not yet reached a full resolution of all talc matters and the Company is unable to estimate the possible loss or range of loss beyond the remaining amount accrued.

The principal considerations for our determination that performing procedures relating to the talc litigation is a critical audit matter are the significant judgment by management when assessing the likelihood of a loss being incurred, when determining whether a reasonable estimate of the loss or range of loss for the future and existing talc claims can be made, and when determining the timing of any settlement payments, which in turn led to a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating management's assessment of the loss contingencies associated with this litigation.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's evaluation of the talc litigation, including controls over determining whether a loss is probable and whether the amount of loss can be reasonably estimated, as well as financial statement disclosures. These procedures also included, among others, (i) gaining an understanding of the Company's process around the accounting and reporting for the talc litigation; (ii) obtaining and evaluating certain executed settlement agreements related to the talc litigation (iii) discussing the status of significant known actual and potential litigation and settlements activity with the Company's in-house legal counsel, as well as external counsel when deemed necessary; (iv) obtaining and evaluating the letters of audit inquiry with internal and external legal counsel for significant litigation; (v) evaluating the reasonableness of management's assessment regarding whether an unfavorable outcome is reasonably possible or probable and reasonably estimable; and (vi) evaluating the sufficiency of the Company's litigation contingencies disclosures.

/s/ **PricewaterhouseCoopers LLP**
Florham Park, New Jersey
February 16, 2024

We have served as the Company's auditor since at least 1920. We have not been able to determine the specific year we began serving as auditor of the Company.

Management's report on internal control over financial reporting

Under Section 404 of the Sarbanes-Oxley Act of 2002, management is required to assess the effectiveness of the Company's internal control over financial reporting as of the end of each fiscal year and report, based on that assessment, whether the Company's internal control over financial reporting is effective.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is designed to provide reasonable assurance as to the reliability of the Company's financial reporting and the preparation of external financial statements in accordance with generally accepted accounting principles.

Internal controls over financial reporting, no matter how well designed, have inherent limitations. Therefore, internal control over financial reporting determined to be effective can provide only reasonable assurance with respect to financial statement preparation and may not prevent or detect all misstatements. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management has assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2023. In making this assessment, the Company used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework (2013)." These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. The Company's assessment included extensive documenting, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

Based on the Company's processes and assessment, as described above, management has concluded that, as of December 31, 2023, the Company's internal control over financial reporting was effective.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2023 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which appears herein.

/s/ **J. Duato**
Joaquin Duato
Chairman, Board of Directors
Chief Executive Officer

/s/ **J. J. Wolk**
Joseph J. Wolk
Executive Vice President, Chief Financial Officer

Shareholder return performance graphs

Set forth below are line graphs comparing the cumulative total shareholder return on the Company's Common Stock for periods of five years and ten years ending December 31, 2023, against the cumulative total return of the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Healthcare Equipment Index. The graphs and tables assume that $100 was invested on December 31, 2018 and December 31, 2013 in each of the Company's Common Stock, the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Healthcare Equipment Index and that all dividends were reinvested.

5 Year Shareholder Return Performance J&J vs. Indices

5-year CAGR	
J&J	6.8 %
S&P 500	15.7 %
S&P Pharm	11.1 %
S&P H/C Equip	9.9 %

	2018	2019	2020	2021	2022	2023
Johnson & Johnson	$100.00	$116.21	$128.82	$143.57	$152.14	$139.05
S&P 500 Index	$100.00	$131.47	$155.65	$200.29	$163.98	$207.04
S&P Pharmaceutical Index	$100.00	$115.09	$123.75	$155.62	$168.77	$169.33
S&P Healthcare Equipment Index	$100.00	$129.32	$152.12	$181.56	$147.32	$160.64

10 Year Shareholder Return Performance J&J vs. Indices

10-year CAGR	
J&J	8.4 %
S&P 500	12.0 %
S&P Pharm	10.1 %
S&P H/C Equip	13.3 %

	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Johnson & Johnson	$100.00	$117.34	$118.69	$136.88	$170.29	$161.54	$187.73	$208.10	$231.92	$245.76	$224.62
S&P 500 Index	$100.00	$113.67	$115.23	$129.00	$157.15	$150.24	$197.53	$233.85	$300.91	$246.37	$311.06
S&P Pharmaceutical Index	$100.00	$122.22	$129.29	$127.27	$143.27	$154.86	$178.23	$191.64	$240.99	$261.37	$262.23
S&P Healthcare Equipment Index	$100.00	$126.28	$133.82	$142.50	$186.53	$216.82	$280.39	$329.83	$393.66	$319.42	$348.30

Item 9. Changes in and disagreements with accountants on accounting and financial disclosure

Not applicable.

Item 9A. Controls and procedures

Disclosure controls and procedures. At the end of the period covered by this Report, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Joaquin Duato, Chairman and Chief Executive Officer, and Joseph J. Wolk, Executive Vice President, Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Duato and Wolk concluded that, as of the end of the period covered by this Report, the Company's disclosure controls and procedures were effective.

Reports on internal control over financial reporting. The information called for by this item is incorporated herein by reference to Management's report on internal control over financial reporting, and the attestation regarding internal controls over financial reporting included in the report of independent registered public accounting firm included in Item 8 of this Report.

Changes in internal control over financial reporting. During the fiscal quarter ended December 31, 2023, there were no changes in the Company's internal control over financial reporting identified in connection with the evaluation required under Rules 13a-15 and 15d-15 under the Exchange Act that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting. The Company continues to monitor and assess the effectiveness of the design and operation of its disclosure controls and procedures.

The Company is implementing a multi-year, enterprise-wide initiative to integrate, simplify and standardize processes and systems for the human resources, information technology, procurement, supply chain and finance functions. These are enhancements to support the growth of the Company's financial shared service capabilities and standardize financial systems. This initiative is not in response to any identified deficiency or weakness in the Company's internal control over financial reporting. In response to this initiative, the Company has and will continue to align and streamline the design and operation of its financial control environment.

Item 9B. Other information

Securities trading plans of Directors and Executive Officers. During the fiscal fourth quarter of 2023, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) informed us of the adoption or termination of a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," each as defined in Item 408 of Regulation S-K.

Item 9C. Disclosure regarding foreign jurisdictions that prevent inspections

Not applicable.

Part III

Item 10. Directors, executive officers and corporate governance

The information called for by this item is incorporated herein by reference to the discussion of the Audit Committee under the caption Item 1. Election of Directors - Board committees; and the material under the captions Item 1. Election of Directors and, if applicable, Delinquent Section 16(a) reporting in the Proxy Statement; and the material under the caption "Executive Officers of the Registrant" in Part I of this Report.

The Company's Code of Business Conduct, which covers all employees (including the Chief Executive Officer, Chief Financial Officer and Controller), meets the requirements of the SEC rules promulgated under Section 406 of the Sarbanes-Oxley Act of 2002. The Code of Business Conduct is available on the Company's website at www.jnj.com/code-of-business-conduct, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code of Business Conduct or any waiver of the Code granted to the Chief Executive Officer, the Chief Financial Officer or the Controller will be posted on the Company's website at www.jnj.com/code-of-business-conduct within five business days (and retained on the website for at least one year).

In addition, the Company has adopted a Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers. The Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers is available on the Company's website at www.investor.jnj.com/governance/corporate-governance-overview/code-of-business-conduct--ethics, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code or any waiver of the Code granted to any member of the Board of Directors or any executive officer will be posted on the Company's website at www.investor.jnj.com/governance/corporate-governance-overview/code-of-business-conduct--ethics within five business days (and retained on the website for at least one year).

Item 11. Executive compensation

The information called for by this item is incorporated herein by reference to the material under the captions Item 1. Election of Directors – Director compensation, and Item 2. Compensation Committee report, Compensation discussion and analysis and Executive compensation tables in the Proxy Statement.

The material incorporated herein by reference to the material under the caption Compensation Committee report in the Proxy Statement shall be deemed furnished, and not filed, in this Report and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, as a result of this furnishing, except to the extent that the Company specifically incorporates it by reference.

Item 12. Security ownership of certain beneficial owners and management and related stockholder matters

The information called for by this item is incorporated herein by reference to the material under the caption Item 1. Stock ownership in the Proxy Statement; and Note 16 Common stock, stock option plans and stock compensation agreements of the Notes to Consolidated Financial Statements in Item 8 of this Report.

Equity compensation plan information

The following table provides certain information as of December 31, 2023 concerning the shares of the Company's Common Stock that may be issued under existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights	Weighted Average Exercise Price of Outstanding Options and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans[2][3]
Equity Compensation Plans Approved by Security Holders[1]	127,211,785	$123.41	130,112,007
Equity Compensation Plans Not Approved by Security Holders	—	—	—
Total	**127,211,785**	**$123.41**	**130,112,007**

(1) Included in this category are the following equity compensation plans which have been approved by the Company's shareholders: 2012 Long-Term Incentive Plan and 2022 Long-Term Incentive Plan.

(2) This column excludes shares reflected under the column "Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights."

(3) The 2012 Long-Term Incentive Plan expired April 26, 2022. All options and restricted shares granted subsequent to that date were under the 2022 Long-Term Incentive Plan.

Item 13. Certain relationships and related transactions, and director independence

The information called for by this item is incorporated herein by reference to the material under the captions Item 1. Election of Directors - Related person transactions & Director independence in the Proxy Statement.

Item 14. Principal accountant fees and services

The information called for by this item is incorporated herein by reference to the material under the caption Item 3. Ratification of appointment of independent registered public accounting firm in the Proxy Statement.

Part IV

Item 15. Exhibits and financial statement schedules

The following documents are filed as part of this report:

1. *Financial Statements*

   Consolidated balance sheets at end of fiscal years 2023 and 2022

   Consolidated statements of earnings for fiscal years 2023, 2022 and 2021

   Consolidated statements of comprehensive income for Fiscal Years 2023, 2022 and 2021

   Consolidated statements of equity for fiscal years 2023, 2022 and 2021

   Consolidated statements of cash flows for fiscal years 2023, 2022 and 2021

   Notes to Consolidated Financial Statements

   Report of independent registered public accounting firm

All schedules are omitted because they are not applicable or the required information is included in the financial statements or notes.

2. *Exhibits required to be filed by item 601 of regulation S-K*

   The information called for by this item is incorporated herein by reference to the Exhibit Index in this Report.

Item 16. Form 10-K summary

Registrants may voluntarily include a summary of information required by Form 10-K under this Item 16. The Company has elected not to include such summary information.

Signatures

Pursuant to the requirements of Section 13 of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 16, 2024

JOHNSON & JOHNSON
(Registrant)

By /s/ **J. Duato**
J. Duato, Chairman of the Board
and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ **J. Duato** **J. Duato**	Chairman of the Board Chief Executive Officer (Principal Executive Officer)	February 16, 2024
/s/ **J. J. Wolk** **J. J. Wolk**	Chief Financial Officer (Principal Financial Officer)	February 16, 2024
/s/ **R. J. Decker Jr.** **R. J. Decker Jr.**	Controller and Chief Accounting Officer (Principal Accounting Officer)	February 16, 2024
/s/ **D. Adamczyk** **D. Adamczyk**	Director	February 16, 2024
/s/ **M. C. Beckerle** **M. C. Beckerle**	Director	February 16, 2024
/s/ **D. S. Davis** **D. S. Davis**	Director	February 16, 2024
/s/ **J. A. Doudna** **J. A. Doudna**	Director	February 16, 2024

Signature	Title	Date
/s/ M. A. Hewson M. A. Hewson	Director	February 16, 2024
/s/ P. A. Johnson P. A. Johnson	Director	February 16, 2024
/s/ H. Joly H. Joly	Director	February 16, 2024
/s/ M. B. McClellan M. B. McClellan	Director	February 16, 2024
/s/ A. M. Mulcahy A. M. Mulcahy	Director	February 16, 2024
/s/ M. A. Weinberger M. A. Weinberger	Director	February 16, 2024
/s/ N. Y. West N. Y. West	Director	February 16, 2024
/s/ E. A. Woods E. A. Woods	Director	February 16, 2024

Exhibit index

Reg. S-K Exhibit Table Item No.	Description of Exhibit
2(i)	Agreement and Plan of Merger, dated as of October 31, 2022, by and among Johnson & Johnson, Athos Merger Sub, Inc. and ABIOMED, Inc. – Incorporated herein by reference to Exhibit 2.1 of the Registrant's Form 8-K Current Report filed November 1, 2022.†
3(i)	Restated Certificate of Incorporation effective February 19, 2016 — Incorporated herein by reference to Exhibit 3(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.
3(ii)	Certificate of Amendment to the Certificate of Incorporation of Johnson & Johnson effective April 30, 2020 — Incorporated herein by reference to Exhibit 3.1 of the Registrant's Form 8-K Current Report filed April 29, 2020.
3(iii)	By-Laws of the Company, as amended effective June 9, 2020 — Incorporated herein by reference to Exhibit 3.1 of the Registrant's Form 8-K Current Report filed June 10, 2020.
4(a)	Upon the request of the Securities and Exchange Commission, the Registrant will furnish a copy of all instruments defining the rights of holders of long-term debt of the Registrant.
4(b)	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 — Incorporated herein by reference to Exhibit 4.1 of the Registrant's Form 8-K Current Report filed August 12, 2020.
10(a)	2012 Long-Term Incentive Plan — Incorporated herein by reference to Appendix A of the Registrant's Proxy Statement filed on March 15, 2012.*
10(b)	Form of Stock Option Certificate under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.2 of the Registrant's Form 10-Q Quarterly Report for the quarter ended April 1, 2012.*
10(c)	Form of Restricted Share Unit Certificate under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.3 of the Registrant's Form 10-Q Quarterly Report for the quarter ended April 1, 2012.*
10(d)	Form of Performance Share Unit Certificate under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.4 of the Registrant's Form 10-Q Quarterly Report for the quarter ended April 1, 2012.*
10(e)	Global NonQualified Stock Option Award Agreement under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended April 1, 2018.*
10(f)	Global Restricted Share Unit Award Agreement under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.2 of the Registrant's Form 10-Q Quarterly Report for the quarter ended April 1, 2018.*
10(g)	Global Performance Share Unit Award Agreement under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.3 of the Registrant's Form 10-Q Quarterly Report for the quarter ended April 1, 2018.*
10(h)	Global Restricted Share Unit Award Agreement granted to John Reed on May 1, 2023 under the 2022 Long-Term Incentive Plan — Filed with this document.*
10(i)	Domestic Deferred Compensation (Certificate of Extra Compensation) Plan — Incorporated herein by reference to Exhibit 10(g) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2003.*
10(j)	Amendments to the Certificate of Extra Compensation Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(k)	2009 Certificates of Long-Term Performance Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 27, 2009.*
10(l)	Amended and Restated Deferred Fee Plan for Directors (Amended as of January 17, 2012) — Incorporated herein by reference to Exhibit 10(k) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 1, 2012.*

Reg. S-K Exhibit Table Item No.	Description of Exhibit
10(m)	The Johnson & Johnson Executive Income Deferral Plan Amended and Restated Effective January 1, 2010 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*
10(n)	The Johnson & Johnson Excess Savings Plan (amended and restated as of January 1, 2022) — Incorporated herein by reference to Exhibit 10(l) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 1, 2023.*
10(o)	Excess Benefit Plan of Johnson & Johnson and Affiliated Companies (amended and restated as of January 1, 2020) — incorporated by reference to Exhibit 10(n) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2021.*
10(p)**	Executive Life Plan Agreement — Incorporated herein by reference to Exhibit 10(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 1993.*
10(q)	Executive Life Plan Agreement Closure Letter — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended March 29, 2015.*
10(r)	2022 Long-Term Incentive Plan — Incorporated by reference to Appendix A of the Registrant's Proxy Statement filed on March 16, 2022.*
10(s)	Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies, Amended and Restated as of October 1, 2014 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 28, 2014.*
10(t)	First Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended June 28, 2015.*
10(u)	Second Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10(x) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.*
10(v)	Contingent Value Rights Agreement, dated as of December 22, 2022, by and between Johnson & Johnson and American Stock Transfer & Trust Company, LLC – Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 8-K Current Report filed December 22, 2022.†
10(w)	Separation Agreement, dated as of May 3, 2023, by and between Johnson & Johnson and Kenvue Inc.
10(x)	Tax Matters Agreement, dated as of May 3, 2023, by and between Johnson & Johnson and Kenvue Inc.
10(y)	Employee Matters Agreement, dated as of May 3, 2023, by and between Johnson & Johnson and Kenvue Inc.
10(z)	Intellectual Property Agreement, dated as of May 3, 2023, by and between Johnson & Johnson and Kenvue Inc.
10(aa)	Trademark Phase-Out License Agreement, dated as of April 3, 2023, by and between Johnson & Johnson and Johnson & Johnson Consumer Inc.
10(ab)	Transition Services Agreement, dated as of May 3, 2023, by and between Johnson & Johnson and Kenvue Inc.
10(ac)	Transition Manufacturing Agreement, dated as of May 3, 2023, by and between Johnson & Johnson and Kenvue Inc.
10(ad)	Registration Rights Agreement, dated as of May 3, 2023, by and between Johnson & Johnson and Kenvue Inc.
10(ae)	Johnson & Johnson Deferred Compensation Plan*
10(af)	Global Performance Share Unit Award Agreement*

Reg. S-K Exhibit Table Item No.	Description of Exhibit
10(ag)	Global Restricted Share Unit Award Agreement*
10(ah)	Global Nonqualified Stock Option Award Agreement*
10(ai)	Amendment One to the Johnson & Johnson Excess Savings Plan (amended and restated effective as of January 1, 2022) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended October 1, 2023.*
10(aj)	Johnson & Johnson Executive Incentive Plan (Amended as of September 7, 2023) — Incorporated herein by reference to Exhibit 10.2 of the Registrant's Form 10-Q Quarterly Report for the quarter ended October 1, 2023.*
19	Johnson & Johnson Stock Trading Policy for Directors, Executive Officers and Insiders (Amended as of April 27, 2023) — Filed with this document.
21	Subsidiaries — Filed with this document.
23	Consent of Independent Registered Public Accounting Firm — Filed with this document.
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
32.1	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
32.2	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
97	Johnson & Johnson Clawback Policy (effective as of August 8, 2023) — Filed with this document.
Exhibit 101:	
EX-101.INS	Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
EX-101.SCH	Inline XBRL Taxonomy Extension Schema
EX-101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
EX-101.LAB	Inline XBRL Taxonomy Extension Label Linkbase
EX-101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
EX-101.DEF	Inline XBRL Taxonomy Extension Definition Document
Exhibit 104:	Cover Page Interactive Data File—the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

* Management contract or compensatory plan.

** Paper filing.

† Certain exhibits and schedules have been omitted pursuant to Item 601(b)(2)(ii) or 601(b)(10)(iv) of Regulation S-K, as applicable.

A copy of any of the Exhibits listed above will be provided without charge to any shareholder submitting a written request specifying the desired exhibit(s) to the Secretary at the principal executive offices of the Company. Pursuant to Item 601(b)(4)(iii)(A) of Regulation S-K, the Company has not filed as exhibits to this Form 10-K certain long-term debt instruments, including indentures, under which the total amount of securities authorized does not exceed 10% of the total assets of the Company and its subsidiaries on a consolidated basis. The Company hereby agrees to furnish a copy of any such instrument to the SEC upon request.

Exhibit 10(h)

JOHNSON & JOHNSON
2022 LONG-TERM INCENTIVE PLAN

GLOBAL RESTRICTED SHARE UNIT AWARD AGREEMENT

Granted To: John Christian Reed

WWID #:	Total Units: **75,765**
Grant Date: **05/01/2023**	Scheduled Vesting Date(s): the date(s) set forth in the table below (each, a "Scheduled Vesting Date")

Grant No.	Grant Type	No. of Units	Scheduled Vesting Date
REED050123	Restricted Share Units	25,255	05/01/2024
REED050123	Restricted Share Units	25,255	05/01/2025
REED050123	Restricted Share Units	25,255	05/01/2026

In addition to such other conditions as may be established by the Committee in its sole discretion, in consideration of the granting of an award under the terms of the Johnson & Johnson 2022 Long-Term Incentive Plan, as amended from time to time (the "Plan"), you agree as follows:

1. Grant of Restricted Share Units.

a. *Award.* Subject to the terms and conditions of this Global Restricted Share Unit Award Agreement, including any country-specific terms in Appendix A hereto and any other exhibits or addendums to these documents (collectively, this "Agreement") and the Plan, Johnson & Johnson, a New Jersey corporation (the "Corporation"), hereby grants you the above-stated number of Restricted Share Units ("RSUs"), which will become vested subject to the terms and conditions of this Agreement. Upon vesting of each RSU, you will receive one share of Common Stock of the Corporation, par value $1.00 per share ("Common Stock"), or cash in lieu thereof, in either case subject to and in accordance with the terms of Section 4 of this Agreement. Except where the context clearly indicates otherwise, each capitalized term used herein shall have the definition assigned to it by this Agreement or, to the extent that this Agreement does not define a capitalized term used herein, by the Plan. The RSUs granted herein are subject to all of the terms and conditions of the Plan, and the terms of the Plan are hereby incorporated herein by reference.

b. *Conditions*. This grant of RSUs is conditioned on your (i) electronically accepting this grant on the website of the Plan recordkeeper (or in such other manner as the Corporation may establish or permit from time to time) and (ii) opening and maintaining a brokerage account that is permitted for use with respect to awards granted under the Plan, in each case by the deadline established by the Corporation and/or set forth on the website of the Plan recordkeeper. By accepting this grant of RSUs, you will have confirmed your acceptance of all

of the terms and conditions of this Agreement. **If you do not accept this grant of RSUs by the applicable deadline, your grant will be cancelled.**

2. Vesting of RSUs; Competition with the Corporation Group.

a. *General*. Except as otherwise provided in this Section 2, the RSUs granted herein shall become vested on the above-stated Scheduled Vesting Dates in accordance with the schedule set forth above, provided, that, with respect to each RSU, (i) you are Employed on the applicable Scheduled Vesting Date and have been Employed at all times since the Grant Date and (ii) you have complied with and are in compliance with the terms of this Agreement, as determined by the Corporation in its sole discretion.

b. *Termination of Employment - General.* If, prior to the applicable Scheduled Vesting Date, you cease to be Employed for any reason, then except as otherwise provided in Section 2(c) (Certain Terminations; Disability), the RSUs shall be forfeited for no consideration on the Date of Termination.

c. *Certain Terminations; Disability*

i. .*Termination of Employment due to Death*. If you die while Employed, then the RSUs shall immediately become vested in full as of your date of death (to the extent still outstanding and not already vested), and your estate, beneficiary or any person who acquires the RSUs by inheritance or devise, as applicable, shall receive a number of shares of Common Stock (or cash in lieu thereof), as provided in Section 4 (Settlement of RSUs; Tax Withholding; Compliance With Securities Laws; Compliance with Compensation Recoupment Policy).

ii. *Disability*. If you become Disabled while Employed, you shall immediately become vested in full in the RSUs (to the extent still outstanding and not already vested) on the date of Disability.

iii. *Termination for Cause*. Without limiting the generality of Section 2(b), and notwithstanding any other provision of this Section 2(c), if you cease to be Employed for any reason (including, without limitation, as a result of your voluntary resignation) in connection with or following the occurrence of an event that constitutes Cause, then the RSUs and any other awards that you hold under the Plan shall immediately be forfeited for no consideration as of the Date of Termination. If following your Date of Termination, the Corporation becomes aware of conduct or activity by you that occurred during or following your Employment that would have constituted Cause, then any RSUs (or portions thereof) or any other awards held by you under the Plan that are unvested or unexercised (and any payments or benefits in respect thereto) as of the date that the Corporation becomes aware of such conduct or activity shall be forfeited.

iv. *Corporation Determinations*. In the event of your termination of Employment, the determination of the reason for such termination and the applicable treatment under this Section 2 shall be made by the Corporation in its sole discretion.

d. *Competition With the Corporation Group*. In order to protect the Corporation Group's goodwill and investments in research and development and Customer and business

relationships and to prevent the disclosure of the Corporation Group's confidential and trade secret information, thereby promoting the long-term success of the Corporation Group's business, you agree to the following:

i. During your Employment, you will not, without the prior written consent of the Corporation, directly or indirectly engage in Competitive Activities.

ii. For a period of eighteen (18) months following your Date of Termination, you will not, without the prior written consent of the Corporation, directly or indirectly perform, or assist others to perform, work for a Competitor in a position or in any geographic location in which you could disadvantage the Corporation Group or advantage the Competitor through (a) your disclosure or use of the Corporation Group's confidential or trade secret information and/or (b) your use of the Corporation Group's Customer relationships and goodwill.

iii. *Rescission and Forfeiture*. You understand and agree that if the Corporation determines you have violated Section 2(d)(i) and/or Section 2(d)(ii) and/or any non- competition or non-solicitation agreement that you have with any member of the Corporation Group, then, in addition to injunctive relief, damages, and all other equitable and legal rights and remedies:

A. the RSUs shall be forfeited for no consideration on the earliestdate on which you are first in violation o f Section 2(d)(i) and/or Section 2(d)(ii) or any non-competition or non-solicitation agreement that you have with any member of the Corporation Group; and

B. upon the Corporation's demand, you shall immediately deliver to the Corporation (I) a number of shares of Common Stock equal to the number of RSUs that vested and were settled in the form of Common Stock (for the avoidance of doubt, without reduction for any shares of Common Stock that may have been withheld and/or sold to satisfy applicable withholding taxes) and (II) the gross amount of cash paid to you (for the avoidance of doubt, without reduction for amounts withheld to satisfy applicable withholding taxes) for any RSUs that were settled in the form of cash, in each case in respect of any RSUs that vested within the twelve (12) month period of time immediately preceding the earliest date on which you are first in violation of Section 2(d)(i) and/or Section 2(d)(ii) or any non-competition or non- solicitation agreement that you have with any member of the Corporation Group. To the extent that you do not, as of the date of the Corporation's demand for repayment, hold a number of shares of Common Stock sufficient to satisfy your obligation set forth in clause (I) above, you shall pay the Corporation an amount in cash equal to the result of (x) (i) the number shares required to be delivered by you to the Corporation pursuant to clause (I) above, less (ii) the number of shares actually delivered by you to the Corporation pursuant to clause (I), multiplied by (y) the Fair Market Value per share of Common Stock as of the business day immediately preceding the date of the Corporation's demand for repayment. You agree to deliver and execute such documents (including, if applicable, share certificates) as the Corporation may deem necessary to effect the repayment obligations referred to in this Section 2(d)(iii)(B).

iv. You understand and agree that the remedies set forth in Section 2(d)(iii) shall not be the Corporation Group's exclusive remedies in the event of a breach of the non-competition obligations set forth in Section 2(d)(i) and/or Section 2(d)(ii) or in any other applicable non-competition or non-solicitation agreement that you have with any member of the

Corporation Group, and that the Corporation Group reserves all other rights and remedies available to it at law or in equity.

e. *Conditions on Vesting upon or following Termination of Employment*. Your eligibility to vest in any of the RSUs upon or following the date of your termination of Employment shall be subject to (i) your compliance with the non-competition obligations in Section 2(d)(i) and/or Section 2(d)(ii) and/or any other applicable non-competition or non-solicitation agreement with any member of the Corporation Group and (ii) if required by any member of the Corporation Group at the time of your termination of Employment, your execution of a separation agreement and/or a general release of claims in favor of the Corporation and its subsidiaries and affiliates containing such provisions and in such form as required by the Corporation Group that becomes effective prior to the latest date for settlement of the RSUs set forth in Section 4(a) (or such earlier date as the Corporation Group may require). In the event a separation agreement and/or a release of claims is required by the Corporation Group and (A) (I) the RSUs vest upon the Date of Termination or (II) the Vesting Date falls within the period that you have to provide such release of claims, and (B) the period in which the RSUs must be settled pursuant to Section 4(a) spans two calendar years, then settlement of the vested RSUs will be made in the second calendar year.

3. **Rights to Common Stock.** Prior to the delivery of shares of Common Stock to you pursuant to Section 4(a) (if applicable), you shall not have any rights in, or with respect to, any of the shares of Common Stock underlying the RSUs, including, but not limited to, any voting rights and the right to receive any dividends (or dividend equivalents) that may be paid or any distributions that may be made with respect to such Common Stock.

4. Settlement of RSUs; Tax Withholding; Compliance With Securities Laws; Compliance with Compensation Recoupment Policy.

a. *General*. Subject to the terms of this Agreement, within sixty (60) days following the Vesting Date (but in no event later than the first March 15th occurring thereafter), you will receive from the Corporation one share of Common Stock for each RSU that vested on that date, or, at the discretion of the Committee, the cash equivalent of the Fair Market Value on the Vesting Date, reduced by any whole shares of Common Stock that are withheld or sold or any cash withheld to satisfy applicable Federal, state and local income taxes, social insurance, payroll tax, fringe benefits tax, payment on account or other tax-related items related to your participation in the Plan and legally applicable or deemed applicable to you (the "Tax-Related Items") in the amount determined by the Corporation. In lieu of the foregoing, the Corporation or other applicable member of the Corporation Group may determine that withholding of Tax-Related Items shall be satisfied by any other method permitted under the Plan. Notwithstanding the foregoing, if you are a Section 16 officer of the Corporation under the Securities Exchange Act of 1934, as amended, then the Corporation will satisfy any applicable tax withholding obligations by withholding in shares of Common Stock upon the relevant taxable event (with such withholding obligations determined based on the applicable statutory withholding rates and without regard to Section 83(c)(3) of the Internal Revenue Code of 1986, as amended), unless otherwise determined by the Committee.

b. *Registration and Listing*. Notwithstanding Section 4(a) hereof, shares of Common Stock shall not be issued pursuant to this Agreement unless, on the Vesting Date, there is in effect a current registration statement or amendment thereto under the Securities Act of 1933, as

amended, covering the shares of Common Stock to be issued upon vesting of the RSUs, and such shares are authorized for listing on the New York Stock Exchange or another securities exchange as determined by the Corporation. Nothing herein shall be deemed to require the Corporation to apply for, to effect, or to obtain such registration or listing.

c. *Compensation Recoupment Policy*. You hereby acknowledge and agree that you and the RSUs, including any cash and/or shares of Common Stock that may be delivered to you pursuant to the RSUs, are subject to the Corporation's Compensation Recoupment Policy, as may be amended and/or restated from time to time, a current copy of which can be found on the Corporation's website at http://www.investor.jnj.com/gov/compensation-recoupment-policy.cfm. The terms and conditions of the Compensation Recoupment Policy hereby are incorporated by reference into this Agreement.

5. Nontransferability of RSUs. The RSUs and any rights granted hereunder may not be sold, transferred, assigned, pledged, or hypothecated in any way (whether by operation of law or otherwise), other than by will or the laws of descent and distribution or in accordance with any beneficiary designation procedures that may be established by the Corporation. Nor shall any such rights be subject to execution, attachment, or similar process, other than in accordance with the terms of the Plan. Upon any attempt to sell, transfer, assign, pledge, hypothecate, or otherwise dispose of the RSUs or of any rights granted herein contrary to the provisions of the Plan or this Agreement, or upon the levy of any attachment or similar process upon the RSUs or such rights, the RSUs and such rights shall, at the election of the Corporation, be forfeited for no consideration.

6. No Special Employment Rights; No Rights to Awards. Nothing contained in the Plan or this Agreement shall be construed or deemed by any person under any circumstances to bind any member of the Corporation Group to continue your employment for the vesting period or for any other period, to create a right to employment with the Corporation, to form or amend an employment or service contract with the Corporation or to interfere in any way with any right of a member of the Corporation Group to terminate your employment at any time. You hereby acknowledge and agree that (i) the Plan is established voluntarily by the Corporation, is discretionary in nature and may be modified, amended, or terminated by the Corporation at any time, as provided in the Plan, (ii) your participation in the Plan is voluntary and you are voluntarily accepting the grant of RSUs, (iii) the RSUs and the shares of Common Stock subject to the RSUs, and the income and value of same, do not constitute par of your normal or expected compensation or salary for any purposes, including, but not limited to, calculating any severance, resignation, termination indemnities, redundancy, dismissal, end-of-service payments, bonuses, long-service awards, pension or retirement benefits or welfare benefits or similar payments, and in no event should be considered as compensation for, or in any way relating to, past services to the Corporation Group, (iv) the RSUs and shares of Common Stock subject to the RSUs, and the income and value of same, are not intended to replace any pension rights or compensation, (v) the grant of the RSUs is exceptional, voluntary and occasional and does not create any contractual or other right to receive future grants of RSUs, or benefits in lieu of RSUs, even if RSUs have been granted in the past, (vi) unless otherwise agreed with the Corporation, the RSUs and the shares of Common Stock subject to the RSUs, and the income and value of same, are not granted as consideration, or in connection with, the service you may provide as a director of a subsidiary of the Corporation, (vii) the future value of the underlying shares of Common Stock is unknown, indeterminable and cannot be predicted with certainty, (viii) no

claim or entitlement to compensation or damages shall arise from forfeiture or recoupment of the RSU resulting from the termination of your Employment or other service relationship (regardless of the reason for such termination and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where you are employed or the terms of your employment agreement, if any), (ix) you shall seek all necessary approvals under, make all required notifications under, and comply with all laws, rules, and regulations applicable to the ownership of the RSUs and, if applicable, shares of Common Stock, including currency and exchange laws, rules, and regulations, (x) neither the Corporation nor any of its subsidiaries or affiliates shall be liable for any foreign exchange rate fluctuation between your local currency and the US dollar that may affect the value of the RSUs or of any amounts due to you pursuant to settlement of the RSUs or the subsequent sale of any shares of Common Stock acquired upon settlement, (xi) the determination of the form of any award granted under the Plan is made by the Committee in its sole discretion and (xii) the Corporation is not providing any tax, legal, or financial advice, nor is the Corporation making any recommendations regarding your participation in the Plan, or your acquisition or sale of the underlying shares of Common Stock, you should consult your own personal tax, legal and financial advisors regarding your participation in the Plan before taking any action related to the RSUs.

7. Notices. Unless the Corporation notifies you otherwise in writing, all notices, designations, and payments to be submitted to the Corporation in connection with the RSUs shall be addressed to:

Equity Compensation Resources
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
USA

8. Definitions. The following capitalized terms shall have the definitions set forth below for purposes of this Agreement:

a. "Cause" means (i) your conviction for or a plea of *nolo contendere* to the commission of a felony under federal or state law, or (ii) any act by you that, in the Corporation's opinion, constitutes fraud, embezzlement, dishonesty, disclosure of confidential information, the willful and deliberate failure to perform your employment duties in any material respect, a conflict of interest, a violation of the non-competition obligations set forth in Section 2(d)(i) of this Agreement or any other applicable non-competition, non-solicitation, or confidentiality agreement or obligation that you have with any member of the Corporation Group, a violation of any standards of conduct policies or other policies of the Corporation Group to which you are subject, or any other event that is inimical or contrary to the best interests of the Corporation Group. Any determination of "Cause" shall be made by the Corporation in its sole discretion, and its determination shall be final and binding.

b. "Committee" means the Compensation & Benefits Committee of the Board of Directors of the Corporation (or any successor committee), or any person or persons to whom the Committee has delegated authority to administer, construe or interpret the terms of the Plan, pursuant to Section 3(d) of the Plan.

c. "Competitor" means any person or entity including, but not limited to, you or anyone acting on your behalf, that is engaged or preparing to be engaged in research, development, production, manufacturing, marketing or selling of, or consulting on, any product, process, technology, machine, invention or service in existence or under development that resembles, competes with, may now or in the future compete with, can be substituted for or can be marketed as a substitute for any product, process, technology, machine, invention, or service of the Corporation Group that is in existence or that is, was, or is planned to be under development. The Corporation shall determine whether any individual or entity is a "Competitor" in its sole discretion, and its determination shall be final.

d. "Competitive Activities" means any and all activities (including preparations) which compete with, are intended to compete with, or which otherwise may adversely affect or interfere with the Corporation Group's business or advantage a Competitor whether immediately or in the future. The Corporation shall determine whether any conduct constitutes "Competitive Activities" in its sole discretion, and its determination shall be final.

e. "Corporation Group" means the Corporation and its subsidiaries and affiliates, as determined by the Corporation.

f. "Customer" means any entity, client, account, or person, including the employees, agents, or representatives of the foregoing, or any entity or person who participates, influences or has any responsibility in making purchasing decisions on behalf of such entities, clients, accounts, or persons, to whom or to which you contacted, solicited any business from, sold to, rendered any service to, were assigned to, had responsibilities for, received commissions or any compensation on, or promoted or marketed any products or services to during the eighteen (18) month period of time preceding your Date of Termination. The Corporation shall determine whether any individual or entity is a "Customer" in its sole discretion, and its determination shall be final.

g. "Date of Termination" means the date on which your Employment terminates.

h. "Disability" or "Disabled" means that you have been determined to be unable to work because of a disability (i) that lasts for a period in excess of twenty-six (26) weeks and (ii) (A) that entitles you to long-term disability benefits under the long-term disability policy of the Corporation or its applicable affiliate under which you are covered, or (B) if there is no such policy, that you have been determined to be "disabled" (or of similar status) by the Corporation (or its applicable affiliate) in accordance with applicable procedures and policies. Notwithstanding the foregoing, (I) you will not be considered to have incurred a Disability unless you are identified as "disabled" (or of similar status) in accordance with the personnel and/or human resources policies of the Corporation or its applicable affiliate, as in effect from time to time and (II) if the RSUs are subject to Section 409A (as determined by the Corporation), then you will not be considered to have incurred a Disability unless such condition also constitutes a "disability" within the meaning of Treasury Regulation Section 1.409A-3(i)(4).

i. "Employed" or "Employment" means any period of time during which you are an employee of the Corporation Group in good standing, as determined by the Corporation Group in accordance with its applicable practices, policies and records; provided, that, during such period

you are (i) in active employment status with the Corporation Group or (ii) on a Corporation Group-approved leave of absence (as determined by the Corporation Group in its sole discretion). For the avoidance of doubt, you shall not be considered to be Employed (x) for any period during which you are not considered to be an employee in good standing pursuant to the Corporation Group's practices, policies and records, (y) during any notice period or salary continuation period required by contract, practice or local law (such as a "garden leave" or similar period) or any severance period (if you are covered by a severance agreement or arrangement) or (z) for any period of leave that is not approved by the Corporation Group (as determined by the Corporation Group in its sole discretion).

j. "Grant Date" means the date on which the RSUs are granted, as identified on the first page of this Agreement.

k. "Vesting Date" means, with respect to an RSU, the earliest of (to the extent applicable): (i) the applicable Scheduled Vesting Date; or (ii) the date of death, in the event of a termination of Employment pursuant to Section 2(c)(i) (Termination Due to Death); or (iii) the date you become Disabled, in the event of a Disability described in Section 2(c)(ii) (Disability); or (x) the date the RSUs vest and become payable pursuant to any applicable provision of the Plan (provided, that, if the RSUs are subject to Section 409A (as determined by the Corporation), payment will occur on the earliest permissible date determined by the Corporation that would not result in accelerated taxation and/or tax penalties under Section 409A).

9. Miscellaneous.

a. *Amendments*. Except as provided herein, this Agreement may not be amended or otherwise modified unless evidenced in writing and signed by an authorized representative of the Corporation.

b. *Third-Party Beneficiaries*. You acknowledge and agree that all affiliates and subsidiaries of the Corporation have, or will as the result of a future acquisition, merger, assignment, or otherwise have, an interest in your Employment and your compliance with the obligations in Section 2(d) (Competition with the Corporation Group), and that those entities are each express, third-party beneficiaries of this Agreement.

c. *Binding Effect*. This Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective heirs, executors, administrators, successors and assigns.

d. *Severability*. In the event that Section 2(d) (Competition with the Corporation Group) of this Agreement is invalidated or not enforced under applicable law, this shall not affect the validity or enforceability of the remaining provisions of this Agreement or the Plan. To the extent that Section 2(d) of this Agreement is unenforceable because it is deemed overbroad, the provision shall be applied and enforced in a more limited manner to the fullest extent permissible under the applicable law. You further understand and agree that, in the event Section 2(d) of this Agreement is declared invalid, void, overbroad, or unenforceable, in whole or in part, for any reason, you shall remain bound by any non-competition, confidentiality, non-solicitation, and/or non-disclosure agreement previously entered between you and any member of the Corporation Group.

e. *Appendix A.* Notwithstanding any provisions in this Agreement, the RSUs shall be subject to any additional terms and conditions set forth in Appendix A for your country. Moreover, if you relocate to one of the countries included in Appendix A, the additional terms and conditions for such country will apply to you, to the extent the Corporation determines that the application of such terms and conditions is necessary or advisable for legal or administrative reasons. Appendix A constitutes part of this Agreement.

f. Data Privacy Consent. By accepting this grant, you hereby unconditionally consent to the collection, use and transfer, in electronic or other form, of your personal data as described in this document by and among, as applicable, your employing entity (the "Employer") and the Corporation and the Corporation Group for the exclusive purpose of implementing, administering and managing any awards issued to you under the Plan. You understand that the Corporation and your Employer may hold certain personal information about you, including, but not limited to, your name, home address, email address, telephone number, date of birth, social insurance number or other identification number, salary, nationality, job title, details of all RSUs or any other entitlement to shares of stock awarded, canceled, vested, unvested or outstanding in your favor ("Data"), for the purpose of implementing, administering and managing any grants issued to you under the Plan. You understand that Data may be transferred to any third parties, as may be selected by the Corporation, which are assisting in the implementation, administration and management of the Plan and the fulfillment of this Agreement. You understand that the recipients of the Data may be located in the United States or elsewhere, and that the recipients' country may have different data privacy laws and protections from your country. You understand that if you reside outside of the United States, you may request a list with the names and addresses of any potential recipients of the Data by contacting your local human resources representative. You authorize the recipients, which may assist the Corporation (presently or in the future) with implementing, administering and managing the Plan to receive, possess, use, retain and transfer the Data, in electronic or other form, for the purposes of implementing, administering and managing grants under the Plan and the fulfillment of this Agreement. You understand the Data will be held only as long as is necessary to implement, administer and manage grants under the Plan and this Agreement. You understand that if you reside outside of the United States, you may, at any time, view Data, request information about the storage and processing of Data, require any necessary amendments to Data or refuse or withdraw the consents herein, in any case without cost, by contacting in writing your human resources representative. Further, you understand that your consent herein is being provided on a purely voluntary basis. If you do not consent, or if you later seek to revoke your consent, your Employment status or Service will not be affected; the only consequence of refusing or withdrawing your consent is that the Corporation may not be able to grant RSUs or other equity awards to you or administer or maintain such awards. Therefore, you understand that refusing or withdrawing your consent may affect your ability to participate in the Plan. For more information on the consequences of your refusal to consent or withdrawal of consent, you understand that you may contact your local human resources representative.

g. *Entire Agreement*. This Agreement and the Plan constitute the entire agreement between the parties relating to the subject matter hereof, and any previous agreement or understanding between the parties with respect thereto is superseded by this Agreement and the Plan.

h. *Section 409A*. The intent of the parties is that payments and benefits under this Agreement comply with Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations and guidance issued thereunder ("Section 409A"), to the extent subject thereto, and accordingly, to the maximum extent permitted, this Agreement shall be interpreted and administered to be in compliance therewith. Notwithstanding anything to the contrary in the Plan or this Agreement, the Corporation reserves the right to revise this Agreement as it deems necessary or advisable, in its sole discretion and without your consent, to comply with Section 409A or to otherwise avoid imposition of any additional tax or income recognition under Section 409A prior to the actual payment of cash or shares of Common Stock pursuant to the RSUs. However, the Corporation makes no representation that the RSUs are not subject to Section 409A nor makes any undertaking to preclude Section 409A from applying to the RSUs. The Corporation shall not have any liability under the Plan or this Agreement for any taxes, penalties or interest due on amounts paid or payable pursuant to the Plan or this Agreement, including any taxes, penalties or interest imposed under Section 409A. For purposes of the Plan and this Agreement, to the extent necessary to avoid accelerated taxation and/or tax penalties under Section 409A, a termination of Employment shall not be deemed to have occurred for purposes of settlement of any portion of the RSUs unless such termination constitutes a "separation from service" within the meaning of Section 409A and, for purposes of any such provision of this Agreement, references to a "termination," "termination of Employment" or similar terms shall mean "separation from service." Each amount to be paid under this Agreement shall be construed as a separately identified payment for purposes of Section 409A. In addition, notwithstanding anything herein to the contrary, if you are deemed on the Date of Termination to be a "specified employee" within the meaning of that term under Section 409A and you are subject to U.S. federal taxation, then, to the extent the settlement of the RSUs following such termination of Employment is considered the payment of "non-qualified deferred compensation" under Section 409A payable on account of a "separation from service" that is not exempt from Section 409A, such settlement shall be delayed until the date that is the earlier of (i) the expiration of the six-month period measured from the date of such "separation from service" or (ii) the date of your death.

i. *Acknowledgement*. By electing to accept this Agreement, you acknowledge receipt of this Agreement and hereby confirm your understanding of the terms set forth in this Agreement. In the event of any conflict between the terms of the Plan and this Agreement, the terms of the Plan shall control. The Corporation may, in its sole discretion, decide to deliver any documents (including, without limitation, information required to be delivered to you pursuant to applicable securities laws) related to current or future participation in the Plan by electronic means. You hereby consent to receive such documents by electronic delivery and agree to participate in the Plan through an online or electronic system established and maintained by the Corporation or a third party designated by the Corporation.

j. *Language*. You acknowledge that you are proficient in the English language, or have consulted with an advisor who is proficient in the English language, so as to enable you to understand the provisions of this Agreement and the Plan. If you have received this Agreement or any other document related to the Plan translated into a language other than English, and the meaning of the translated version is different than the English version, the English version will control.

k. *Imposition of Other Requirements.* The Corporation reserves the right to impose other requirements on your participation in the Plan, on the RSUs and on any shares of Common Stock acquired under the Plan, to the extent the Corporation determines it is necessary or advisable in order to comply with local law or to facilitate the administration of the Plan, to make any corrections or adjustments that it deems necessary or appropriate, and to require you to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

l. *Waiver*. You acknowledge that a waiver by the Corporation of breach of any provision of this Agreement shall not operate or be construed as a waiver of any other provision of this Agreement, or of any subsequent breach by you or any other grantee.

m. *Governing Law.* This Agreement shall be governed by and construed in accordance with the laws of the State of New Jersey without giving effect to conflict of laws principles, except to the extent superseded by federal law and as set forth in this Section 9(m). Provided that you primarily resided and worked in California during and in connection with your employment with the Corporation Group and at the time that you accepted this Agreement and participation in the Plan, (i) this Agreement shall be governed by and construed in accordance with the laws of the State of California; and (ii) Section 2(d)(ii) shall not apply with respect to services you render in California that do not involve your use or disclosure of the Corporation Group's confidential or trade secret information.

n. *Submission to Jurisdiction; Waiver of Jury Trial.* Any litigation brought against a party to this Agreement shall be brought in any U.S. federal or state court located in the State of New Jersey and each of the parties submits to the exclusive jurisdiction of such courts for the purpose of any such litigation; provided, that, a final judgment in any such litigation shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other matter provided by law. Each party agrees not to assert (A) any objection which it may have to venue in U.S. federal or state court located in the State of New Jersey, (B) any claim that litigation has been brought in an inconvenient forum and (C) any claim that such court does not have jurisdiction with respect to such litigation. Each party waives any right to a trial by jury with respect to any matters arising under this Agreement or any other awards granted under the Plan.

JOHNSON & JOHNSON
By: /s/ Carolyn Hoenish
Carolyn Hoenisch Senior Finance Director
Savings Plan, Pension, Equity Compensation Operations
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
USA

APPENDIX A

COUNTRY-SPECIFIC PROVISIONS FOR PARTICIPANTS OUTSIDE OF THE U.S.

Certain capitalized terms used but not defined in this Appendix A shall have the meanings set forth in the Plan and/or the Agreement to which this Appendix A is attached.

TERMS AND CONDITIONS

This Appendix A includes additional terms and conditions that govern any RSUs granted under the Plan if, under applicable law, you are a resident of, are deemed to be a resident of or are working in one of the countries listed below. Furthermore, the additional terms and conditions that govern any RSUs granted hereunder may apply to you if you transfer Employment and/or residency to one of the countries listed below and the Corporation shall, in its discretion, determine to what extent the terms and conditions contained herein shall apply to you.

NOTIFICATIONS

This Appendix A also includes notifications relating to exchange control, securities and other issues of which you should be aware with respect to your participation in the Plan. The information is based on the exchange control, securities and other laws in effect in the respective countries as of October 2022. Such laws are often complex and change frequently. As a result, the Corporation strongly recommends that you not rely on the notifications herein as the only source of information relating to the consequences of your participation in the Plan because the information may be outdated when you vest in the RSUs and acquire shares of Common Stock under the Plan, or when you subsequently sell shares of Common Stock acquired under the Plan.

In addition, the notifications are general in nature and may not apply to your particular situation, and the Corporation is not in a position to assure you of any particular result. Accordingly, you are strongly advised to seek appropriate professional advice as to how the relevant laws in your country may apply to your situation. Finally, if you are a citizen or resident of a country other than the one in which you are currently residing and/or working or are considered a resident of another country for local law purposes, the information contained herein may not be applicable to you or you may be subject to the provisions of one or more jurisdictions.

ALL NON-U.S. JURISDICTIONS

NOTIFICATIONS

Insider Trading Restrictions/Market Abuse Laws You acknowledge that, depending on your or your broker's country of residence or where the shares of Common Stock are listed, you may be subject to insider trading restrictions and/or market abuse laws which may affect your ability to accept, acquire, sell or otherwise dispose of shares of Common Stock, rights to shares of Common Stock (*e.g.*, RSUs) or rights linked to the value of shares of Common Stock (*e.g.*, phantom awards, futures) during such times you are considered to have "inside information" regarding the Corporation as defined by the laws or regulations in your country. Local insider trading laws and regulations may prohibit the cancellation or amendment of orders you placed before you possessed inside information. Furthermore, you could be prohibited from (i) disclosing the inside information to any third party and (ii) "tipping" third parties or causing

them otherwise to buy or sell securities. Keep in mind third parties includes fellow Employees. Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under any applicable insider trading policy of the Corporation. You acknowledge that it is your responsibility to comply with any restrictions and are advised to speak to your personal advisor on this matter.

Foreign Asset/Account Reporting Your country of residence may have certain foreign asset and/or account reporting requirements which may affect your ability to acquire or hold shares of Common Stock under the Plan or cash received from participating in the Plan (including from sale proceeds arising from the sale of shares of Common Stock) in a brokerage or bank account outside of your country. You may be required to report such accounts, assets or transactions to the tax or other authorities in your country. You also may be required to repatriate sale proceeds or other funds received as a result of your participation in the Plan to your country through a designated broker or bank and/or within a certain time after receipt. You acknowledge that it is your responsibility to comply with such regulations and you understand and agree that you should consult your personal legal advisor for any details.

EUROPEAN UNION / EUROPEAN ECONOMIC AREA COUNTRIES, SWITZERLAND AND THE UNITED KINGDOM

TERMS AND CONDITIONS

Data Privacy. The following provision replaces Section 9(f) (Data Privacy Consent) of the Agreement in its entirety:

The Corporation, with its principal executive offices at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, USA is the controller responsible for the processing of your personal data by the Corporation and the third parties noted below.

a. ***Data Collection and Usage Pursuant to applicable data protection laws, you are hereby notified that the Corporation collects, processes and uses certain personal information about you for the legitimate purpose of implementing, administering and managing the Plan and generally administering awards, specifically: your name, home address, email address, date of birth, hire date, rehire date (if applicable), termination date (if applicable), employee identification number, work country, pay frequency, associated legal entity and management reporting company, any shares or directorships held in the Corporation, and details of all Awards, any entitlement to shares of Common Stock awarded, canceled, exercised, vested, or outstanding in your favor, which the Corporation receives from you or the Employer ("Personal Data"). In granting the RSUs under the Plan, the Corporation will collect, process, use, disclose and transfer (collectively, "Processing") Personal Data for purposes of implementing, administering and managing the Plan. The Corporation's legal basis for the Processing of Personal Data is the Corporation's legitimate business interests of managing the Plan, administering awards and complying with its contractual and statutory obligations, as well as the necessity of the Processing for the Corporation to perform its contractual obligations under this Agreement and the Plan. Your refusal to provide Personal Data would make it impossible for the Corporation to perform its contractual obligations and may affect your ability to participate in the Plan. As such, by***

accepting the RSUs, you voluntarily acknowledge the Processing of your Personal Data as described herein.

b. *Stock Plan Administration Service Provider The Corporation may transfer Personal Data to Fidelity Stock Plan Services, LLC ("Fidelity"), an independent service provider based, in relevant part, in the United States, which may assist the Corporation with the implementation, administration and management of the Plan. In the future, the Corporation may select a different service provider and share Personal Data with another company that serves in a similar manner. The Corporation's service provider will open an account for you to receive and trade shares of Common Stock pursuant to the RSUs. The Processing of Personal Data will take place through both electronic and non-electronic means. Personal Data will only be accessible by those individuals requiring access to it for purposes of implementing, administering and operating the Plan. When receiving your Personal Data, if applicable, Fidelity provides appropriate safeguards in accordance with the EU Standard Contractual Clauses or other appropriate cross-border transfer solutions. By participating in the Plan, you understand that the service provider will Process your Personal Data for the purposes of implementing, administering and managing your participation in the Plan.*

c. *International Data Transfers The Plan and the RSUs are administered in the United States, which means it will be necessary for Personal Data to be transferred to, and processed in the United States. When transferring your Personal Data to the United States, the Corporation provides appropriate safeguards in accordance with the EU Standard Contractual Clauses or other appropriate cross-border transfer solutions. You may request a copy of the appropriate safeguards with Fidelity or the Corporation by contacting your local human resources representative. You may also contact the data protection officer responsible for your country or region, if applicable, by emailing: emeaprivacy@its.jnj.com.*

d. *Data Retention The Corporation will use Personal Data only as long as is necessary to implement, administer and manage your participation in the Plan or as required to comply with legal or regulatory obligations, including tax and securities laws. This period may extend beyond your point of Service. When the Corporation no longer needs Personal Data related to the Plan, the Corporation will remove it from its systems. If the Corporation keeps Personal Data longer, it would be to satisfy legal or regulatory obligations and the Corporation's legal basis would be for compliance with relevant laws or regulations.Data Retention The Corporation will use Personal Data only as long as is necessary to implement, administer and manage your participation in the Plan or as required to comply with legal or regulatory obligations, including tax and securities laws. This period may extend beyond your point of Service. When the Corporation no longer needs Personal Data related to the Plan, the Corporation will remove it from its systems. If the Corporation keeps Personal Data longer, it would be to satisfy legal or regulatory obligations and the Corporation's legal basis would be for compliance with relevant laws or regulations.*

e. *Data Subject Rights To the extent provided by law, you have the right to (i) subject to certain exceptions, request access or copies of Personal Data the Corporation Processes, (ii) request rectification of incorrect Personal Data, (iii) request deletion of Personal Data, (iv) place restrictions on Processing of Personal Data, (v) lodge complaints with competent authorities in your country, and/or (vi) request a list with the names and*

addresses of any potential recipients of Personal Data. To receive clarification regarding your rights or to exercise your rights, you may contact your local human resources representative. You also have the right to object, on grounds related to a particular situation, to the Processing of Personal Data, as well as opt-out of the Plan herein, in any case without cost, by contacting your local human resources representative in writing. Your provision of Personal Data is a contractual requirement. You understand, however, that the only consequence of refusing to provide Personal Data is that the Corporation may not be able to administer the RSUs, or grant other awards or administer or maintain such awards. For more information on the consequences of the refusal to provide Personal Data, you may contact your local human resources representative in writing. You may also contact the data protection officer responsible for your country or region, if applicable, by emailing: emeaprivacy@its.jnj.com. You may also have the right to lodge a complaint with the relevant data protection supervisory authority.

ARGENTINA

TERMS AND CONDITIONS

Labor Law Policy and Acknowledgement This provision supplements Section 6 (No Special Employment Rights; No Rights to Awards) of the Agreement:

In accepting the grant of RSUs, you acknowledge and agree that the grant of RSUs is made by the Corporation (not your Employer) in its sole discretion and that the value of the RSUs or any shares of Common Stock acquired under the Plan shall not constitute salary or wages for any purpose under Argentine labor law, including, but not limited to, the calculation of (i) any labor benefits including, but not limited to, vacation pay, thirteenth salary, compensation in lieu of notice, annual bonus, disability, and leave of absence payments, etc., or (ii) any termination or severance indemnities or similar payments.

If, notwithstanding the foregoing, any benefits under the Plan are considered salary or wages for any purpose under Argentine labor law, you acknowledge and agree that such benefits shall not accrue more frequently than on the Vesting Date.

NOTIFICATIONS

Securities Law Information Neither the RSUs nor the underlying shares of Common Stock are publicly offered or listed on any stock exchange in Argentina.

AUSTRALIA

NOTIFICATIONS

Tax Information. The Plan is a plan to which Subdivision 83A-C of the Income Tax Assessment Act 1997 (Cth) (the "Act") applies (subject to the conditions in that Act).

Securities Law Information This offer to participate in the Plan is being made under Division 1A, Part 7.12 of the *Corporations Act 2001 (Cth)*. Please note that if you offer your shares of Common Stock for sale to a person or entity resident in Australia, your offer may be subject to

disclosure requirements under Australian law. You should consult with your own personal legal advisor regarding your disclosure obligations prior to making any such offer.

BELGIUM

TERMS AND CONDITIONS

Shareholding Agreement. Under current Belgian tax law, you understand that you may enter into an agreement with the Corporation to hold the shares of Common Stock for two (2) years from the date on which the shares are acquired upon vesting of your RSUs under the Plan to obtain specific tax treatment for the income received under the Plan. If you are interested in learning more information about the tax treatment of the Plan income, you should check with your personal tax advisor. You further understand that if you wish to take advantage of this specific tax treatment, you should review and execute the shareholding agreement in the form provided by the Corporation.

BRAZIL

TERMS AND CONDITIONS

Compliance with Law. By accepting the RSUs, you acknowledge that you agree to comply with applicable Brazilian laws and report and pay any and all applicable taxes associated with the receipt and vesting of the RSUs, the sale of shares of Common Stock acquired under the Plan and the payment of any dividends on such shares.

Acknowledgement of Nature of Plan and RSUs This provision supplements Section 6 (No Special Employment Rights; No Rights to Awards) of the Agreement:

In accepting this Agreement, you acknowledge that (i) you are making an investment decision, and (ii) the value of the underlying shares of Common Stock is not fixed and may increase or decrease in value over the vesting period without compensation to you.

CANADA

TERMS AND CONDITIONS

Form of Settlement - RSUs Payable Only in Common Stock Notwithstanding any discretion in the Plan or anything to the contrary in the Agreement, the RSUs do not provide any right for you, as a resident of Canada, to receive a cash payment and shall be paid in shares of Common Stock only.

Conditions on Vesting upon or following Termination of Employment. This provision replaces subsection (y) of the definition of "Employed" or "Employment" in Section 8 of the Agreement:

(y) any period that follows the date you receive written notice of termination of employment or any notice period (such as a "garden leave" or similar period), period of pay in lieu of such notice or salary continuation period requirement under local law (including, but not limited to statutory law, regulatory law and/or common law).

The following provisions will apply to you if you are a resident of Quebec:

Data Privacy Notice and Consent. This provision supplements Section 9(f) (Data Privacy Consent) of the Agreement:

If you are a resident of Quebec, you hereby authorize the Corporation and the Corporation's representative to discuss with and obtain all relevant information from all personnel (professional or not) involved in the administration and operation of the Plan. You further authorize the Corporation and your Employer within the Corporation Group to disclose and discuss your participation in the Plan with their advisors. You also authorize the Corporation and your Employer to record such information and keep it in your employee file. Finally, you acknowledge and authorize the Corporation and other parties involved in the administration of the Plan to use technology for profiling purposes and to make automated decisions that may have an impact on you or the administration of the Plan.

NOTIFICATIONS

Securities Law Information. You are permitted to sell shares of Common Stock acquired through the Plan through the designated broker appointed under the Plan, if any, provided that the resale of such shares of Common Stock takes place outside of Canada through the facilities of a stock exchange on which the shares are listed. The shares of Common Stock are currently listed on the New York Stock Exchange in the United States of America.

CHILE

NOTIFICATIONS

Securities Law Information This offer conforms to general ruling N°336 of the Chilean Commission for the Financial Market ("CMF"). The offer deals with securities not registered in the registry of securities or in the registry of foreign securities of the CMF, and therefore such securities are not subject to its oversight. The issuer is not obligated to provide public information in Chile regarding the foreign securities, since such securities are not registered with the CMF. The securities shall not be subject to public offering as long as they are not registered with the corresponding registry of securities in Chile, unless they fulfill the requirements set forth in general ruling N°336 of the CMF.

Esta oferta se acoge a la norma de carácter general N°336 de la Comision para el Mercado Financiero de Chile. La oferta versa sobre valores no inscritos en el registro de valores o en el registro de valores extranjeros que lleva la Comision para el Mercado Financiero de Chile, por lo que tales valores no están sujetos a la fiscalización de ésta. Por tratar de valores no inscritos no existe la obligación por parte del emisor de entregar en Chile información pública respecto de esos valores. Esos valores no podrán ser objeto de oferta pública mientras no sean inscritos en el registro de valores correspondiente, a menos que se cumplan las condiciones establecidas en la norma de carácter general N°336 de la Comision para el Mercado Financiero de Chile.

CHINA

The following terms apply only to individuals who are subject to exchange control restrictions in the People's Republic of China (the "PRC"), as determined by the Corporation in its sole discretion:

TERMS AND CONDITIONS

Restriction on Vesting. You will not be permitted to vest in any shares of Common Stock unless and until the necessary approvals for the Plan have been obtained from the State Administration of Foreign Exchange ("SAFE") and remain in place, as determined by the Corporation in its sole discretion. Further, the Corporation is under no obligation to issue shares of Common Stock if the Corporation has not or does not obtain SAFE approval or if any such SAFE approval subsequently becomes invalid or ceases to be in effect by the time you vest in the RSUs. The Corporation reserves the right to settle RSUs in cash.

Termination of Employment. In the event of your termination of Employment with the Corporation Group, the Corporation will require the sale of any shares of Common Stock you may then hold, or any other shares of Common Stock you may then hold which were issued to you pursuant to any award granted to you under the Plan or any predecessor plan, within six (6) months following your Date of Termination (or such other period as may be required by SAFE). You understand and agree that the Corporation is authorized to instruct its designated broker to assist with the mandatory sale of such shares of Common Stock on your behalf pursuant to this authorization, and you expressly authorize your designated broker to complete the sale of such shares. You understand and agree that the Corporation's designated broker is under no obligation to arrange for the sale of shares at any particular price. You also agree to sign any agreements, forms or consents that may be reasonably requested by the Corporation (or the Corporation's designated broker) to effectuate the sale of the shares of Common Stock (including, without limitation, as to the transfer of the proceeds and other exchange control matters noted below) and to otherwise cooperate with the Corporation with respect to such matters, provided, that, you shall not be permitted to exercise any influence over how, when or whether the sales occur. Upon the sale of the shares of Common Stock, the Corporation agrees to pay you the cash proceeds from the sale, less any brokerage fees or commissions and subject to any obligation to satisfy applicable Tax- Related Items.

Designated Broker Account. If shares issued upon the settlement of the RSUs are not immediately sold, you acknowledge that you are required to maintain the shares of Common Stock in an account with the designated broker selected by the Corporation until the shares of Common Stock are sold through such Corporation-designated broker. If the Corporation changes its designated broker, you acknowledge and agree that the Corporation may transfer any shares of Common Stock issued under the Plan to the new designated brokerage firm, if necessary for legal or administrative reasons. You agree to sign any documentation necessary to facilitate the transfer of shares of Common Stock.

Exchange Control Requirements. You understand and agree that, pursuant to local exchange control requirements, you will be required to immediately repatriate the cash proceeds from the sale of shares of Common Stock related to the RSUs (or any other award granted under the Plan or any predecessor plan) to China. You further understand that, under applicable laws, such repatriation of cash proceeds will need to be effectuated through a special exchange control

account established by the Corporation (or any affiliate or subsidiary), and you hereby consent and agree that any proceeds from the sale of shares of Common Stock will be transferred to such special account prior to being delivered to you. You understand that the Corporation may face delays in converting the proceeds to local currency due to exchange control restrictions in China. Proceeds may be paid to you in U.S. dollars or local currency at the Corporation's discretion. If the proceeds are paid to you in U.S. dollars, you will be required to set up a U.S. dollar bank account in China so that the proceeds may be deposited in this account. If the proceeds are paid to you in local currency, the Corporation is under no obligation to secure any particular currency conversion rate, and you understand that the Corporation may face delays in converting the proceeds to local currency due to exchange control restrictions in China. You agree to bear any currency fluctuation risk between the time the shares are sold and the time the sale proceeds are distributed through any such special exchange account. You further agree to comply with any other requirements that may be imposed by the Corporation in the future in order to facilitate compliance with the exchange control requirements in China.

COLOMBIA

TERMS AND CONDITIONS

The following supplements Section 6 (No Special Employment Rights; No Rights to Awards) of the Agreement:

Labor Law Policy and Acknowledgement By accepting your award of RSUs, you acknowledge that pursuant to Article 128 of the Colombia Labor Code, the Plan and related benefits do not constitute a component of "salary" for any purposes.

NOTIFICATIONS

Securities Law Information The shares of Common Stock subject to the RSUs are not and will not be registered with the Colombian registry of publicly traded securities (*Registro Nacional de Valores y Emisores*) and therefore the shares of Common Stock may not be offered to the public in Colombia. Nothing in this document should be construed as the making of a public offer of securities in Colombia.

DENMARK

TERMS AND CONDITIONS

Danish Stock Option Act You acknowledge that you have received an Employer Statement translated into Danish, which is being provided to comply with the Danish Stock Option Act, as amended January 1, 2019.

FRANCE

TERMS AND CONDITIONS

Qualified Tax Treatment. Your RSUs may have been granted pursuant to an Addendum for Participants in France for Qualified Share Units and Qualified Performance Share Units (the "French Sub-Plan for RSUs"). The French Sub-Plan for RSUs modifies the terms of the Plan and this Agreement, and in the event of any conflict between the terms and conditions of the French Sub-Plan for RSUs and the Plan or this Agreement, the French Sub-Plan for RSUs shall prevail for any grants made thereunder.

The Corporation does not make any undertaking or representation to maintain the qualified status of these RSUs or of the underlying shares of Common Stock.

Conditions on Vesting and Settlement: If you have been granted RSUs pursuant to the French Sub-Plan for RSUs, irrespective of the provisions of the Agreement and except in the case of death or Disability (as defined in the French Sub-Plan for RSUs), no RSUs subject to the Agreement shall vest prior to the date that is one (1) year after the Grant Date and no shares of Common Stock shall be issued in settlement of any vested RSUs prior to the date that is two (2) years after the Grant Date.

Minimum Holding Period. If you have been granted RSUs pursuant to the French Sub-Plan for RSUs and you are issued shares of Common Stock pursuant to the Agreement prior to the two (2) year anniversary of the Grant Date, then you must hold such shares of Common Stock for a minimum period of two (2) years from the Grant Date. For the avoidance of doubt, the two-year holding period will not be applicable for any shares of Common Stock vested on or following the two (2) year anniversary of the Grant Date.

Sale Restriction During Closed Period You acknowledge that the shares of Common Stock issued and delivered in settlement of the RSUs may not be sold, transferred, or otherwise disposed of during the periods set forth in Section 7.5 of the French Sub-Plan for RSUs. You acknowledge and agree that you are personally responsible for complying with these specific restrictions.

Termination of Employment due to Death: Notwithstanding anything to the contrary provided in the Section 2(c)(i) of this Agreement, if you have been granted RSUs under the French Sub-Plan for RSUs, upon the Corporation's receipt within six months following your death of a written request from your heirs in a form satisfactory to the Corporation, the Corporation shall transfer the shares underlying any unvested RSUs to your heirs. In this case, shares shall cease immediately to be subject to the above-mentioned Minimum Holding Period.

Termination of Employment due to Disability: If, prior to the Vesting Date, you become Disabled while employed under the definition of Section 2.3 of the French Sub-Plan for RSUs, you shall immediately become vested in the RSUs on the date of the Disability. In this case, shares shall cease immediately to be subject to the above-mentioned Minimum Holding Period.

Language Consent. By accepting the grant, you confirm having read and understood the Plan and Agreement which were provided in the English language. You accept the terms of these documents accordingly.

En acceptant l'attribution, vous confirmez avoir lu et compris le Plan et le Contrat, qui ont été communiqués en langue anglaise. Vous acceptez les termes de ces documents en connaissance de cause.

NOTIFICATIONS

Exchange Control Information You must report to the French Customs and Excise Authorities the value of any cash or securities that you transfer into or out of France without the use of a financial institution when the value of such cash or securities equals or exceeds a certain threshold.

Foreign Asset/Account Reporting Information You are required to report all foreign accounts (whether open, current or closed) to the French tax authorities when filing your annual tax return.

HONG KONG

TERMS AND CONDITIONS

Form of Settlement - RSUs Payable Only in Common Stock Notwithstanding any discretion in the Plan or anything to the contrary in the Agreement, the RSUs do not provide any right for you to receive a cash payment. The RSUs shall be paid in shares of Common Stock only.

Sale of Common Stock. Shares of Common Stock received at vesting are accepted as a personal investment. In the event that Common Stock is issued in respect of the RSUs within six (6) months of the Grant Date, you agree that you will not offer to the public or otherwise dispose of the shares of Common Stock prior to the six (6)-month anniversary of the Grant Date.

NOTIFICATIONS

SECURITIES WARNING: *The contents of this document have not been reviewed by any regulatory authority in Hong Kong. You should exercise caution in relation to the offer. If you are in doubt about any of the contents of the Agreement, including this Appendix A, or the Plan, you should obtain independent professional advice. The RSUs and any shares of Common Stock issued in respect of the RSUs do not constitute a public offering of securities under Hong Kong law and are available only to eligible service providers under the Plan. The Agreement, including this Appendix A, the Plan and other incidental communication materials have not been prepared in accordance with and are not intended to constitute a "prospectus" for a public offering of securities under the applicable securities legislation in Hong Kong. The RSUs and any documentation related thereto are intended solely for the personal use of each member of the award recipient and may not be distributed to any other person.*

INDONESIA

TERMS AND CONDITIONS

Language Consent and Notification. By accepting the grant of RSUs, you (i) confirm having read and understood the documents relating to this grant (i.e., the Plan and the Agreement) which were provided in the English language, (ii) accept the terms of those documents accordingly, and (iii) agree not to challenge the validity of this document based on Law No. 24 of 2009 on National Flag, Language, Coat of Arms and National Anthem or the implementing Presidential Regulation (when issued).

Language Consent and Notification *Dengan manikin tombol "Saya menerima" atau dengan menandatangani dan mengembalikan dokumen ini yang memuat syarat dan ketentuan pemberian anda, (i) anda mengkonfirmasi bahwa anda telah membaca dan mengerti isi dokumen yang terkait dengan pemberian ini yang disediakan untuk anda dalam bahasa Inggris, (ii) Anda menerima syarat dari dokumen-dokumen tersebut, dan (iii) anda setuju bahwa anda tidak akan mengajukan keberatan atas keberlakuan dokumen ini berdasarkan Undang-Undang No. 24 tahun 2009 tentang Bendera, Bahasa dan Lambang Negara serta Lagu Kebangsaan atau Peraturan Presiden pelaksana (ketika diterbitkan).*

IRELAND

TERMS AND CONDITIONS

Acknowledgement of Nature of Plan and RSUs. The following supplements Section 6 (No Special Employment Rights; No Rights to Awards) of the Agreement:

In accepting this Agreement, you understand and agree that the benefits received under the Plan will not be taken into account for any redundancy or unfair dismissal claim.

ISRAEL

TERMS AND CONDITIONS

This provision supplements Section 4(a) of the Agreement: Tax withholding in Israel will be in accordance with applicable law including any tax ruling which may be received by the Corporation and/or its Israeli subsidiaries.

The following provision applies to participants who are in Israel on the Grant Date.

Trustee Arrangement. You hereby agree that the RSUs, to the extent granted to you by the Corporation under the Israeli Sub-Plan to the Plan, shall be allocated under the provisions of the track referred to as the "Capital Gains Track," according to Section 102(b)(2) and 102(b)(3) of the Israeli Income Tax Ordinance and shall be held by the trustee (the "Trustee") for the periods stated in Section 102 (the "Holding Period"). You acknowledge that if, during the Holding Period, you sell any shares of Common Stock issued in settlement of the RSUs, tax treatment will differ from the treatment that would apply if the Holding Period is met. You should consult your personal tax advisor in this regard.

ITALY

TERMS AND CONDITIONS

Acknowledgement of Nature of Agreement. In accepting this Agreement, you acknowledge that (1) you have received a copy of the Plan, the Agreement and this Appendix A; (2) you have reviewed the applicable documents in their entirety and fully understand the contents thereof; and (3) you accept all provisions of the Plan, the Agreement and this Appendix A.

MEXICO

TERMS AND CONDITIONS

Acknowledgement of the Agreement. In accepting the RSUs granted hereunder, you acknowledge that you have received a copy of the Plan, have reviewed the Plan and the Agreement, including this Appendix A, in their entirety and fully understand and accept all provisions of the Plan and the Agreement, including this Appendix A. You further acknowledge that you have read and specifically and expressly approve the terms and conditions of Section 6 (No Special Employment Rights; No Rights to Awards) of the Agreement which clearly provide as follows:

1. Your participation in the Plan does not constitute an acquired right;

2. The Plan and your participation in it are offered by the Corporation on a wholly discretionary basis;

3. Your participation in the Plan is voluntary; and

4. The Corporation and its subsidiaries or affiliates are not responsible for any decrease in the value of any shares of Common Stock acquired at vesting of the RSUs.

Labor Law Acknowledgement and Policy Statement. In accepting any RSUs granted hereunder, you expressly recognize that the Corporation, with registered offices at One Johnson & Johnson Plaza, New Brunswick, NJ 08933, USA, is solely responsible for the administration of the Plan and that your participation in the Plan and acquisition of shares of Common Stock do not constitute an employment relationship between you and the Corporation since you are participating in the Plan on a wholly commercial basis and your Employer ("Johnson & Johnson Mexico") is your sole employer. Based on the foregoing, you expressly recognize that the Plan and the benefits that you may derive from participation in the Plan do not establish any rights between you and your Employer, Johnson & Johnson Mexico, and do not form part of the employment conditions and/or benefits provided by Johnson & Johnson Mexico and any modification of the Plan or its termination shall not constitute a change or impairment of the terms and conditions of your Employment.

You further understand that your participation in the Plan is as a result of a unilateral and discretionary decision of the Corporation; therefore, the Corporation reserves the absolute right to amend and/or discontinue your participation in the Plan at any time without any liability to you.

Finally, you hereby declare that you do not reserve to yourself any action or right to bring any claim against the Corporation for any compensation or damages regarding any provision of the Plan or the benefits derived under the Plan, and you therefore grant a full and broad release to the Corporation, its affiliates, shareholders, officers, agents or legal representatives with respect to any claim that may arise.

Spanish Translation

Reconocimiento del Contrato. Al aceptar el otorgamiento de las RSUs, usted reconoce que ha recibido una copia del Plan, que ha revisado el Plan y el Contrato, incluyendo este Apéndice A, en su totalidad y que entiende y acepta todas las disposiciones del Plan y del Contracto, incluyendo este Apéndice A. Además, usted reconoce que ha leído y que específica y expresamente aprueba de los términos y condiciones de la Sección 6 del Contrato, que claramente dispone lo siguiente:

1. *Su participación en el Plan no constituye un derecho adquirido;*
2. *El Plan y su participación en el Plan se ofrecen por la Corporación en de manera totalmente discrecional;*
3. *Su participación en el Plan es voluntaria; y*
4. *La Corporación y sus subsidiarias o afiliadas no son responsables por ninguna disminución del valor de las Acciones en el momento de tener derecho a conforme a las RSUs.*

Reconocimiento Ley Laboral y Declaración de la Política Al aceptar el otorgamiento de las RSUs, usted reconoce expresamente que la Corporación, con oficinas registradas en One Johnson & Johnson Plaza, New Brunswick, NJ 08933, EE.UU, es únicamente responsable por la administración del Plan. Además, usted reconoce que su participación en el Plan y cualquier adquisición de Acciones de conformidad con el Plan no constituyen una relación laboral entre usted y la Corporación, ya que usted está participando en el Plan sobre una base totalmente comercial y que su Empleador ("Johnson & Johnson Mexico") es su único patrón. Derivado de lo anterior, usted reconoce expresamente que el Plan y los beneficios que le puedan derivar al participar en el Plan no establecen ningún derecho entre usted y su patrón, Johnson & Johnson Mexico, y que no forman parte de las condiciones de trabajo y/o prestaciones otorgadas por Johnson & Johnson Mexico, y que cualquier modificación del Plan o la terminación del mismo no constituirán un cambio o deterioro de los términos y condiciones de su Empleo.

Además, usted entiende que su participación en el Plan es resultado de una decisión unilateral y discrecional de la Corporación, por lo que la Corporación se reserva el derecho absoluto a modificar y/o discontinuar su participación en el Plan en cualquier momento, sin responsabilidad alguna para con usted.
Finalmente, usted declara por la presente que no se reserva acción o derecho alguno para interponer una reclamación o demanda en contra de la Corporación por cualquier compensación o daño en relación con cualquier disposición del Plan o de los beneficios derivados del Plan, y, por lo tanto, otorga un amplio y total finiquito a la Corporación y sus

afiliadas, accionistas, funcionarios, agentes y representantes legales con respecto a cualquier reclamación o demanda que pudiera surgir.

NOTIFICATIONS

Securities Law Information The RSUs granted, and any shares of Common Stock acquired, under the Plan have not been registered with the National Register of Securities maintained by the Mexican National Banking and Securities Commission and cannot be offered or sold publicly in Mexico. In addition, the Plan, the Agreement and any other document relating to the RSUs may not be publicly distributed in Mexico. These materials are addressed to you because of your existing relationship with the Corporation and any subsidiary or affiliate of the Corporation (e.g., Johnson & Johnson Mexico), and these materials should not be reproduced or copied in any form. The offer contained in these materials does not constitute a public offering of securities but rather constitutes a private placement of securities addressed specifically to individuals who are present employees of Johnson & Johnson Mexico made in accordance with the provisions of the Mexican Securities Market Law, and any rights under such offering shall not be assigned or transferred.

NEW ZEALAND

NOTIFICATIONS

Securities Law Information Warning: This is an offer of rights to receive shares of Common Stock upon settlement of the RSUs subject to the terms of the Plan and this Agreement. RSUs give you a stake in the ownership of the Corporation. You may receive a return if dividends are paid on the shares of Common Stock.

If the Corporation runs into financial difficulties and is wound up, you will be paid only after all creditors have been paid. You may lose some or all of your investment.

New Zealand law normally requires people who offer financial products to give information to investors before they invest. This information is designed to help investors to make an informed decision. The usual rules do not apply to this offer because it is made under an employee share purchase scheme. As a result, you may not be given all the information usually required. You will also have fewer other legal protections for this investment.

You should ask questions, read all documents carefully, and seek independent financial advice before committing to participate in the Plan.

No interest in any RSUs may be transferred (legally or beneficially), assigned, mortgaged, charged or encumbered.

The shares of Common Stock are quoted on the New York Stock Exchange. This means that if you acquire shares of Common Stock under the Plan, you may be able to sell them on the New

York Stock Exchange if there are interested buyers. You may get less than you invested. The price will depend on the demand for the shares of Common Stock.

A copy of the Corporation's most recent Annual Report on Form 10-K and most recent published financial statements (Quarterly Reports on Form 10-Q or Form 10-K) and the auditor's report on those financial statements, which are filed with the U.S. Securities and Exchange Commission are available online at www.sec.gov/, as well as on the Corporation's "Investor Relations" website at http://www.investor.jnj.com/. A copy of the above documents will be sent to you free of charge on written request to Equity Compensation Resources, One Johnson & Johnson Plaza, New Brunswick, NJ 08933, USA.

As noted above, you are advised to carefully read the materials provided before making a decision whether to participate in the Plan. You are also encouraged to contact your tax advisor for specific information concerning your personal tax situation with regard to Plan participation.

PHILIPPINES

TERMS AND CONDITIONS

Restriction on Vesting. You will not be permitted to vest in any shares of Common Stock unless and until the necessary securities law approvals for the Plan have been obtained and remain in place, as determined by the Corporation in its sole discretion. Further, the Corporation is under no obligation to issue shares of Common Stock if the Corporation has not or does not obtain necessary securities approval or if any such approval subsequently becomes invalid or ceases to be in effect by the time you vest in the RSUs. The Corporation reserves the right to settle RSUs in cash.

NOTIFICATIONS

Securities Law Information. You should be aware of the risks of participating in the Plan, which include (without limitation) the risk of fluctuation in the price of the shares of Common Stock on the New York Stock Exchange ("NYSE") and the risk of currency fluctuations between the U.S. Dollar and your local currency. In this regard, you should note that the value of any shares of Common Stock you may acquire under the Plan may decrease, and fluctuations in foreign exchange rates between your local currency and the U.S. Dollar may affect the value of the RSUs or any amounts due to you upon vesting and settlement of the RSUs or upon sale of any shares of Common Stock you acquire under the Plan. The Corporation is not making any representations, projections or assurances about the value of the shares of Common Stock now or in the future.

For further information on risk factors impacting the Corporation's business that may affect the value of the shares of Common Stock, you should refer to the risk factors discussion in the Corporation's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, which are filed with the U.S. Securities and Exchange Commission and are available online at www.sec.gov/, as well as on the Corporation's "Investor Relations" website at http://www.investor.jnj.com/.

You are permitted to sell the shares of Common Stock acquired under the Plan through the designated broker appointed under the Plan (or such other broker to whom you transfer the shares of Common Stock), provided the resale of shares of Common Stock acquired under the

Plan takes place outside of the Philippines through the facilities of a stock exchange on which the shares of Common Stock are listed (e.g., the NYSE).

PORTUGAL

TERMS AND CONDITIONS

Consent to Receive Information in English. You hereby expressly declare that you have full knowledge of the English language and have read, understood and fully accepted and agreed with the terms and conditions established in the Plan and Agreement.

Conhecimento da Lingua. *Por meio do presente, eu declaro expressamente que tem pleno conhecimento da língua inglesa e que li, compreendi e livremente aceitei e concordei com os termos e condições estabelecidas no Plano e no Acordo.*

RUSSIA

TERMS AND CONDITIONS

Securities Law Requirements. Any RSUs granted hereunder, the Agreement, including this Appendix A, the Plan and all other materials you may receive regarding your participation in the Plan or any RSUs granted hereunder do not constitute advertising or an offering of securities in Russia. The issuance of shares of Common Stock under the Plan has not and will not be registered in Russia; therefore, shares of Common Stock may not be offered or placed in public circulation in Russia.

In no event will shares of Common Stock acquired under the Plan be delivered to you in Russia; all shares of Common Stock will be maintained on your behalf in the United States.

You are not permitted to sell any shares of Common Stock acquired under the Plan directly to a Russian legal entity or resident.

Labor Law Acknowledgement. You acknowledge that if you continue to hold shares of Common Stock acquired under the Plan after an involuntary termination of your Employment, you will not be eligible to receive unemployment benefits in Russia.

Data Privacy Notice. You hereby acknowledge that you have read and understood the terms regarding collection, processing and transfer of Data contained in Section 9(f) (Data Privacy Consent) of the Agreement and by participating in the Plan, you agree to such terms. In this regard, upon request of the Corporation or your Employer, you agree to provide an executed data privacy consent form to your Employer or the Corporation (or any other agreements or consents that may be required by your Employer or the Corporation) that the Corporation and/or your Employer may deem necessary to obtain under the data privacy laws in your country, either now or in the future. You understand you will not be able to participate in the Plan if you fail to execute any such consent or agreement.

NOTIFICATIONS

Anti-Corruption Legislation Information Individuals holding public office in Russia, as well as their spouses and dependent children, may be prohibited from opening or maintaining a foreign brokerage or bank account and holding any securities, whether acquired directly or indirectly, in a foreign company (including shares of Common Stock acquired under the Plan). You should consult with your personal legal advisor to determine whether this restriction applies to your circumstances.

SINGAPORE

TERMS AND CONDITIONS

Restriction on Sale and Transferability. You hereby agree that any shares of Common Stock acquired pursuant to the RSUs will not be offered for sale in Singapore prior to the six-month anniversary of the Grant Date, unless such sale or offer is made pursuant to one or more exemptions under Part XIII Division 1 Subdivision (4) (other than section 280) of the Securities and Futures Act (Chap. 289, 2006 Ed.) ("SFA").

NOTIFICATIONS

Securities Law Information The grant of the RSUs is being made pursuant to the "Qualifying Person" exemption under section 273(1)(f) of the SFA and is not made with a view to the RSUs being subsequently offered for sale to any other party. The Plan has not been lodged or registered as a prospectus with the Monetary Authority of Singapore.

SOUTH AFRICA

NOTIFICATIONS

Securities Law Information. In compliance with South African Securities Law, you acknowledge that you have been notified that the Corporation's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, which are filed with the U.S. Securities and Exchange Commission and are available online at www.sec.gov/, as well as on the Corporation's "Investor Relations" website at http://www.investor.jnj.com/.

SPAIN

TERMS AND CONDITIONS

Labor Law Acknowledgement. The following supplements Section 6 (No Special Employment Rights; No Rights to Awards) of the Agreement:

By accepting the RSUs granted hereunder, you consent to participation in the Plan and acknowledge that you have received a copy of the Plan.

You understand that the Corporation has unilaterally, gratuitously and in its sole discretion decided to grant any RSUs under the Plan to individuals who may be employees of the Corporation Group throughout the world. The decision is a limited decision, which is entered into upon the express assumption and condition that the RSU granted will not economically or

otherwise bind the Corporation or any of its affiliates on an ongoing basis, other than as expressly set forth in the Agreement, including this Appendix A. Consequently, you understand that the RSUs granted hereunder are given on the assumption and condition that they shall not become a part of any employment contract (either with the Corporation or any of its affiliates) and shall not be considered a mandatory benefit, salary for any purposes (including severance compensation) or any other right whatsoever. Further, you understand and freely accept that there is no guarantee that any benefit whatsoever shall arise from any gratuitous and discretionary grant of RSUs since the future value of the RSUs and the underlying shares of Common Stock is unknown and unpredictable. In addition, you understand that any RSUs granted hereunder would not be made but for the assumptions and conditions referred to above; thus, you understand, acknowledge and freely accept that, should any or all of the assumptions be mistaken or should any of the conditions not be met for any reason, then any grant of RSUs or right to RSUs shall be null and void.

Further, the vesting of the RSUs is expressly conditioned on your active employment status with the Corporation Group, such that if your Service terminates, the RSUs may cease vesting immediately and be forfeited, in whole or in part, effective on the date of your termination of Employment (unless otherwise specifically provided in Section 2(c) (Certain Terminations) of the Agreement). This will be the case, for example, even if (1) you are considered to be unfairly dismissed without good cause (*i.e.*, subject to a "despido improcedente"); (2) you are dismissed for disciplinary or objective reasons or due to a collective dismissal; (3) you terminate Service due to a change of work location, duties or any other employment or contractual condition; or (4) you terminate Service due to a unilateral breach of contract by the Corporation or an affiliate of the Corporation. Consequently, upon termination of your Employment for any of the above reasons, you will automatically lose any rights to RSUs that were not vested on the date of your termination of Employment except as described in Section 2(c) of the Agreement.

You acknowledge that you have read and specifically accept the conditions referred to in Section 2 of the Agreement.

NOTIFICATIONS

Securities Law Information. No "offer of securities to the public," as defined under Spanish law, has taken place or will take place in the Spanish territory. The Agreement (including this Appendix A) has not been nor will it be registered with the *Comisión Nacional del Mercado de Valores*, and does not constitute a public offering prospectus.

SWEDEN

TERMS AND CONDITIONS

Tax Withholding. This provision supplements Section 4(a) of the Agreement:

Without limiting the Corporation's or the Employer's authority to satisfy their withholding obligations for Tax-Related Items as set forth in the Agreement, by accepting the RSUs, you authorize the Corporation to withhold shares of Common Stock or to sell shares of Common Stock otherwise deliverable to you upon vesting/settlement to satisfy Tax-Related Items,

regardless of whether the Corporation and/or the Employer have an obligation to withhold such Tax-Related Items.

SWITZERLAND

NOTIFICATIONS

Securities Law Information. Neither this document nor any other materials relating to the RSUs (i) constitutes a prospectus according to articles 35 et seq. of the Swiss Federal Act on Financial Services ("FinSA") (ii) may be publicly distributed or otherwise made publicly available in Switzerland to any person other than an employee of the Corporation or (iii) has been or will be filed with, approved or supervised by any Swiss reviewing body according to article 51 FinSA or any Swiss regulatory authority, including the Swiss Financial Supervisory Authority, FINMA.

TAIWAN

NOTIFICATIONS

Securities Law Information. The offer of participation in the Plan is available only for Employees. The offer of participation in the Plan is not a public offer of securities by a Taiwanese company.

TURKEY

NOTIFICATIONS

Securities Law Information The Plan is made available only to employees of the Corporation and its affiliates, and the offer of participation in the Plan is a private offering as to employees in Turkey. The RSUs and the issuance of shares of Common Stock under the Plan takes place outside Turkey. You are not permitted to sell shares of Common Stock acquired under the Plan in Turkey. The shares of Common Stock are currently traded on the New York Stock Exchange, which is located outside of Turkey, under the ticker symbol "JNJ" and the shares of Common Stock may be sold through this exchange.

UNITED ARAB EMIRATES

NOTIFICATIONS

Securities Law Information. RSUs under the Plan are granted only to select employees of the Corporation and its affiliates and are for the purpose of providing equity incentives. The Plan and the Agreement are intended for distribution only to such employees and must not be delivered to, or relied on by, any other person. You should conduct your own due diligence on the RSUs offered pursuant to this Agreement. If you do not understand the contents of the Plan and/or the

Agreement, you should consult an authorized financial adviser. The Emirates Securities and Commodities Authority and the Dubai Financial Services Authority have no responsibility for reviewing or verifying any documents in connection with the Plan. Neither the Ministry of the Economy and the Dubai Department of Economic Development have approved the Plan or the

Agreement nor taken steps to verify the information set out therein, and have no responsibility for such documents.

UNITED KINGDOM

TERMS AND CONDITIONS

Tax Withholding. This provision supplements Section 4(a) of the Agreement:

Without limitation to Section 4(a) of the Agreement, you agree that you are liable for all Tax- Related Items and hereby covenant to pay all Tax-Related Items, as and when requested by the Corporation or, if different, your Employer or by HM Revenue & Customs ("HMRC") (or any other tax authority or any other relevant authority). You also agree to indemnify and keep indemnified the Corporation and, if different, your Employer against any Tax-Related Items that they are required to pay or withhold or have paid or will pay to HMRC on your behalf (or any other tax authority or any other relevant authority). For the purposes of this Agreement, Tax- Related Items include (without limitation) employment income tax and the employee portion of the Health and Social Care levy.

Notwithstanding the foregoing, if you are a director or executive officer of the Corporation (within the meaning of Section 13(k) of the Exchange Act), you understand that you may not be able to indemnify the Corporation for the amount of any income tax not collected from or paid by you within ninety (90) days of the end of the U.K. tax year in which the event giving rise to the Tax- Related Items occurs as it may be considered to be a loan and therefore, it may constitute a benefit to you on which additional income tax and National Insurance contributions ("NICs") and Health and Social Care levy may be payable. You understand that you will be responsible for reporting and paying any income tax due on this additional benefit directly to HMRC under the self- assessment regime and for paying to the Corporation and/or your Employer (as appropriate) the amount of any employee NICs and Health and Social Care levy due on this additional benefit, which may also be recovered from you by any of the means referred to in Section 4(a) of the Agreement.

URUGUAY

TERMS AND CONDITIONS

Data Privacy Acknowledgement. This provision supplements Section 9(f) of the Agreement:

You understand that your Data will be collected by your Employer and will be transferred to the Corporation at One Johnson & Johnson Plaza, New Brunswick, NJ 08933, U.S.A and/or any financial institutions or brokers involved in the management and administration of the Plan. You further understand that any of these entities may store your Data for purposes of administering your participation in the Plan.

VENEZUELA

TERMS AND CONDITIONS

Settlement of RSUs Settlement of vested RSUs shall be made in shares of Common Stock, provided, however, that the Corporation has the discretion to settle the RSUs in cash if it determines that cash settlement is necessary or advisable in light of changes in regulatory requirements in Venezuela. In the event that the RSUs are settled in cash, the amount of the cash payment upon vesting and settlement of the RSUs shall be based on the fair market value (as determined by the Corporation) of the shares of Common Stock subject to the vested RSUs, less any applicable Tax-Related Items.

Investment Representation As a condition of the grant of the RSUs, you acknowledge and agree that any shares of Common Stock you may acquire upon the settlement of the RSUs are acquired as and intended to be an investment rather than for the resale of the shares of Common Stock and conversion of such shares into foreign currency.

NOTIFICATIONS

Securities Law Information The RSUs granted under the Plan and the shares of Common Stock issued under the Plan are offered as a personal, private, exclusive transaction and are not subject to Venezuelan government securities regulations.

Exhibit 19

JOHNSON & JOHNSON

STOCK TRADING POLICY FOR DIRECTORS, EXECUTIVE OFFICERS AND INSIDERS

Federal and state laws prohibit Insiders (as defined below) from buying or selling securities of Johnson & Johnson ("J&J") when they are aware of material non-public information about J&J and from passing along (or "tipping") such information to others who then trade. This illegal activity is commonly referred to as insider trading. Individuals who trade on material non-public information (or tip information to others who trade) can be liable for civil and criminal penalties, in addition to legal and disciplinary action from J&J, up to and including dismissal for cause.

This Stock Trading Policy (this "Policy") for Directors and Executive Officers (and family members living in the same household) and other Insiders provides guidelines with respect to transactions in the securities of J&J. J&J has adopted this Policy regarding securities transactions to help prevent insider trading and to protect our reputation for integrity and ethical conduct.

I. When does this Policy Apply?

General prohibition: The general prohibition on trading or "tipping" when aware of material non-public information is always applicable.

Blackout Period: Starting on the date two weeks prior to the end of each fiscal quarter, through and until 24 hours after financial results for that fiscal quarter (or the fiscal year) are announced, no Insiders may trade in J&J securities. This period when trading is not allowed is called a "Blackout Period."

Example: If the fiscal quarter ends on September 30 and financial results are released at 8:00 AM (EDT) on October 16, then trading is prohibited under this Policy from September 16 through and until 8:00 AM (EDT) on October 17.

II. Who is Covered by this Policy?

"**Section 16 Insiders**" who are:
a. Members of the Board of Directors;
b. Members of the Executive Committee;
c. Corporate Controller; or
d. Family members living in the same household as any Section 16 Insider (see "Additional Guidance" section below).

"**Restricted Insiders**" who are:
- Treasurer, Corporate Secretary and any other individual as may be designated from time to time by the General Counsel;
- Company Group Chairmen;
- Members of Group Operating Committees and Sector Leadership Teams;

- All individuals reporting directly to the Chief Financial Officer (excluding non-finance staff members);
- Certain employees in the Corporate Controller's group who are involved in the preparation of financial statements (to be determined by the Chief Financial Officer);
- Investor Relations professionals; or
- Family members living in the same household as any Restricted Insider (see "Additional Guidance" section below).

"**Insiders**" who are:
- Section 16 Insiders; or
- Restricted Insiders.

III. What Transactions are Prohibited by this Policy?

- Trading in J&J securities when in possession of material non-public information.
- Trading in J&J securities during a Blackout Period, as described further in Section IV below.
- Gifts of J&J securities when in possession of material non-public information or during a Blackout Period, except as otherwise permitted under Section VII below.

IV. What Transactions are Prohibited During a Blackout Period?

- Open market purchase or sale of J&J securities.
- Purchase or sale of J&J securities through a broker (unless in accordance with pre-arranged and pre-approved written plans or irrevocable instructions -- see "Additional Guidance" section below).
- Sale or exchange of J&J securities in connection with the exercise of stock options (including any sale of shares subject to a stock option as part of a cashless exercise of an option, or any sale or exchange of shares to generate the consideration needed to fund the exercise of an option or to pay taxes).
- Elections to make or change existing elections under the Dividend Reinvestment Plan. Switching existing balances into or out of the J&J Stock Fund in the Company 401(k) Savings Plan.
- Increasing or decreasing future contributions to the J&J Stock Fund in the Company 401(k) Savings Plan.
- Gifts of J&J securities except as otherwise permitted in Section VII below.

V. What Transactions are Allowed During a Blackout Period?

- Regular and matching contributions to the J&J Stock Fund in the Company 401(k) Savings Plan.
- Regular reinvestment of dividends under the Dividend Reinvestment Plan.
- Transfers of J&J securities to or from a trust.
- Regular purchase of J&J securities under the Employee Stock Purchase Plan.

VI. Pre-Clearance of Stock Transactions for Section 16 Insiders

At all times, even when a Blackout Period is not in effect, before purchasing or selling J&J securities, or engaging in any other transaction prohibited during a Blackout Period, Section 16 Insiders must pre-clear all transactions in J&J securities (including gifts) in writing by notifying the General Counsel or Corporate Secretary at least two (2) business days in advance of the proposed transaction. In addition, (i) the Chief Executive Officer will be notified of any transaction requests by other Section 16 Insiders and (ii) the Lead Director of the Board of Directors or any Non-Executive Chairman of the Board of Directors, as applicable, will be notified of any transaction requests by the Chief Executive Officer and any Executive Chairman of the Board of Directors. The transaction must be placed within four (4) business days of the receipt of written pre-clearance from the General Counsel or Corporate Secretary.

VII. Gifts of J&J Securities

Gifts of J&J securities may include gifts to trusts for estate planning purposes, as well as donations to a charitable organization. Whether a gift of securities is a transaction that should be avoided while the person making the gift is in possession of material non-public information may depend on the various circumstances surrounding the gift. Accordingly, you are encouraged to consult the Legal Department when contemplating a gift, and Section 16 Insiders are required to obtain pre-clearance of the gift.

VIII. Pre-Arranged Rule 10b5-1 Trading Plans

An Insider may trade in J&J securities (including the exercise of stock options and the sale or exchange of shares underlying such stock options) during a Blackout Period in accordance with certain pre-arranged written plans or irrevocable instructions ("Trading Plans") that meet the requirements set forth in this Section VIII; provided however, a Section 16 Insider who is subject to the Stock Ownership Guidelines may not use a Trading Plan until their required ownership level has been met.

- First, the proposed Trading Plan must be entered into in good faith at a time when the Insider is not in possession of any material non-public information and not during a Blackout Period.
- Second, the proposed Trading Plan must either specify the number of shares to be purchased or sold on specific dates, or else provide a written formula for that trading.
- Third, the proposed Trading Plan must be pre-approved in writing by the General Counsel or the Corporate Secretary at least five business days prior to entry into a Trading Plan or modification thereof.
- Fourth, the proposed Trading Plan must comply with SEC Rule 10b5-1 (17 CFR 240.10b5-1), or any successor rule.

Single Plan: An Insider may not enter into (i) multiple Trading Plans providing for transactions during overlapping periods or (ii) a Trading Plan providing for the open-market purchase or sale of the total amount of J&J securities under the plan as a single transaction more than once in a 12-month period. The foregoing restrictions do not

apply to eligible “sell-to-cover” transactions to sell only such shares as are necessary to satisfy tax withholding obligations arising exclusively from the vesting of certain types of compensatory awards under SEC Rule 10b5-1(c)(1)(ii)(D)(3).

Waiting Period: The first trade made under any Trading Plan may not take place until 30 days following entry into such Trading Plan. For Section 16 Insiders, the first trade may not take place until the later of (i) 90 days following entry into such Trading Plan, or (ii) 2 business days following J&J’s filing of Form 10-Q or 10-K with the SEC for the completed fiscal quarter in which the plan was adopted (subject to a maximum of 120 days following entry into such Trading Plan).

Early Termination: A Trading Plan is deemed terminated upon the expiration of its term or the sale of all of the J&J securities subject to such Trading Plan. A Trading Plan may be terminated by an Insider before either the expiration of its term or the sale of all of the J&J securities subject to the Trading Plan (an “early termination”) only after receipt of written approval by the General Counsel or the Corporate Secretary. Note any new Trading Plan would be subject to the waiting period described above. Early termination is strongly discouraged, but in certain limited circumstances, the General Counsel or the Corporate Secretary may consider whether early termination of a plan is warranted.

Amendments: Amendments or modifications to a Trading Plan may only be made after receipt of written approval by the General Counsel or Corporate Secretary. In addition, (i) an Insider may not amend a Trading Plan when in possession of material non-public information or during a Blackout Period and (ii) the amendment may not be effective until 30 days (or for Section 16 Insiders, the longer waiting period described above) thereafter. Amendments are strongly discouraged.

Section 16 Insider Representations: A new or modified Trading Plan by a Section 16 Insider must include a representation certifying that, on the date of adoption of the plan, the individual Section 16 Insider (i) is not aware of any material non-public information about the security or J&J; and (ii) is adopting such plan in good faith and not as part of a plan or scheme to evade the prohibitions of SEC Rule 10b-5.

Notwithstanding the foregoing, adoption of a Trading Plan does not preclude trades outside of such Trading Plan that are otherwise made in accordance with this Policy.

For further information about Trading Plans, please contact the Corporate Secretary’s Office.

IX. Additional Guidance for People Covered by this Policy:

Actual Knowledge of Financial Results does not Matter: This Policy applies regardless of your actual knowledge of financial results. An Insider may not trade in J&J securities during a Blackout Period even if that person has no knowledge of the current financial results.

Trading while Knowing Material Non-public Information. SEC rules, as well as the J&J Code of Business Conduct and the J&J Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers, prohibit buying or selling J&J securities while in possession of material non-public information about the Company. In no event should anyone covered by this Policy trade in J&J securities at any time when he or she has knowledge of

material information involving the Company, which has not been disclosed publicly. In the event that an Insider is unsure as to whether any news, development or other information would be considered material, or has any other question as to whether he or she should refrain from trading in J&J securities, they should contact the Corporate Secretary's Office (as stated above, Section 16 Insiders are always required to pre-clear all trades).

Derivative Instruments: Persons covered by this Policy are prohibited at all times from buying or selling "put" or "call" options on J&J securities, short sales, hedging transactions and other types of derivative instruments linked to the performance of J&J securities.

Family Members who Live in Your Household: Family members of people covered by this Policy, who share the same household, are also covered by this Policy to the same extent as the person covered by this Policy. In addition, children who go away to college or otherwise leave home, but remain financially dependent on you, should be considered to be living in your household and subject to this Policy. If your spouse or children own any J&J securities, it is important to advise them of this Policy. If any other "family members" live in an Insider's household, they should also be aware of these restrictions and should not engage in any transactions involving J&J securities without first discussing with the Insider.

Other J&J Securities an Insider may Control. This Policy applies to all investment decisions made by people covered by this Policy. If an Insider has the power to direct the purchase or sale of J&J securities by virtue of his or her position as a shareholder, director or officer of a corporation or not-for-profit organization, or as a trustee of a trust or executor of an estate, then for the purposes of this Policy that Insider should not engage in a transaction in J&J securities on behalf of that corporation, organization, trust or estate that would not be permitted to be engaged in by them in their personal capacity under this Policy.

Exceptions to Policy. Exceptions to this Policy may be granted only under the most extenuating of circumstances. Any exception must be approved by the General Counsel and requires that the individual not be in possession of material non-public information. An urgent or unexpected need for money is not a defense to charges of trading on material non-public information.

Post-Termination Transaction. Subject to any additional terms, conditions, or restrictions that may be set forth in an agreement between an Insider and J&J, for a period of time after their status with J&J terminates, all aspects of this Policy (including mandatory preclearance of any transactions in J&J securities) shall continue to apply until the later of (i) the end of the first black out period following the public release of earnings for the fiscal quarter in which the Insider's status with J&J terminates or (ii) the beginning of the second market trading day after the earlier of (a) the public disclosure of any material non-public information known to the Insider or (b) such time as any material non-public information known to the Insider is no longer material.

X. Whom do I Contact with Questions about this Policy?

Please contact the Office of Corporate Secretary at 732-524-2455 or by email at AskCorpSec@its.jnj.com with any questions.

As amended by the Board of Directors of Johnson & Johnson
Effective: April 27, 2023

EXHIBIT 21

SUBSIDIARIES

Johnson & Johnson, a New Jersey corporation, had the U.S. and international subsidiaries shown below as of December 31, 2023. Johnson & Johnson is not a subsidiary of any other entity.

Name of Subsidiary	Jurisdiction
U.S. Subsidiaries:	
ABD Holding Company, Inc.	Delaware
ABIOMED COMMERCIAL, LLC	Delaware
ABIOMED R&D, Inc.	Delaware
ABIOMED, Inc.	Delaware
Acclarent, Inc.	Delaware
Actelion Pharmaceuticals US, Inc.	Delaware
Albany Street LLC	New Jersey
ALZA Corporation	Delaware
Alza Land Management, Inc.	Delaware
AMO Development, LLC	Delaware
AMO Manufacturing USA, LLC	Delaware
AMO Sales and Service, Inc.	Delaware
AMO Spain Holdings, LLC	Delaware
Anakuria Therapeutics, Inc.	Delaware
AorTx, Inc.	Delaware
Aragon Pharmaceuticals, Inc.	Delaware
Asia Pacific Holdings, LLC	New Jersey
Atrionix, Inc.	California
AUB Holdings LLC	Delaware
Auris Health, Inc.	Delaware
Bandol Merger Sub, Inc.	Delaware
BeneVir BioPharm, Inc.	Delaware
BioMedical Enterprises, Inc.	Texas
Biosense Webster, Inc.	California
Breethe, Inc.	Delaware
Cerenovus, Inc.	New Jersey
Charm Merger Sub, Inc.	Delaware
Coherex Medical, Inc.	Delaware
CoTherix Inc.	Delaware
CRES Holdings, Inc.	Delaware
CrossRoads Extremity Systems, LLC	Tennessee
CSATS, Inc.	Washington
DePuy Mitek, LLC	Massachusetts
DePuy Orthopaedics, Inc.	Indiana
DePuy Products, Inc.	Indiana
DePuy Spine, LLC	Ohio
DePuy Synthes Institute, LLC	Delaware
DePuy Synthes Products, Inc.	Delaware
DePuy Synthes Sales, Inc.	Massachusetts
DePuy Synthes, Inc.	Delaware
Dutch Holding LLC	Delaware
ECL7, LLC	Delaware
Ethicon Endo-Surgery, Inc.	Ohio
Ethicon Endo-Surgery, LLC	Delaware
Ethicon LLC	Delaware
Ethicon US, LLC	Texas
Ethicon, Inc.	New Jersey

Name of Subsidiary	Jurisdiction
Hansen Medical International, Inc.	Delaware
Hansen Medical, Inc.	Delaware
I.D. Acquisition Corp.	New Jersey
Janssen Biotech, Inc.	Pennsylvania
Janssen Global Services, LLC	New Jersey
Janssen Oncology, Inc.	Delaware
Janssen Ortho LLC	Delaware
Janssen Pharmaceuticals, Inc.	Pennsylvania
Janssen Products, LP	New Jersey
Janssen Research & Development, LLC	New Jersey
Janssen Scientific Affairs, LLC	New Jersey
Janssen Supply Group, LLC	Pennsylvania
Janssen-Cilag Manufacturing, LLC	Delaware
Jevco Holding, Inc.	New Jersey
JJHC, LLC	Delaware
JNJ International Investment LLC	Delaware
JNTL (Russia) HoldCo LLC	Delaware
Johnson & Johnson	New Jersey
Johnson & Johnson (Middle East) Inc.	New Jersey
Johnson & Johnson (Singapore) HoldCo LLC	Delaware
Johnson & Johnson Enterprise Innovation Inc.	Delaware
Johnson & Johnson Finance Corporation	New Jersey
Johnson & Johnson Gateway, LLC	New Jersey
Johnson & Johnson Health Care Systems Inc.	New Jersey
Johnson & Johnson Holdco (NA) Inc.	New Jersey
Johnson & Johnson Innovation - JJDC, Inc.	Delaware
Johnson & Johnson Innovation LLC	Delaware
Johnson & Johnson International	New Jersey
Johnson & Johnson Medical Devices & Diagnostics Group - Latin America, L.L.C.	Florida
Johnson & Johnson S.E., Inc.	New Jersey
Johnson & Johnson Services, Inc.	New Jersey
Johnson & Johnson Surgical Vision, Inc.	Delaware
Johnson & Johnson Urban Renewal Associates	New Jersey
Johnson & Johnson Vision Care, Inc.	Florida
JOM Pharmaceutical Services, Inc.	Delaware
Laminar, Inc.	Delaware
LLT Management LLC	Texas
Medical Device Business Services, Inc.	Indiana
Medical Devices & Diagnostics Global Services, LLC	Delaware
MegaDyne Medical Products, Inc.	Utah
Mentor Partnership Holding Company I, LLC	Delaware
Mentor Texas GP LLC	Delaware
Mentor Texas L.P.	Delaware
Mentor Worldwide LLC	Delaware
Middlesex Assurance Company Limited	Vermont
Momenta Pharmaceuticals, Inc.	Delaware
Netherlands Holding Company	Delaware
NeuWave Medical, Inc.	Delaware
NuVera Medical, Inc.	Delaware
OMJ Pharmaceuticals, Inc.	Delaware
Omrix Biopharmaceuticals, Inc.	Delaware
Ortho Biologics LLC	Delaware
Ortho Biotech Holding LLC	Delaware
Patriot Pharmaceuticals, LLC	Pennsylvania

Name of Subsidiary	Jurisdiction
Percivia LLC	Delaware
Princeton Laboratories, Inc.	Delaware
Prosidyan, Inc.	Delaware
Pulsar Vascular, Inc.	Delaware
Regency Urban Renewal Associates	New Jersey
Royalty A&M LLC	North Carolina
Rutan Realty LLC	New Jersey
Scios LLC	Delaware
Serotiny, Inc.	Delaware
SterilMed, Inc.	Minnesota
Synthes USA Products, LLC	Delaware
Synthes USA, LLC	Delaware
Synthes, Inc.	Delaware
TalCo LLC	Texas
TARIS Biomedical LLC	Delaware
TearScience, Inc.	Delaware
The Anspach Effort, LLC	Florida
Tibotec, LLC	Delaware
Torax Medical, Inc.	Delaware
Verb Surgical Inc.	Delaware
WH4110 Development Company, L.L.C.	Georgia
Percivia LLC	Delaware
Princeton Laboratories, Inc.	Delaware
Prosidyan, Inc.	Delaware
Pulsar Vascular, Inc.	Delaware
Regency Urban Renewal Associates	New Jersey
Royalty A&M LLC	North Carolina
Rutan Realty LLC	New Jersey
Scios LLC	Delaware
Serotiny, Inc.	Delaware
SterilMed, Inc.	Minnesota
Synthes USA Products, LLC	Delaware
Synthes USA, LLC	Delaware
Synthes, Inc.	Delaware
TalCo LLC	Texas
TARIS Biomedical LLC	Delaware
TearScience, Inc.	Delaware
The Anspach Effort, LLC	Florida
Tibotec, LLC	Delaware
Torax Medical, Inc.	Delaware
Verb Surgical Inc.	Delaware
WH4110 Development Company, L.L.C.	Georgia

Name of Subsidiary	Jurisdiction
International Subsidiaries:	
ABIOMED AUSTRALIA PTY LTD	Australia
Abiomed Europe GmbH	Germany
Abiomed Europe GmbH, Aachen, Zweigniederlassung Zug	Switzerland
Abiomed Japan K.K.	Japan
ABIOMED SARL	France
ABIOMED SINGAPORE PTE. LTD.	Singapore
ABIOMED, LTD.	United Kingdom
Actelion Pharmaceuticals Ltd	Switzerland
Actelion Pharmaceuticals Trading (Shanghai) Co., Ltd.	China
Actelion Treasury Unlimited Company	Ireland
AIS GmbH Aachen Innovative Solutions	Germany
AMO (Hangzhou) Co., Ltd.	China
AMO (Shanghai) Medical Devices Trading Co., Ltd.	China
AMO ASIA LIMITED	Hong Kong
AMO Australia Pty Limited	Australia
AMO Canada Company	Canada
AMO Denmark ApS	Denmark
AMO France	France
AMO Germany GmbH	Germany
AMO Groningen B.V.	Netherlands
AMO International Holdings Unlimited Company	Ireland
AMO Ireland	Cayman Islands
AMO Italy SRL	Italy
AMO Japan K.K.	Japan
AMO Netherlands BV	Netherlands
AMO Norway AS	Norway
AMO Puerto Rico Manufacturing, Inc.	Cayman Islands
AMO Singapore Pte. Ltd.	Singapore
AMO Switzerland GmbH	Switzerland
AMO United Kingdom, Ltd.	United Kingdom
AMO Uppsala AB	Sweden
Apsis	France
Berna Rhein B.V.	Netherlands
Biosense Webster (Israel) Ltd.	Israel
C Consumer Products Denmark ApS	Denmark
ChromaGenics B.V.	Netherlands
Cilag AG	Switzerland
Cilag GmbH International	Switzerland
Cilag Holding AG	Switzerland
Cilag Holding Treasury Unlimited Company	Ireland
Cilag-Biotech, S.L.	Spain
Cordis de Mexico, S.A. de C.V.	Mexico
Corimmun GmbH	Germany
DePuy Hellas SA	Greece
DePuy International Limited	United Kingdom
DePuy Ireland Unlimited Company	Ireland
DePuy Mexico, S.A. de C.V.	Mexico
ECP Entwicklungsgesellschaft mbH	Germany
EES Holdings de Mexico, S. de R.L. de C.V.	Mexico
EES, S.A. de C.V.	Mexico
EIT Emerging Implant Technologies GmbH	Germany
Ethicon Endo-Surgery (Europe) GmbH	Germany
Ethicon Sarl	Switzerland

Name of Subsidiary	Jurisdiction
Ethicon Women's Health & Urology Sarl	Switzerland
Ethnor (Proprietary) Limited	South Africa
Ethnor del Istmo S.A.	Panama
Ethnor Farmaceutica, S.A.	Venezuela, Bolivarian Republic of
Finsbury (Development) Limited	United Kingdom
Finsbury (Instruments) Limited	United Kingdom
Finsbury Medical Limited	United Kingdom
Finsbury Orthopaedics International Limited	United Kingdom
Finsbury Orthopaedics Limited	United Kingdom
FMS Future Medical System SA	Switzerland
GATT Technologies B.V.	Netherlands
GBSC Division of Janssen Biologics B.V.	Netherlands
GH Biotech Holdings Limited	Ireland
GMED Healthcare BV	Belgium
Guangzhou Bioseal Biotech Co., Ltd.	China
Hansen Medical Deutschland GmbH	Germany
Hansen Medical UK Limited	United Kingdom
Healthcare Services (Shanghai) Ltd.	China
Innomedic Gesellschaft für innovative Medizintechnik und Informatik mbH	Germany
J & J Company West Africa Limited	Nigeria
J&J Argentina S.A.	Argentina
J&J Pension Trustees Limited	United Kingdom
J&J Productos Medicos & Farmaceuticos del Peru S.A.	Peru
J.C. General Services BV	Belgium
Janssen (Scientific Office)	Egypt
Janssen Biologics B.V.	Netherlands
Janssen Cilag Farmaceutica S.A.	Argentina
Janssen Cilag S.p.A.	Italy
Janssen Cilag SPA	Algeria
Janssen Cilag, C.A.	Venezuela, Bolivarian Republic of
Janssen Egypt LLC	Egypt
Janssen Farmaceutica Portugal Lda	Portugal
Janssen France Treasury Unlimited Company	Ireland
Janssen Inc.	Canada
Janssen Irish Finance Unlimited Company	Ireland
Janssen Japan Treasury Unlimited Company	Ireland
Janssen Korea Ltd.	Korea, Republic of
Janssen Mexico Treasury Unlimited Company	Ireland
Janssen Pharmaceutica (Proprietary) Limited	South Africa
Janssen Pharmaceutica NV	Belgium
Janssen Pharmaceutical K.K.	Japan
Janssen Pharmaceutical Sciences Unlimited Company	Ireland
Janssen Pharmaceutical Unlimited Company	Ireland
Janssen R&D Ireland Unlimited Company	Ireland
Janssen Sciences Ireland Unlimited Company	Ireland
Janssen Scientific Office (Syria)	Syrian Arab Republic
Janssen Vaccines & Prevention B.V.	Netherlands
Janssen Vaccines Corp.	Korea, Republic of
Janssen-Cilag	France
Janssen-Cilag (New Zealand) Limited	New Zealand
Janssen-Cilag A/S	Denmark
Janssen-Cilag AG	Switzerland
Janssen-Cilag Aktiebolag	Sweden
Janssen-Cilag AS	Norway

Name of Subsidiary	Jurisdiction
Janssen-Cilag B.V.	Netherlands
Janssen-Cilag d.o.o. Beograd	Serbia
Janssen-Cilag de Mexico S. de R.L. de C.V.	Mexico
Janssen-Cilag Farmaceutica Lda.	Portugal
Janssen-Cilag Farmaceutica Ltda.	Brazil
Janssen-Cilag GmbH	Germany
Janssen-Cilag International NV	Belgium
Janssen-Cilag Kft.	Hungary
Janssen-Cilag Limited	Thailand
Janssen-Cilag Limited	United Kingdom
Janssen-Cilag NV	Belgium
Janssen-Cilag OY	Finland
Janssen-Cilag Pharma GmbH	Austria
Janssen-Cilag Pharmaceutical S.A.C.I.	Greece
Janssen-Cilag Polska, Sp. z o.o.	Poland
Janssen-Cilag Pty Ltd	Australia
Janssen-Cilag S.A.	Colombia
Janssen-Cilag s.r.o.	Czech Republic
Janssen-Cilag, S.A.	Spain
Janssen-Cilag, S.A. de C.V.	Mexico
Janssen-Pharma, S.L.	Spain
J-C Health Care Ltd.	Israel
JJ Surgical Vision Spain, S.L.	Spain
JJ Surgical Vision Spain, S.L. - Sucursal EM Portugal	Portugal
JJC Acquisition Company B.V.	Netherlands
JJSV Belgium BV	Belgium
JJSV Manufacturing Malaysia SDN. BHD.	Malaysia
JJSV Norden AB	Sweden
JJSV Norden AB, filial i Finland	Finland
JJSV Produtos Oticos Ltda.	Brazil
JNJ Global Business Services s.r.o.	Czech Republic
JNJ Holding EMEA B.V.	Netherlands
Johnson & Johnson (Angola), Limitada	Angola
Johnson & Johnson (Australia) Pty Ltd	Australia
Johnson & Johnson (Canada) Inc.	Canada
Johnson & Johnson (China) Investment Ltd.	China
Johnson & Johnson (Ecuador) S.A.	Ecuador
Johnson & Johnson (Hong Kong) Limited	Hong Kong
Johnson & Johnson (Ireland) Limited	Ireland
Johnson & Johnson (Kenya) Limited	Kenya
Johnson & Johnson (Mozambique), Limitada	Mozambique
Johnson & Johnson (Namibia) (Proprietary) Limited	Namibia
Johnson & Johnson (New Zealand) Limited	New Zealand
Johnson & Johnson (Philippines), Inc.	Philippines
Johnson & Johnson (Private) Limited	Zimbabwe
Johnson & Johnson (Trinidad) Limited	Trinidad and Tobago
Johnson & Johnson (Vietnam) Co., Ltd	Vietnam
Johnson & Johnson AB	Sweden
Johnson & Johnson AG	Switzerland
Johnson & Johnson Bulgaria EOOD	Bulgaria
Johnson & Johnson d.o.o.	Slovenia
Johnson & Johnson de Chile S.A.	Chile
Johnson & Johnson de Mexico, S.A. de C.V.	Mexico
Johnson & Johnson de Uruguay S.A.	Uruguay

Name of Subsidiary	Jurisdiction
Johnson & Johnson do Brasil Industria E Comercio de Produtos Para Saude Ltda.	Brazil
Johnson & Johnson Dominicana, S.A.S.	Dominican Republic
Johnson & Johnson European Treasury Unlimited Company	Ireland
Johnson & Johnson Finance Limited	United Kingdom
Johnson & Johnson Financial Services GmbH	Germany
Johnson & Johnson for Export and Import LLC	Egypt
Johnson & Johnson GT, Sociedad Anónima	Guatemala
Johnson & Johnson Healthcare SPC	Kuwait
Johnson & Johnson Hemisferica S.A.	Puerto Rico
Johnson & Johnson Holding GmbH	Germany
Johnson & Johnson Holdings (Austria) GmbH	Austria
Johnson & Johnson Innovation Limited	United Kingdom
Johnson & Johnson International (Singapore) Pte. Ltd.	Singapore
Johnson & Johnson International Financial Services Unlimited Company	Ireland
Johnson & Johnson Irish Finance Company Limited	Ireland
Johnson & Johnson K.K.	Japan
Johnson & Johnson Kazakhstan Limited Liability Partnership	Kazakhstan
Johnson & Johnson Kft.	Hungary
Johnson & Johnson LLC	Russian Federation
Johnson & Johnson Management Limited	United Kingdom
Johnson & Johnson Medical (China) Ltd.	China
Johnson & Johnson Medical (Proprietary) Ltd	South Africa
Johnson & Johnson Medical (Shanghai) Ltd.	China
Johnson & Johnson Medical (Suzhou) Ltd.	China
Johnson & Johnson Medical B.V.	Netherlands
Johnson & Johnson Medical GmbH	Germany
Johnson & Johnson Medical Greece Single Member S.A.	Greece
Johnson & Johnson Medical Korea Ltd.	Korea, Republic of
Johnson & Johnson Medical Limited	United Kingdom
Johnson & Johnson Medical Mexico, S.A. de C.V.	Mexico
Johnson & Johnson Medical NV	Belgium
Johnson & Johnson Medical Products GmbH	Austria
Johnson & Johnson Medical Pty Ltd	Australia
Johnson & Johnson Medical S.A.	Argentina
Johnson & Johnson Medical S.p.A.	Italy
Johnson & Johnson Medical SAS	France
Johnson & Johnson Medical Saudi Arabia Limited	Saudi Arabia
Johnson & Johnson Medical Taiwan Ltd.	Taiwan (Province of China)
Johnson & Johnson Medical, S.C.S.	Venezuela, Bolivarian Republic of
Johnson & Johnson Medikal Sanayi ve Ticaret Limited Sirketi	Turkey
Johnson & Johnson MedTech (Thailand) Ltd.	Thailand
Johnson & Johnson Medtech Colombia S.A.S.	Colombia
Johnson & Johnson Medtech CR Limitada	Costa Rica
Johnson & Johnson MENA RHQ Limited	Saudi Arabia
Johnson & Johnson Middle East - Scientific Office	United Arab Emirates
Johnson & Johnson Middle East FZ-LLC	United Arab Emirates
Johnson & Johnson Morocco Societe Anonyme	Morocco
Johnson & Johnson Nordic AB	Sweden
Johnson & Johnson Pakistan (Private) Limited	Pakistan
Johnson & Johnson Pharmaceutical Ltd.	China
Johnson & Johnson Poland Sp. z o.o.	Poland
Johnson & Johnson Private Limited	India
Johnson & Johnson Romania S.R.L.	Romania
Johnson & Johnson S.E. d.o.o.	Croatia

Name of Subsidiary	Jurisdiction
Johnson & Johnson SDN. BHD.	Malaysia
Johnson & Johnson Sociedade Previdenciaria (Non Profit)	Brazil
Johnson & Johnson Surgical Vision India Private Limited	India
Johnson & Johnson Taiwan Ltd.	Taiwan (Province of China)
Johnson & Johnson Trading Limited	Saudi Arabia
Johnson & Johnson UK Treasury Company Limited	United Kingdom
Johnson & Johnson Ukraine II LLC	Ukraine
Johnson & Johnson Vision Care (Australia) Pty Ltd	Australia
Johnson & Johnson Vision Care (Shanghai) Ltd.	China
Johnson & Johnson Vision Care Ireland Unlimited Company	Ireland
Johnson & Johnson Vision Korea, Ltd.	Korea, Republic of
Johnson & Johnson, Lda	Portugal
Johnson & Johnson, S.A.	Spain
Johnson & Johnson, s.r.o.	Czech Republic
Johnson & Johnson, s.r.o.	Slovakia
Johnson and Johnson Sihhi Malzeme Sanayi Ve Ticaret Limited Sirketi	Turkey
La Concha Land Investment Corporation	Philippines
McNeil Panama, LLC	Panama
Medos International Sarl	Switzerland
Medos Sarl	Switzerland
Medos Sàrl, succursale de Neuchâtel (Branch)	Switzerland
Menlo Care De Mexico, S.A. de C.V.	Mexico
Mentor B.V.	Netherlands
Mentor Deutschland GmbH	Germany
Mentor Medical Systems B.V.	Netherlands
Neuravi Limited	Ireland
Obtech Medical Mexico, S.A. de C.V.	Mexico
OBTECH Medical Sarl	Switzerland
OMJ Holding GmbH	Switzerland
Omrix Biopharmaceuticals Ltd.	Israel
Omrix Biopharmaceuticals NV	Belgium
Orthospin Ltd.	Israel
Orthotaxy	France
preCARDIA	France
Proleader S.A.	Uruguay
PT Johnson and Johnson Indonesia Two	Indonesia
RespiVert Ltd.	United Kingdom
Serhum S.A. de C.V.	Mexico
Spectrum Vision Limited Liability Partnership	Kazakhstan
Surgical Process Institute Deutschland GmbH	Germany
Synthes Costa Rica S.C.R., Limitada	Costa Rica
SYNTHES GmbH	Germany
Synthes GmbH	Switzerland
Synthes Holding AG	Switzerland
Synthes Holding Limited	United Arab Emirates
SYNTHES Medical Immobilien GmbH	Germany
Synthes Medical Surgical Equipment & Instruments Trading LLC	United Arab Emirates
Synthes Produktions GmbH	Switzerland
Synthes S.M.P., S. de R.L. de C.V.	Mexico
Synthes Tuttlingen GmbH	Germany
UAB "Johnson & Johnson"	Lithuania
Vision Care Finance Unlimited Company	Ireland
Xian Janssen Pharmaceutical Ltd.	China

Name of Subsidiary	Jurisdiction
XO1 Limited	United Kingdom

EXHIBIT 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-264596, 333-211250, 333-181092, and 333-129542) and Form S-3 (No. 333-269836) of Johnson & Johnson of our report dated February 16, 2024 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/PricewaterhouseCoopers LLP
Florham Park, NJ
February 16, 2024

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT

I, Joaquin Duato, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (the "report") of Johnson & Johnson (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter (the Company's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

/s/ Joaquin Duato
Joaquin Duato
Chief Executive Officer

Date: February 16, 2024

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT

I, Joseph J. Wolk certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (the "report") of Johnson & Johnson (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter (the Company's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

/s/ Joseph J. Wolk
Joseph J. Wolk
Chief Financial Officer

Date: February 16, 2024

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT

The undersigned, Joaquin Duato, the Chief Executive Officer of Johnson & Johnson, a New Jersey corporation (the "Company"), pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certifies that, to the best of my knowledge:

(1) the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (the "Report") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Joaquin Duato
Joaquin Duato
Chief Executive Officer

Dated: February 16, 2024

This certification is being furnished to the SEC with this Report on Form 10-K pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section.

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT

The undersigned, Joseph J. Wolk, the Chief Financial Officer of Johnson & Johnson, a New Jersey corporation (the "Company"), pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certifies that, to the best of my knowledge:

(1) the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (the "Report") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Joseph J. Wolk
Joseph J. Wolk
Chief Financial Officer

Dated: February 16, 2024

This certification is being furnished to the SEC with this Report on Form 10-K pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section.

Exhibit 97

JOHNSON & JOHNSON

CLAWBACK POLICY

The Board of Directors (the "Board") of Johnson & Johnson (the "Company") has determined that it is appropriate for the Company to adopt this Clawback Policy (the "Policy") to be applied to the Executive Officers of the Company as of the Effective Date.

1. Definitions

For purposes of this Policy, the following definitions shall apply:

a. "Committee" means the Compensation and Benefits Committee of the Board.

b. "Company Group" means the Company and each of its Subsidiaries, as applicable.

c. "Covered Compensation" means any Incentive-Based Compensation granted, vested or paid to a person who served as an Executive Officer at any time during the performance period for the Incentive-Based Compensation and that was received (i) on or after the effective date of NYSE listing standard Section 303A.14, (ii) after the person became an Executive Officer and (iii) at a time that the Company had a class of securities listed on a national securities exchange or a national securities association.

d. "Effective Date" means August 8, 2023.

e. "Erroneously Awarded Compensation" means the amount of Covered Compensation granted, vested or paid to a person during the fiscal period when the applicable Financial Reporting Measure relating to such Covered Compensation was attained that exceeds the amount of Covered Compensation that otherwise would have been granted, vested or paid to the person had such amount been determined based on the applicable Restatement, computed without regard to any taxes paid (i.e., on a pre-tax basis). For Covered Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in a Restatement, the Committee will determine the amount of such Covered Compensation that constitutes Erroneously Awarded Compensation, if any, based on a reasonable estimate of the effect of the Restatement on the stock price or total shareholder return upon which the Covered Compensation was granted, vested or paid and the Committee shall maintain documentation of such determination and provide such documentation to the NYSE.

f. "Exchange Act" means the Securities Exchange Act of 1934.

g. "Executive Officer" means each "officer" of the Company as defined under Rule 16a-1(f) under Section 16 of the Exchange Act, which shall be deemed to include any individuals identified by the Company as executive officers pursuant to Item 401(b) of Regulation S-

K under the Exchange Act. Both current and former Executive Officers are subject to the Policy in accordance with its terms.

h. "Financial Reporting Measure" means (i) any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures and may consist of GAAP or non-GAAP financial measures (as defined under Regulation G of the Exchange Act and Item 10 of Regulation S-K under the Exchange Act), (ii) stock price or (iii) total shareholder return. Financial Reporting Measures may or may not be filed with the SEC and may be presented outside the Company's financial statements, such as in Managements' Discussion and Analysis of Financial Conditions and Result of Operations or in the performance graph required under Item 201(e) of Regulation S-K under the Exchange Act.

i. "Home Country" means the Company's jurisdiction of incorporation.

j. "Incentive-Based Compensation" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

k. "Lookback Period" means the three completed fiscal years (plus any transition period of less than nine months that is within or immediately following the three completed fiscal years and that results from a change in the Company's fiscal year) immediately preceding the date on which the Company is required to prepare a Restatement for a given reporting period, with such date being the earlier of: (i) the date the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare a Restatement, or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare a Restatement. Recovery of any Erroneously Awarded Compensation under the Policy is not dependent on if or when the Restatement is actually filed.

l. "NYSE" means the New York Stock Exchange.

m. Received. Incentive-Based Compensation is deemed received in the Company's fiscal period during which the Financial Reporting Measure specified in or otherwise relating to the Incentive-Based Compensation award is attained, even if the grant, vesting or payment of the Incentive-Based Compensation occurs after the end of that period.

n. "Restatement" means a required accounting restatement of any Company financial statement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including (i) to correct an error in previously issued financial statements that is material to the previously issued financial statements (commonly referred to as a "Big R" restatement) or (ii) to correct an error in previously issued financial statements that is not material to the previously issued financial statements but that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (commonly referred to as a "little r" restatement), within the meaning of Exchange Act Rule 10D-1 and NYSE listing standard Section 303A.14. Changes to the Company's financial statements that do not represent error corrections under the then-current relevant accounting standards will not

constitute Restatements. Recovery of any Erroneously Awarded Compensation under the Policy is not dependent on fraud or misconduct by any person in connection with the Restatement.

o. "SEC" means the United States Securities and Exchange Commission.

p. "Subsidiary" means any domestic or foreign corporation, partnership, association, joint stock company, joint venture, trust or unincorporated organization "affiliated" with the Company, that is, directly or indirectly, through one or more intermediaries, "controlling", "controlled by" or "under common control with", the Company. "Control" for this purpose means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of such person, whether through the ownership of voting securities, contract or otherwise.

2. Recoupment of Erroneously Awarded Compensation

In the event of a Restatement, any Erroneously Awarded Compensation received during the Lookback Period prior to the Restatement (a) that is then-outstanding but has not yet been paid shall be automatically and immediately forfeited and (b) that has been paid to any person shall be subject to reasonably prompt repayment to the Company Group in accordance with Section 3 of this Policy. The Committee must pursue (and shall not have the discretion to waive) the forfeiture and/or repayment of such Erroneously Awarded Compensation in accordance with Section 3 of this Policy, except as provided below.

Notwithstanding the foregoing, the Committee (or, if the Committee is not composed entirely of independent directors, a majority of the independent directors serving on the Board) may determine not to pursue the forfeiture and/or recovery of Erroneously Awarded Compensation from any person if the Committee determines that such forfeiture and/or recovery would be impracticable due to any of the following circumstances: (i) the direct expense paid to a third party (for example, reasonable legal expenses and consulting fees) to assist in enforcing the Policy would exceed the amount to be recovered (following reasonable attempts by the Company Group to recover such Erroneously Awarded Compensation, the documentation of such attempts, and the provision of such documentation to the NYSE), (ii) pursuing such recovery would violate the Company's Home Country laws adopted prior to November 28, 2022 (provided that the Company obtains an opinion of Home Country counsel acceptable to the NYSE that recovery would result in such a violation and provides such opinion to the NYSE), or (iii) recovery would likely cause any otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of Company Group, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

3. Means of Repayment

In the event that the Committee determines that any person shall repay any Erroneously Awarded Compensation, the Committee shall provide written notice to such person by email or certified mail to the physical address on file with the Company Group for such person, and the person shall satisfy such repayment in a manner and on such terms as required by the Committee, and the Company Group shall be entitled to set off the repayment amount against any amount owed to the person by the Company Group, to require the forfeiture of any award granted by the Company Group to the person, or to take any and all necessary actions to reasonably promptly

recoup the repayment amount from the person, in each case, to the fullest extent permitted under applicable law, including without limitation, Section 409A of the Internal Revenue Code and the regulations and guidance thereunder. If the Committee does not specify a repayment timing in the written notice described above, the applicable person shall be required to repay the Erroneously Awarded Compensation to the Company Group by wire, cash or cashier's check no later than thirty (30) days after receipt of such notice.

4. No Indemnification

No person shall be indemnified, insured or reimbursed by the Company Group in respect of any loss of compensation by such person in accordance with this Policy, nor shall any person receive any advancement of expenses for disputes related to any loss of compensation by such person in accordance with this Policy, and no person shall be paid or reimbursed by the Company Group for any premiums paid by such person for any third-party insurance policy covering potential recovery obligations under this Policy. For this purpose, "indemnification" includes any modification to current compensation arrangements or other means that would amount to *de facto* indemnification (for example, providing the person a new cash award which would be cancelled to effect the recovery of any Erroneously Awarded Compensation). In no event shall the Company Group be required to award any person an additional payment if any Restatement would result in a higher incentive compensation payment.

5. Miscellaneous

This Policy generally will be administered and interpreted by the Committee. Any determination by the Committee with respect to this Policy shall be final, conclusive and binding on all interested parties. The determinations of the Committee under this Policy need not be uniform with respect to all persons, and may be made selectively amongst persons, whether or not such persons are similarly situated.

This Policy is intended to satisfy the requirements of Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, as it may be amended from time to time, and any related rules or regulations promulgated by the SEC or the NYSE, including any additional or new requirements that become effective after the Effective Date which upon effectiveness shall be deemed to automatically amend this Policy to the extent necessary to comply with such additional or new requirements.

The provisions in this Policy are intended to be applied to the fullest extent of the law. To the extent that any provision of this Policy is found to be unenforceable or invalid under any applicable law, such provision will be applied to the maximum extent permitted and shall automatically be deemed amended in a manner consistent with its objectives to the extent necessary to conform to applicable law. The invalidity or unenforceability of any provision of this Policy shall not affect the validity or enforceability of any other provision of this Policy. Recoupment of Erroneously Awarded Compensation under this Policy is not dependent upon the Company Group satisfying any conditions in this Policy, including any requirements to provide applicable documentation to the NYSE.

The rights of the Company Group under this Policy to seek forfeiture or reimbursement are in addition to, and not in lieu of, any rights of recoupment, or remedies or rights other than recoupment, that may be available to the Company Group pursuant to the terms of any law,

government regulation or stock exchange listing requirement or any other policy, code of conduct, employee handbook, employment agreement, equity award agreement, or other plan or agreement of the Company Group.

6. Amendment and Termination

To the extent permitted by, and in a manner consistent with applicable law, including SEC and NYSE rules, the Committee may terminate, suspend or amend this Policy at any time in its discretion.

7. Successors

This Policy shall be binding and enforceable against all persons and their respective beneficiaries, heirs, executors, administrators or other legal representatives with respect to any Covered Compensation granted, vested or paid to or administered by such persons or entities.

Exhibit “J2”

This is Exhibit “J2” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.
Arash Rouhi

Health Canada Santé Canada

Guidance Document

Information and Submission Requirements for Biosimilar Biologic Drugs

Published by authority of the
Minister of Health

Date Adopted	2010-03-05
Revised Date	2016-11-14
Administrative Changes Date	2017-04-20
Revised Date	2022-08-26

Health Products and Food Branch

Canada

Our mission is to help the people of Canada maintain and improve their health. *Health Canada*	Our mandate is to take an integrated approach to managing the health-related risks and benefits of health products and food by: • minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, • promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. *Health Products and Food Branch*

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Web address: www.hc-sc.gc.ca/index-eng.php

Également disponible en français sous le titre : Ligne directrice - Exigences en matière de renseignements et de présentation relatives aux médicaments biologiques biosimilaire

Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document ***may be*** acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant programme area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy, or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

Document Change Log

Version	Change made	Date
1	Initial issuance of document	2010-03-05
2	Comprehensive revision	2016-11-14
3	2.3.5 Labelling requirements - Product Monograph • Section revised with reference to the *Product Monograph Template - Schedule D - Biosimilar Biologic Drug* added	2017-04-20
4	2.4.2 Post-notice of compliance (NOC) changes • Section revised to apply the labelling-only fee to Supplemental New Drug Submissions seeking the addition of an indication with no/minimal data	2022-08-26

Table of Contents

1. INTRODUCTION

Health Canada, the federal regulatory authority that evaluates the safety, efficacy, and quality of drugs available in Canada, recognises that with the expiration of patents for biologic drugs, manufacturers may be interested in pursuing subsequent entry versions of these biologic drugs. The term biosimilar biologic drug, hereafter referred to as biosimilar, is used by Health Canada to describe subsequent entry versions of a Canadian approved innovator biologic with demonstrated similarity to a reference biologic drug. Biosimilars were previously referred to as Subsequent Entry Biologics (SEBs) in Canada.

1.1 Objective

The objective of this document is to provide guidance to sponsors to enable them to satisfy the information and regulatory requirements under the *Food and Drugs Act* and Part C of the *Food and Drug Regulations* for the authorization of biosimilars in Canada.

1.2 Scope and application

This guidance document applies to all biologic drug submissions where the sponsor seeks authorization for sale based on demonstrated similarity to a previously approved biologic drug and relies, in part, on prior information regarding that biologic drug in order to present a reduced clinical and non-clinical package as part of the submission.

The following criteria determine the scope of products that are eligible to be authorized as biosimilars:

- a suitable reference biologic drug exists that: a) was originally authorized for sale based on a full quality, non-clinical and clinical data package; and b) has been used in the post market setting such that the demonstration of similarity will bring into relevance a substantial body of reliable data on safety, efficacy and effectiveness;
- the biosimilar and reference biologic drug can be well characterized by a set of modern analytical methods;
- the biosimilar, through extensive characterization and analysis, can be judged similar to the reference biologic drug by meeting an appropriate set of pre-determined criteria.

The demonstration of similarity depends upon detailed and comprehensive product characterization. This guidance applies to biologic drugs that contain, as their active substances, well characterized proteins derived through modern biotechnological methods such as use of recombinant DNA and/or cell culture.

Biosimilars employing clearly different approaches to manufacture than the reference biologic drug may be eligible; however, careful consideration should be given to expression system

differences that may present challenges to demonstrating similarity to the reference biologic drug.

In this guidance document, "must" is used to express a requirement that the user is obliged to satisfy in order to comply with the regulatory requirements; "should" is used to express a recommendation or that which is advised but not required; and "may" is used to express an option or that which is permissible within the limits of the guidance document.

1.3 Policy statements

The following statements outline the fundamental concepts and principles of the regulatory framework for biosimilars:

1.3.1 The sponsor is responsible for providing the necessary evidence to support all aspects of a biosimilar submission.

1.3.2 A biosimilar sponsor is eligible to apply for the indication(s) and condition(s) of use that are held by the reference biologic drug authorized in Canada.

1.3.3 Biosimilars are new drugs subject to the *Food and Drugs Act* and Part C of the *Food and Drug Regulations*. The concepts and the scientific and regulatory principles within the existing regulatory frameworks for biologic, pharmaceutical, and generic pharmaceutical drugs are used as the basis for the regulatory framework for biosimilars.

1.3.4 The basis for accepting a reduced non-clinical and clinical data package for a biosimilar hinges on demonstrated similarity between the biosimilar and the suitable reference biologic drug. A final determination of similarity will be based on the entire submission, including data derived from comparative structural, functional, non-clinical and clinical studies.

1.3.5 Biosimilars are not "generic biologics" and many characteristics associated with the authorization process and marketed use for generic pharmaceutical drugs do not apply. Authorization of a biosimilar is not a declaration of pharmaceutical equivalence, bioequivalence or clinical equivalence to the reference biologic drug.

1.3.6 A biosimilar submission involves a comparison to another product. Hence all biosimilars are subject to the laws, and patent and intellectual property principles outlined within the *Food and Drug Regulations (Data Protection)*, *Patented Medicines (Notice of Compliance) Regulations*, and the *Patent Act*.

1.3.7 As a biosimilar is authorized using a reduced non-clincial and clinical package, it should not be used as a reference biologic drug for another biosimilar submission.

1.4 Definitions

Biologic drug (Médicament biologique)
A drug listed in Schedule D to the *Food and Drugs Act*. Schedule D lists individual products (such as *insulin*), product classes (such as *immunizing agents*), references to particular sources (such as "drugs, other than antibiotics, prepared from microorganisms"), and methodology (such as "drugs obtained by recombinant DNA procedures"). Biologic drugs are derived through the metabolic activity of living organisms and tend to be significantly more variable and structurally complex than chemically synthesized drugs.

Biosimilar biologic drug (Médicament biologique biosimilaire)
A biologic drug that obtains market authorization subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. A biosimilar relies in part on prior information regarding safety, efficacy and effectiveness that is deemed relevant due to the demonstration of similarity to the reference biologic drug and which influences the amount and type of original data required. Biosimilar biologic drugs were previously referred to as Subsequent Entry Biologics.

Reference biologic drug (Médicament biologique de référence)
A biologic drug authorized on the basis of a complete quality, non-clinical, and clinical data package, to which a biosimilar is compared to demonstrate similarity.

Specification (Spécification)
A specification is defined as a list of tests, references to analytical procedures, and appropriate acceptance criteria which are numerical limits, ranges, or other criteria for the tests described. It establishes the set of criteria to which a drug substance, drug product or materials at other stages of its manufacture should conform to be considered acceptable for its intended use.

Conformance to specification means that the drug substance and drug product, when tested according to the listed analytical procedures, will meet the acceptance criteria. Specifications are critical quality standards that are proposed and justified by the manufacturer and approved by regulatory authorities as conditions of approval.

Abbreviations and acronyms
ADA = Anti-Drug Antibody
ADR = Adverse Drug Reaction
BGTD = Biologics and Genetic Therapies Directorate
CTA = Clinical Trial Application
CTD = Common Technical Document
ICH = International Council for Harmonisation
NDS = New Drug Submission
NOC = Notice of Compliance

PK/PD = Pharmacokinetic/Pharmacodynamic
PBRER = Periodic Benefit-Risk Evaluation Reports
PSUR = Periodic Safety Update Reports
RMP = Risk Management Plan
SAM = Scientific Advice Meeting
SNDS = Supplemental New Drug Submission

1.5 Background

Biologic drugs have contributed to the health of Canadians through their use as treatments in the management of various complex diseases and medical conditions. Unlike pharmaceutical drugs, biologic drugs are derived through the metabolic activity of living organisms and are variable and structurally complex. Biologics tend to be labile and sensitive to changes in manufacturing processes. Biological source materials, production cells, or their fermentation media can present risks, such as the presence of pathogens or the growth of adventitious agents such as viruses. Due to these risks, careful attention is paid to raw material controls, viral/bacterial inactivation or clearance during product purification, and product testing. Changes to source materials, manufacturing processes, equipment, or facilities can result in significant unexpected changes to the intermediate and/or final product.

The expiration of patents and/or data protection for some biologic drugs is creating opportunities for subsequent entry versions. The term biosimilar is used by Health Canada to describe a biologic drug that receives market authorization subsequent to a version previously authorized in Canada and with demonstrated similarity to a reference biologic drug. Demonstration of similarity enables the sponsor to rely partially on relevant information about the reference biologic drug and to seek authorization based on a reduced non-clinical and clinical data package tailored to a particular class of products or to a specific case. In order to clearly distinguish between the regulatory process and product characteristics for biosimilars and those for generic pharmaceutical drugs, the terms “biogeneric” or “generic biologic” are not used.

The Biologics and Genetic Therapies Directorate (BGTD) within the Health Products and Food Branch of Health Canada is the regulator of biologic drugs for human use and provides regulatory oversight for biologics with its comprehensive reviews of biologic drug submissions covering quality, safety and efficacy.

2. GUIDANCE FOR IMPLEMENTATION

2.1 General

2.1.1 Applicable regulations

Biosimilars, like all new biologic drugs, are subject to Part C of the *Food and Drug Regulations* for authorization and oversight. Conforming to the guidance provided in this document, along with other guidance for biologics, should enable a sponsor to satisfy the following notable requirements in Part C, Division 8 of the *Food and Drug Regulations*:

> C.08.002 (1)(*a)*: No person shall sell or advertise a new drug unless the manufacturer of the new drug has filed with the Minister a new drug submission relating to the new drug that is satisfactory to the Minister.
>
> C.08.002 (2): A new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug.

2.1.2 Patents, intellectual property, and data protection

All biosimilars enter the market subsequent to a biologic drug product previously authorized in Canada and to which the biosimilar is considered similar. As such, biosimilars are subject to existing laws and regulations outlined in the *Patented Medicines (Notice of Compliance) Regulations* and C.08.004.1 of the *Food and Drug Regulations*, and related guidance documents entitled, *Guidance Document: Data Protection under C.08.004.1 of the Food and Drug Regulations* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/data_donnees_protection-eng.php) and *Guidance Document: Patented Medicines (Notice of Compliance) Regulations* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/patmedbrev/pmreg3_mbreg3-eng.php).

In the New Drug Submission (NDS), the biosimilar sponsor must clearly identify the biologic drug authorized in Canada to which it is subsequent and to which it is considered to be making a direct or indirect comparison according to the *Patented Medicines (Notice of Compliance) Regulations* and C.08.004.1 of the *Food and Drug Regulations*. In addition, where there is a non-Canadian reference biologic drug (refer to section 2.1.3), the sponsor must address the relationship between the non-Canadian reference biologic drug and the Canadian version.

2.1.3 Reference biologic drug

A biosimilar must be subsequent to a biologic drug that is authorized in Canada and to which a reference is made. Sponsors may use a non-Canadian sourced version as a proxy for the Canadian drug in the comparative studies. The onus is on the sponsor to demonstrate that the chosen reference biologic drug is suitable to support the submission. The sponsor should consult with BGTD early in the drug development process to ensure the suitability of the reference biologic drug.

The following should be considered when selecting a reference biologic drug:

- The dosage form(s), strength(s), and route(s) of administration of the biosimilar should be the same as that of the reference biologic drug.
- The same reference biologic drug should be used throughout the studies supporting the quality, safety and efficacy of the product (i.e. in the developmental programme for the biosimilar).
- In certain circumstances, it may be possible to use more than one reference biologic drug (e.g. versions of the reference biologic drug sourced from more than one jurisdiction) in clinical studies. As a scientific matter, the type of bridging data needed will always include structural and functional data from analytical studies that directly compares all the products (e.g. the proposed biosimilar product, the U.S.-authorized product, and the EU-authorized product) and may also include clinical pharmacokinetic (PK) and, if appropriate, clinical pharmacodynamic (PD) study data for all the products.
- The active substances (medicinal ingredients) of the biosimilar and the reference biologic drug must be shown to be similar.
- The reference biologic drug should have accumulated adequate safety, efficacy, and effectiveness data in the post market setting such that the demonstration of similarity will bring into relevance a substantial body of reliable data.

A biosimilar should not be used as a reference biologic drug, as it was authorized using a reduced non-clinical and clinical data package.

2.1.3.1 Considerations for the use of a non-Canadian reference biologic drug

In addition to section 2.1.3, the following should be considered when selecting a non-Canadian reference biologic drug used for the purposes of demonstrating similarity:

- The non-Canadian reference biologic drug should have the same medicinal ingredient(s), dosage form and route of administration as the version authorized in Canada. Information on the Canadian version can be found in Health Canada's Drug Product Database.
- The non-Canadian reference biologic drug should be marketed in a jurisdiction that formally adopts International Council for Harmonization (ICH) guidelines and that has regulatory standards and principles for evaluation of medicines, post-market surveillance activities, and approaches to comparability that are similar to Canada.
- If the non-Canadian reference biologic drug is used in clinical studies in Canada, data must be provided to satisfy chemistry and manufacturing (quality) information as per C.05.005 of the *Food and Drug Regulations*. Refer to section 2.2. for more information.

2.1.4 Review time

The target time for review of a biosimilar is the same as that for an NDS. Refer to the Health Canada *Guidance for Industry: Management of Drug Submissions* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/mgmt-gest/mands_gespd-eng.php) for details on review timelines.

2.2 Information requirements for clinical trial applications (CTA)

Clinical trials conducted in Canada involving biosimilars are subject to Part C, Division 5 of the *Food and Drug Regulations*, which outlines the requirements applicable to the sale and importation of drugs for use in human clinical trials in Canada. Clinical Trial Applications (CTAs) should be submitted in accordance with Health Canada's *Guidance for Clinical Trial Sponsors: Clinical Trial Applications* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clini/ctdcta_ctddec-eng.php) and the *Clinical Trials Manual* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clini/cta_intro-eng.php).

If a non-Canadian reference biologic drug is used in clinical studies in Canada, data must be provided to support its safety and to satisfy the intent of the regulatory requirements for chemistry and manufacturing (quality) information. At a minimum, this should include confirmation that the non-Canadian reference biologic drug is sourced from an ICH country and that there is evidence of a history of safe use in the country of origin.

If the comparative structural, functional and non-clinical *in vitro* studies are considered satisfactory and no issues are identified that would preclude administration into humans, *in vivo* animal studies may not be necessary.

Sponsors are encouraged to request scientific advice meetings and pre-CTA consultation meetings for biosimilars. Refer to Section 3 for information on biosimilar scientific advice meetings and Health Canada's *Guidance for Clinical Trial Sponsors: Clinical Trial Applications* for instructions on how to request a pre-CTA meeting.

2.3 Information requirements for new drug submissions (NDS)

Part C, Division 8 of the *Food and Drug Regulations* sets out the requirements for the sale of new drugs in Canada, which include biosimilars, and prohibits the sale of new drugs unless the manufacturer has filed a submission that is satisfactory to the Minister. Section C.08.002 of the *Food and Drug Regulations* outlines the requirements for an NDS.

2.3.1 Organization of data

Electronic documents should be provided in electronic common technical document (eCTD) format. The regulatory activities provided in eCTD format should be prepared using applicable sections of the *Guidance Document: Preparation of Drug Regulatory Activities in the Electronic Common Technical Document Format* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ectd/prep_ectd_format-eng.php).

Alternatively, Health Canada will also accept electronic documents in "non-eCTD electronic-only" format in accordance with the applicable sections of the *Guidance Document: Preparation of Drug Regulatory Activities in the "Non-eCTD Electronic-Only" Format* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ctd/gd_prep_non_ectd_ld-eng.php).

The assessment of similarity should be organized as a distinct collection of data in module 3 with an associated section in the Quality Overall Summary containing appropriate cross-references. However, the reorganization of modules 2 and 3 of a regulatory activity already prepared for another regulatory jurisdiction should not be necessary. Sponsors should provide a note to reviewers indicating the location and organization of the similarity assessment. The biosimilar sponsor is encouraged to consult with BGTD for further guidance.

2.3.2 Quality information

In addition to a typical chemistry and manufacturing data package that is expected for a standard new biologic drug, the biosimilar submission should include extensive data demonstrating similarity with the reference biologic drug. This should include characterization studies conducted in a side-by-side format. For consideration as a biosimilar, similarity should be deduced primarily from comprehensive and well rationalized quality studies.

If excipients do not limit the sensitivity of assays used for characterization, it may be feasible to undertake studies to demonstrate similarity using the formulated drug products. Frequently, studies comparing the drug substance will be beneficial or may be the only scientific option. If the reference drug substance used for characterization is isolated from a formulated reference drug product, additional studies should demonstrate that the drug substance is not changed by the isolation process. One approach to potentially qualifying the isolation process is to use the process on the formulated biosimilar drug product and compare the isolated (de-formulated) biosimilar drug substance to the biosimilar drug substance obtained prior to formulation. The approach used should be justified.

2.3.2.1 Quality considerations for demonstrating similarity

Although the comparison of two independent products is outside of the scope of *ICH Q5E: Comparability of Biotechnology/Biological Products Subject to Changes in their Manufacturing Process*, many of the principles and approaches are applicable.

The sponsor should demonstrate whether the biosimilar and the reference biologic drug can be judged highly similar in terms of quality attributes and thus support a possible conclusion of similarity for safety and efficacy. The product should be evaluated at the process steps most appropriate to detect a difference in the quality attributes. However, in most situations this evaluation will be limited to the drug substance, the drug product, or both. The extent of the studies necessary to demonstrate similarity will depend on the following:

- The nature of the product.
- The availability of suitable analytical techniques to detect potential product differences.
- The relationship between quality attributes and safety and efficacy based on overall non-clinical and clinical experience.
- Differences between the expression systems used to manufacture the biosimilar and the reference biologic drug.

When considering the similarity of products, the manufacturer should evaluate, for example:

- Relevant physicochemical and biological characterization data regarding quality attributes.
- Results from analysis of relevant samples from the appropriate stages of the manufacturing process (i.e. drug substance and drug product).
- Stability data, including those generated from accelerated or stress conditions, to provide insight into potential product differences in the degradation pathways of the drug product and, hence, potential differences in product-related substances and product-related impurities.
- Data obtained from multiple batches of the biosimilar and the reference biologic drug to help generate an understanding of ranges in variability. This evaluation may not entail performing all tests on all batches; a matrix approach may be possible but should be rationalized.

In addition to evaluating the data, the manufacturer should consider if the results provide insights regarding the following:

- Critical control points in the manufacturing process that affect product characteristics.

- Adequacy of the in-process controls including critical control points and in-process testing: in-process controls for the biosimilar should be confirmed, modified, or created, as appropriate, to maintain the quality of the product.

The comparative structural and functional studies will determine the type and extent of data to be derived from non-clinical and clinical studies on the drug product.

2.3.2.2 Quality considerations

Analytical Techniques

Analytical tests should be carefully selected and optimised to maximise the potential for detecting relevant differences in the quality attributes of the biosimilar and the reference biologic drug. It may be appropriate to modify existing tests used in biosimilar product development or to add new tests. To address the full range of physicochemical properties or biological activities, it may be appropriate to apply more than one analytical procedure to evaluate the same quality attribute. In such cases, each method should employ different physicochemical or biological principles to collect data for the same parameter to maximise the possibility that differences between the biosimilar and the reference biologic drug may be detected.

Measurement of quality attributes in characterization studies does not necessarily entail use of validated assays, but assays used should be scientifically sound and provide results that are reliable. Methods used to measure quality attributes for batch release should be validated in accordance with ICH guidelines, *ICH Q2(R1): Validation of Analytical Procedures: Text and Methodology*, *ICH Q5C: Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products*, and *ICH Q6B: Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products* as appropriate.

Characterization

Characterization of a biotechnological/biological product by appropriate techniques, as described in ICH Q6B, includes the determination of physicochemical properties, biological activity, immunochemical properties (if any), purity, impurities, contaminants and quantity.

A complete side-by-side characterization should be performed to directly compare the biosimilar and the reference biologic drug. The significance of any differences should be evaluated.

The following criteria should be considered as a key point when demonstrating similarity:

Physicochemical Properties

The manufacturer should consider the concept of the desired product (and its variants) as defined in ICH Q6B when designing and conducting studies to demonstrate similarity. The complexity of the molecular entity with respect to the degree of molecular heterogeneity should also be considered. The manufacturer should attempt to determine that the higher order structure (secondary, tertiary, and, where applicable, quaternary) is comparable. If appropriate higher order structural information cannot be obtained, a relevant biological activity assay (see biological activity below) could indicate a correct conformational structure.

Biological Activity

Biological assay results can serve multiple purposes in the confirmation of product quality attributes that are useful for characterization and batch analysis, and in some cases, could serve as a link to clinical activity. The manufacturer should consider the limitations of biological assays, such as high variability, that may prevent detection of differences between two highly similar products.

In cases where the biological assay also serves as a complement to physicochemical analysis (e.g. as a surrogate assay for higher order structure), the use of a relevant biological assay with appropriate precision and accuracy may provide a suitable approach to confirm that a change in specific higher order structure has not occurred. Where physicochemical or biological assays are not considered adequate to confirm that the higher order structure is maintained, data from non-clinical or clinical studies may be supportive. However, too much reliance on such studies may indicate that consideration as a biosimilar is not appropriate.

When the products being compared have multiple biological or functional activities, a set of relevant functional assays designed to evaluate the range of activities should be utilized.

Where any of the multiple activities is not sufficiently correlated with clinical safety or efficacy, or if the mechanism of action is not understood, justification should be provided that non-clinical or clinical activity of the biosimilar associated with the clinical indication being sought is not compromised.

Immunochemical Properties

When immunochemical properties are part of the characterization (e.g. for antibodies or antibody-based products), the manufacturer should confirm that the specific properties of the biosimilar are comparable to those of the reference biologic drug.

Purity and Impurity

The combination of analytical procedures selected should provide data to allow evaluation of relevant differences in the purity and impurity profiles.

Differences observed in the purity and impurity profiles of the biosimilar relative to the reference biologic drug should be evaluated to assess their potential impact on safety and efficacy. Where the biosimilar exhibits different impurities, those impurities should be identified and characterized when possible. Depending on the impurity type and amount, the conduct of non-clinical and clinical studies will help to confirm that there is no adverse impact on safety or efficacy of the biosimilar. The potential impact of differences in the impurity profile upon safety should be addressed and supported by appropriate data.

Specifications

The tests and analytical procedures chosen to define drug substance or drug product specifications alone are not considered adequate to assess product differences since they are chosen to confirm the routine quality of the product rather than to fully characterize it. The manufacturer should confirm that the specifications chosen for the biosimilar are appropriate to demonstrate product quality.

Stability

For certain manufacturing processes, even slight differences in the production procedures used for the biosimilar and reference biologic drug may cause differences in the stability of the products.

Proteins are frequently sensitive to changes, such as those made to buffer composition, processing and holding conditions, and the use of organic solvents. Therefore, real-time/real temperature stability studies should be conducted on the biosimilar and reference biologic drug to compare the stability behaviour of both using the same storage conditions and analytical methods. In some cases, it may be possible and beneficial to conduct side-by-side stability studies on samples that have been matched, as far as possible, with respect to date of manufacture.

Such stability studies may be able to detect subtle differences between the biosimilar and the reference biologic drug that are not readily detectable by the characterization studies.

For example, the presence of trace amounts of a protease may only be detected by product degradation that occurs over an extended time period. Or in some cases, divalent ions leached from the container closure system may change the stability profile because of the activation of trace proteases.

Accelerated and stress stability, forced degradation, and photostability studies are often useful tools to establish degradation profiles and can therefore contribute to a direct comparison of a biosimilar and the reference biologic drug. The results may show product differences that warrant additional evaluation. The results may also identify conditions indicating that additional controls should be employed in the manufacturing process and during storage of the biosimilar to eliminate these unexpected differences. Appropriate studies should be considered to confirm that suitable storage conditions and controls are selected.

ICH Q5C and *ICH Q1A (R2): Stability Testing of New Drug Substances and Products* should be consulted to determine the conditions for stability studies that provide relevant data for a product-to-product comparison.

2.3.2.3 Manufacturing process considerations

A well-defined manufacturing process with its associated process controls assures that an acceptable product is produced on a consistent basis.

Approaches to determining the impact of any process differences will vary with respect to the specific process, the product, the extent of the manufacturer's knowledge of and experience with the process and the development data generated.

Where details of the manufacturing process for the reference biologic drug are available to the biosimilar sponsor, a comparison with those for the biosimilar may help to identify which tests should be performed.

2.3.2.4 Determination of similarity

The demonstration of similarity does not signify that the quality attributes of the two products being compared are identical, but that they are highly similar with two consequences: 1) that the existing knowledge of both products is sufficient to predict that any differences in quality attributes should have no adverse impact upon safety or efficacy of the biosimilar; and 2) that non-clinical and clinical data previously generated with the reference biologic drug are relevant to the biosimilar.

A final determination of similarity will be based on all relevant data from structural, functional, non-clinical and clinical studies. To be considered a biosimilar, the weight of

evidence should be provided by the structural and functional studies. The degree of similarity at the quality level will determine the scope and the breadth of the required non-clinical and clinical data. The non-clinical and clinical programs should be designed to complement the structural and functional studies and address potential areas of residual uncertainty.

Consideration as a biosimilar may not be appropriate in situations where extensive reliance on the contribution of non-clinical and clinical studies would be expected, such as:

i) the analytical procedures used are not sufficient to discern relevant differences that can impact the safety and efficacy of the product; or
ii) the relationship between specific quality attributes and safety and efficacy has not been established, and differences between quality attributes of the biosimilar and the reference biologic drug are likely to be observed.

2.3.2.5 Manufacturing changes following issuance of market authorization

A biosimilar is a new drug with all of the associated regulatory requirements. For any changes to the manufacturing process that warrant a demonstration of comparability, the products to be compared will be the pre-change and post-change versions of the biosimilar. Studies should be conducted in accordance with ICH Q5E. Comparisons with the original reference biologic drug are not required.

2.3.3 Non-clinical and clinical information

2.3.3.1 General

Non-clinical and clinical requirements outlined in this guidance document are applicable to biosimilars that have been demonstrated to be similar to the reference biologic drug based on the results of the comparative structural and functional studies included in the chemistry and manufacturing data package. If similarity has not been established, reduced non-clinical and clinical data cannot be justified and the product cannot be considered a biosimilar.

This section provides general guidance on non-clinical and clinical information required for biosimilars. Specific requirements for drug classes (e.g. insulin and growth hormone) may differ depending on the class. Requirements may also differ depending on various clinical parameters related to each specific drug product or class, including elements such as therapeutic index and the type and number of indications for which biosimilar sponsors apply.

A biosimilar product sponsor is eligible to apply for one or more clinical indications granted to the reference biologic drug in Canada. Any claims made by the biosimilar sponsor must be supported by suitable scientific data. Proposals for indications and uses that are not supported by clinical data specific to the biosimilar can be considered for authorization; refer to Section 2.3.4 for additional information.

Clinical data should be generated based on the product for which market authorization is sought. Chemistry and manufacturing changes introduced during the clinical development phase or at the end of the clinical development program may result in the need for additional bridging data. Sponsors should refer to ICH Q5E and consult with BGTD for additional guidance.

2.3.3.2 Non-clinical studies

Where similarity is well established by structural and functional studies, and where extensive *in vitro* mechanistic studies are indicative of similarity, *in vivo* non-clinical studies may not be necessary. Refer to the Biological Activity section within 2.3.2.2. for more information on *in vitro* studies. Sponsors should provide a scientific justification for their approach and should consult with BGTD at the scientific advice and/or pre-submission stage.

If filed in more than one module, sponsors should provide a note to reviewers that communicates where in the e-CTD non-clinical studies are located.

Specialized toxicological studies, including safety pharmacology, reproductive toxicology, mutagenicity and carcinogenicity studies, are not generally required for a biosimilar submission.

2.3.3.3 Clinical studies

The purpose of the clinical program is to show that there are no clinically meaningful differences between the biosimilar and the reference biologic drug.

The clinical program should begin with a PK/PD study(ies) which may be followed by an additional clinical trial(s). Differences observed between the biosimilar and reference biologic drug, such as differences in immunogenicity, should be addressed. If differences cannot be addressed, the sponsor should consider whether the biosimilar submission route is still appropriate or whether the traditional new drug submission route would be more suitable.

Pharmacokinetic (PK) studies

Comparative PK studies should be conducted to rule out differences in PK characteristics between the biosimilar and the reference biologic drug.

PK studies should be carried out in healthy subjects when appropriate as they are usually considered to be a homogeneous and sensitive population. A low or sub-therapeutic dose residing on the linear part of the dose response curve should be considered if studies are performed in healthy subjects.

Studies should be conducted in the patient population when the PK or PK/PD in the patient population is known to be substantially altered by the disease states for which authorisation is requested. The dose(s) used in the PK studies in a relevant patient population should be within the therapeutic dosing range specified in the product monograph of the reference biologic drug.

The following factors should be taken into consideration during comparative PK study design (e.g. when choosing between cross-over versus parallel-group study):

- half-life of the biologics;
- linearity of PK parameters;
- where applicable, the endogenous levels and diurnal variations of the protein under study;
- conditions and diseases to be treated;
- route(s) of administration; and
- indications for which the biosimilar sponsor is applying.

General principles of study design and statistical methods for comparative bioavailability studies should be considered when assessing the similarity of the PK parameters between the biosimilar and the reference biologic drug. The PK comparison should not be limited to parameters reflecting absorption only. Parameters representing elimination (e.g. clearance and terminal half-life) should also be compared. Data should not be excluded from the analysis unless the exclusion can be justified and is considered acceptable by BGTD.

Acceptable criteria for the determination of similarity in comparative pharmacokinetics should be defined and justified prior to the initiation of PK study(ies). The acceptance criteria should be defined taking into consideration the PK parameters being evaluated and their variations, assay methodologies, and available safety and efficacy information regarding the reference biologic drug and the biosimilar. The criteria for comparative bioavailability studies as outlined in Health Canada's *Guidance Document: Conduct and Analysis of Comparative Bioavailability Studies* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/bio/gd_cbs_ebc_ld-eng.php) and *Comparative Bioavailability Standards: Formulations used for Systemic Effects* (http://www.hc-

sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/bio/gd_standards_ld_normes-eng.php) should be considered. When such criteria are not employed or not met in the comparative PK studies, a discussion should be provided regarding the implication of the findings in conjunction with data obtained from other clinical studies.

Pharmacodynamic (PD) studies

As for all other studies in the biosimilar developmental program, PD studies should be comparative in nature.

Parameters investigated in PD studies should be clinically relevant. Use of a particular PD marker should be scientifically justified. PD markers should be relevant to the mechanism of action of the drug but may not need to be established surrogates for efficacy.

In general, the principles regarding study design, conduct, analysis and interpretation that are relevant to equivalence trials with a clinical outcome as the primary endpoint are applicable to equivalence trials with a PD marker as the primary outcome.

PD studies should be combined with PK studies, in which case the PK/PD relationship should be characterized.

Clinical efficacy trial(s)

In most cases, a comparative clinical trial(s) is important to rule out clinically meaningful differences in efficacy and safety between the biosimilar and the reference biologic drug. A clinical efficacy trial may not always be necessary, e.g. where there is a clinically relevant PD endpoint. In such cases, a scientific justification is needed and safety as well as comparative immunogenicity data are still required.

The comparative clinical trial should be adequately sensitive to rule out clinically meaningful differences within predefined comparability margins. Sponsors should consider the following factors when designing an adequately sensitive clinical trial:

- The characteristics of the studied population(s) (e.g. underlying disease, immune competence).
- The characteristics of the clinical trials, such as study duration, route of administration, dosage regimen, clinical endpoint(s) and time of assessment.
- The risk and impact of immunogenicity.
- The impact of concomitant therapies (e.g. monotherapy vs. combination therapy).
- The use of appropriate comparability margins.

In some instances, evaluation of more than one sensitive population may be necessary.

Careful consideration should be given to the design of the study(ies) including the choice of primary efficacy endpoint(s) and clinical comparability margin. Each of these aspects are important and should be justified on clinical grounds. The study should be conducted using a clinically relevant and sensitive endpoint to show that there are no clinically meaningful differences between the biosimilar and reference biologic drug. The chosen endpoint could be different from the original study endpoint for the reference biologic drug (e.g. a well-established surrogate or a more sensitive endpoint). In all cases, an acceptable comparability margin should be defined taking into account the smallest effect size that the reference biologic drug would reliably be expected to have based on publicly available historical data. If multiple endpoints are used, then the principles described above should apply.

In line with the principle of similarity, equivalence trials are generally preferred. If non-inferiority trials are considered, they should be clearly justified and sponsors are advised to consult with BGTD prior to study initiation. Sponsors should be aware that the results from such trials could suggest statistical superiority of the biosimilar relative to the reference biologic drug. In such instances, the superiority observed should be assessed for clinical relevance including its impact on safety. In the event that the superiority observed is considered clinically meaningful and/or is associated with increased adverse drug reactions over those seen with the reference biologic drug, the product would no longer be considered as a biosimilar. In addition, demonstration of non-inferiority of the biosimilar to the reference biologic drug might not provide strong support for the authorization of other indications, particularly if the other indications include different dosages than those tested in the clinical trial.

Safety

The nature, severity and frequency of adverse events should be compared between the biosimilar and the reference biologic drug. Efforts should be made to ensure that comparative clinical studies have a sufficient number of patients treated for an acceptable period of time in order to rule out clinically meaningful differences in safety between the biosimilar and the reference biologic drug.

Immunogenicity

The purpose of the comparative immunogenicity study(ies) is to rule out clinically meaningful differences in immunogenicity between the biosimilar and the reference biologic drug. Of most concern are those antibodies that have the potential to impact safety and/or efficacy; for example, by altering PK, inducing anaphylaxis, or by neutralising the product and/or its endogenous protein counterpart. For each treatment

arm, the comparative study(s) should characterise the incidence and magnitude of the anti-drug antibody (ADA) response, the time-course of ADA development, ADA persistence, and the impact of ADA on safety, efficacy and PK.

A suitable population should be selected in which to compare immunogenicity. In selecting an appropriate population, factors such as immunocompetence, prior or concomitant use of immunosuppressant therapies, and historical data with respect to the immunogenicity of the reference biologic drug should be considered. Because the investigation of immunogenicity is usually undertaken as part of the pivotal comparative safety and efficacy study(ies), it is important that the aforementioned factors are considered during the design of the clinical portion of the program to demonstrate biosimilarity.

Comparative immunogenicity testing should be conducted using a tiered approach that involves screening assays, confirmatory assays and assays to determine whether binding ADA are neutralising. Independent binding ADA assays incorporating the biosimilar or the reference biologic drug as the capture ligand should be developed in parallel. Each assay should be validated and have demonstrated ability to sensitively detect ADA in the presence of drug. Samples from both treatment arms should be tested for ADA using both assays to demonstrate ADA cross-reactivity against the biosimilar and the reference biologic drug. Deviation from this approach should be scientifically justified.

Patient samples that test positive for binding ADA in confirmatory binding assays should be tested for their ability to neutralise the drug unless there exists a strong rationale for not doing so. The selection of an appropriate format for neutralising antibody testing is important and should take into account the mechanism of action of the drug. Depending on the mechanism of action, competitive ligand binding assays or cell based assays may be appropriate.

2.3.4 Authorization of indications

A biosimilar sponsor may request authorization for all indications held by the biologic drug authorized in Canada to which a reference is made.

The decision to authorize the requested indications is dependent on the demonstration of similarity between the biosimilar and reference biologic drug based on data derived from comparative structural, functional, non-clinical and clinical studies. Where similarity has been established, indications may be granted even if clinical studies are not conducted in each indication. A detailed rationale that scientifically justifies authorization of the biosimilar in each indication should be provided taking into consideration mechanism(s) of action, pathophysiological mechanism(s) of the disease(s) or conditions involved, safety profile, dosage regimen, clinical experience with the reference biologic drug, and

any case-by-case considerations. Certain situations may warrant additional clinical data for a particular indication.

Situations where a clinical indication being sought is not authorized in Canada for the reference biologic drug fall outside the scope of this guidance document.

2.3.5 Labelling requirements - Product Monograph

The product monograph for a biosimilar should be developed in a manner consistent with the principles, practices and processes outlined in the *Guidance Document: Product Monograph* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/monograph/pm_mp_2013-eng.php). Sponsors should use the *Product Monograph Template - Schedule D - Biosimilar Biologic Drug* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/monograph/pmappj_mpannj-eng.php) when preparing a product monograph for a biosimilar.

The contents of the product monograph for biosimilars should include the following information:

- A statement indicating that the product is a biosimilar to the reference biologic drug.
- A statement that indications have been granted on the basis of similarity between the biosimilar and the reference biologic drug.
- Comparative data generated by the biosimilar sponsor on which the decision for market authorization was made summarized in a tabular format.
- Relevant safety and efficacy information from the product monograph of the biologic drug authorized in Canada to which a reference is made, including warnings and precautions, Adverse Drug Reactions/Adverse Drug Effects and key post-market safety information for all indications that are authorized for the biosimilar.

There should be no claims for bioequivalence or clinical equivalence between the biosimilar and the reference biologic drug.

2.3.6 Risk Management Plan

A risk management plan (RMP) should be submitted as part of the drug submission. The RMP should be designed to monitor and detect both known inherent safety concerns and potentially unknown safety signals that may result from the impurity profile and other characteristics of the biosimilar. The biosimilar sponsor should continue the assessment of unwanted immunogenicity and its clinical significance following market authorization.

The RMP should consider all identified and potential risks associated with the use of the reference biologic drug and should provide details on how these risks will be addressed in a post-market setting.

Health Canada will work with sponsors to ensure a suitable RMP is developed prior to authorization of the product. The minimum surveillance criteria for the biosimilar should be described in accordance with requirements for a new biologic drug. The RMP should include detailed information on systematic evaluation of the immunogenicity potential of the biosimilar.

The RMP should include specific (routine or additional) pharmacovigilance and risk minimisation activities similar to those in place for the reference biologic drug or justify that these activities are not relevant for the biosimilar.

A discussion about methods to distinguish adverse event reports for the biosimilar from those for other licensed products, including the reference product should be included. The RMP should be maintained and implemented throughout the life-cycle of the product.

For more information on RMPs, please refer to the *Guidance Document - Submission of Risk Management Plans and Follow-up Commitments*(http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2015-risk-risques_management-gestion_plans/index-eng.php).

2.4 Post-market requirements

2.4.1 Adverse drug reaction (ADR) reporting and periodic reports

Sponsors are required to comply with sections C.01.016 to C.01.019 of the *Food and Drug Regulations*, which includes ADR reporting.

On an annual basis or as requested by the Director, the manufacturer will conduct a concise, critical analysis of the adverse drug reactions and serious adverse drug reactions after such an occurrence. After an analysis, the Director may request written summary reports where safety is questionable.

Periodic safety update reports (PSURs) or periodic benefit-risk evaluation reports (PBRERs) should be prepared and/or submitted as discussed in the risk management plan. The periodicity for the submission of PSURs or PBRERs should be consistent with appropriate ICH guidelines for marketed products, or as determined by the Minister, when the product is authorized for market. For more information on PBRERs, please refer to the Health Canada *Guidance Document - Periodic Benefit-Risk Evaluation Report (PBRER) International Conference on Harmonisation (ICH) Topic E2C(R2)*

(http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e2c(r2)_step4_etape4-eng.php).

2.4.2 Post-notice of compliance (NOC) changes

A biosimilar is a new drug with all of the associated regulatory requirements. For guidance on post- NOC changes, refer to the applicable Health Canada guidance documents *Post-Notice of Compliance (NOC) Changes: Framework Document* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/postnoc_change_apresac/noc_pn_framework_ac_sa_cadre-eng.php), *Post-Notice of Compliance (NOC) Changes: Safety and Efficacy Document* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/postnoc_change_apresac/noc_pn_saf_ac_sa_inn-eng.php) and *Post-Notice of Compliance (NOC) Changes: Quality Document* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/postnoc_change_apresac/noc_pn_quality_ac_sa_qualite-eng.php).

Biosimilar sponsors should follow labelling requirements set out in the post-NOC guidance documents referenced above. This includes monitoring any product class type-specific safety information that may indicate the need for a change in labelling.

There may be situations post-NOC where biosimilar sponsors seek authorization of indications held by the reference biologic drug authorized in Canada. A Supplemental New Drug Submission (SNDS) for a biosimilar that relies on the previously demonstrated similarity provided in the original biosimilar NDS may be considered by Health Canada on a case-by-case basis. If accepted for review, these submission would generally be considered a labelling-only SNDS. Biosimilar sponsors should consult with BGTD for regulatory guidance for their specific SNDS.

3. CONSULTATION WITH THE BIOLOGICS AND GENETIC THERAPIES DIRECTORATE (BGTD)

Biosimilar sponsors are encouraged to consult with BGTD for regulatory guidance as early as possible in the development of their biosimilar submission package. Consultation can occur at any stage of the development of a biosimilar.

BGTD is undergoing a 3 year pilot to explore a stepwise review approach that would be complementary to the biosimilar development process. During the pilot, a biosimilar sponsor may request a Scientific Advice Meeting (SAM) in order to receive advice from BGTD on their quality package early in the development process. Sponsors should ensure their drug meets the eligibility criteria for a biosimilar as outlined in this guidance. Sponsors wishing to participate in the pilot should contact the Office of Regulatory Affairs.

For more information, please refer to the *Notice - Subsequent Entry Biologics Scientific Advice Meeting Pilot* (http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/subsequent-entry-biologics-produits-bio-ulterieurs-eng.php).

4. ADDITIONAL INFORMATION

Health Canada will review this guidance document on an ongoing basis in response to new scientific knowledge, best practices and/or experience gained by the Department.

Contact Information:

Questions concerning biosimilar submissions should be directed to:

Office of Regulatory Affairs
Biologics and Genetic Therapies Directorate
Health Products and Food Branch
Health Canada
E-mail: brdd.ora@hc-sc.gc.ca

Questions or comments on this guidance document should be directed to:

Office of Policy and International Collaboration
Biologics and Genetic Therapies Directorate
Health Products and Food Branch
Health Canada
Email: brddopic-bpcidmbr@hc-sc.gc.ca

Exhibit “J3”

This is Exhibit “J3” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.
Arash Rouhi

Health Canada Santé Canada

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Guidance Document

Data Protection under C.08.004.1 of the Food and Drug Regulations

Date adopted:	2009/03/11
Revised date:	2021/04/08
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Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

Également disponible en français sous le titre :
Ligne directrice : La protection des données en vertu de l'article C.08.004.1 du Règlement sur les aliments et drogues

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Document change log

Date	Change	Location (section, paragraph)	Nature of and/or Reason for Change
2021/04/08	Updated in accordance with the new Health Products and Food Branch organizational structure	Throughout	Change in Health Products and Food Branch organizational structure.
2017/05/16	Clarification following judicial considerations and reflecting current practices	All	The updates to the Guidance Document are being made to clarify the interpretation of “innovative drug” following the judicial considerations of the data protection provisions and to reflect current administrative practices.
2011/10/11	Clarification to section 2.1	2.1	The clarifications to the Guidance Document are being made in light of recent inquiries in respect to the interpretation of the definition of “innovative drug” for veterinary drugs and for human drugs under subsection C.08.004.1(1) of the Food and Drug Regulations.
2010/03/08	Change to scope of Data Protection	2.1 & 3.1	Updated to reflect the administration of the data protection provisions in light of the finalized Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs).

Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate scientific justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this guidance, in order to allow the Department to adequately assess the safety, efficacy, or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidances.

Table of Contents

1. Introduction

1.1 Policy objectives

The determination of what is an innovative drug eligible for data protection in accordance with subsection C.08.004.1(1) of the Food and Drug Regulations is to be made with a view to the purpose articulated in subsection C.08.004.1(2), which is stated as follows:

> The purpose of this section is to implement Article 1711 of the North American Free Trade Agreement, as defined in the definition Agreement in subsection 2(1) of the North American Free Trade Agreement Implementation Act, and paragraph 3 of Article 39 of the Agreement on Trade-related Aspects of Intellectual Property Rights set out in Annex 1C to the Agreement Establishing the World Trade Organization, as defined in the definition Agreement in subsection 2(1) of the World Trade Organization Agreement Implementation Act.

Furthermore, Canada's obligations under the North American Free Trade Agreement and the Agreement on Trade-Related Aspects of Intellectual Property Rights require the granting of protection for undisclosed test or other data necessary to determine the safety and effectiveness of a pharmaceutical product which utilizes a new chemical entity, the origination of which involved considerable effort.

1.2 Policy statements

Section C.08.004.1 of the Food and Drug Regulations is intended to provide the manufacturer of an innovative drug with an internationally competitive, guaranteed minimum period of market exclusivity of eight years. The introduction of this market exclusivity will provide an adequate incentive for innovators to invest in research, and to develop and market their products in Canada. An additional six-month extension will be applied if an innovator includes clinical trials which were designed and conducted with the purpose of increasing knowledge about the use of the drug in pediatric populations. Extending market exclusivity in this manner will encourage pediatric research and improve drug information regarding pediatric usage for health professionals, thus providing health benefits to children.

1.3 Scope and application

This guidance document provides information regarding the administration of section C.08.004.1 of the Food and Drug Regulations which came into force on October 5, 2006 by the Office of Patented Medicines and Liaison (OPML) within the Office of Submissions and Intellectual Property, Resource Management and Operations Directorate (RMOD), Health Canada. It is applicable only to those drugs that receive a Notice of Compliance (NOC) on or after June 17, 2006 and includes pharmaceutical, biological and radiopharmaceutical drugs that receive NOCs, including relevant products for veterinary use.[1]

1.4 Background

In 1995, Health Canada amended the Food and Drug Regulations to provide a regulatory framework for abbreviated new drug submissions (ANDSs). Included in the 1995 amendments was a data protection provision that was triggered upon the examination of any information filed by an innovative manufacturer to obtain approval for its drug, to support the review of a

subsequent-entry drug product. Where the Minister relied on the innovator's information, Health Canada would not issue an NOC for the subsequent-entry drug product until five years after the issuance of the NOC to the innovator. In those cases where this would result in a delay in the issuance of the NOC, the Regulatory Impact Analysis Statement (RIAS) stated that Health Canada would give the subsequent-entry manufacturer the option of supplying additional information to support its submission without relying on the innovator's information.

In most cases, Health Canada does not consult the information in the innovator's drug submission and, therefore, does not rely directly on the innovator's information. Therefore in the view of Health Canada, the provision did not allow for an indirect reliance on the innovator's information. The Minister's interpretation was upheld in a Court challenge of the provision where it was held that to trigger the five-year period of data protection required a direct reliance on the innovator's drug submission.

Under the October 5, 2006 data protection provisions, companies introducing a drug containing a new chemical entity (i.e. an "innovative drug") are entitled to an eight-year period of market exclusivity. In addition, a subsequent-entry manufacturer is prevented from filing a submission for a copy of that innovative drug for the first six years of the eight-year period.

The data protection period may be extended a further six months if, within the first five years of the eight-year period, the results of pediatric clinical trials, designed and conducted for the purpose of increasing knowledge of the use of the drug in pediatric populations, are also submitted and found acceptable. Extending the period of data protection in this manner is intended to encourage the submission of pediatric research results to provide health benefits to children.

2. Innovative drugs

2.1 Scope of data protection

The data protection provisions in section C.08.004.1 of the Food and Drug Regulations provide an eight-year period of market exclusivity for innovative drugs.

Section C.08.004.1 of the Food and Drug Regulations defines an "innovative drug" as a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph.

Under the definition of an innovative drug, drugs that contain medicinal ingredients that have been previously approved in Canada, including drugs that have previously received an NOC, a Natural Product Number (NPN) and/or a Drug Identification Number (DIN), will not be afforded protection. An extension of the period is not available for drugs that are issued an NOC for a new indication, dosage form or other changes made through a supplement to a new drug submission (SNDS) with the exception of SNDSs containing pediatric clinical trial data. See section 2.8 of this document for more information.

Consistent with the policy intent underlying the data protection amendments of 2006 and the decision in *Bayer Inc. v. Canada (Attorney General)*, 84 C.P.R. (3d) 129, aff'd 87 C.P.R. (3d) 293, leave to appeal to SCC refused, [1999] S.C.C.A. No. 386, when interpreting the definition of

"innovative drug", the prior approval of a medicinal ingredient in a drug for veterinary use does not preclude the granting of data protection to a drug for human use containing the identical medicinal ingredient or a variation thereof. Conversely, the prior approval of a medicinal ingredient in a drug for human use does not preclude the granting of data protection to a drug for veterinary use containing the identical medicinal ingredient or a variation thereof.

Approval for a biosimilar, as set out in Health Canada's Guidance Document: Information and Submission Requirements for Biosimilar Biologic Drugs (Biosimilar Guidance), is sought by filing a new drug submission (NDS) in which the sponsor seeks to reduce the clinical and non-clinical study requirements by demonstrating similarity to a previously approved reference biologic drug. As such, a biosimilar will not be considered to be an "innovative drug".

2.2 Eligibility of drugs for data protection

Jurisprudence has confirmed, in light of the purpose statement in subsection C.08.004.1(2) of the Food and Drug Regulations, that there are two requirements in the analysis of data protection eligibility. The first is a determination of whether or not the medicinal ingredient under consideration is a new chemical entity. The second is whether or not the generation of the data that supports the approval of the medicinal ingredient under consideration required considerable effort.

2.2.1 New chemical entity

The concept of "new chemical entity" has been incorporated into the Food and Drug Regulations through the definition of "innovative drug". As noted above, an innovative drug is a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph.

Identification of the medicinal ingredient

The medicinal ingredient is identified using the pharmaceutical information in the sponsor's drug submission (e.g. Product Monograph) including the proper name, the chemical name, the molecular formula, the molecular mass, the structural formula and, where appropriate, the amino acid sequence. This information is then used to identify synonyms for the medicinal ingredient using a number of publicly available chemical databases. For more information on drugs containing more than one medicinal ingredient, please see section 2.3 of this document.

Once the medicinal ingredient has been identified, it is necessary to determine whether or not it has been previously approved in a drug by the Minister.

Previous approval

The analysis of whether or not the medicinal ingredient has been previously approved involves a search of Health Canada's databases to look for previous approvals of the very medicinal ingredient that is present in the drug under consideration. All known names and synonyms of the medicinal ingredient are input as search criteria into the various databases.

If the medicinal ingredient has been previously approved, the drug cannot be considered an "innovative drug".

If the medicinal ingredient has not been previously approved, it is necessary to determine whether or not it is a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph.

Variations

The following types of variations are excluded from the consideration of what is an "innovative drug": salts, esters, enantiomers, solvates and polymorphs. Reference will be made to standard internationally recognized resources, e.g. International Union of Pure and Applied Chemistry (IUPAC) Compendium of Chemical Terminology, when considering these terms.

Arguable variations

Molecules with arguable variations have a molecular structure that is similar to a previously approved medicinal ingredient, but that is not a variation enumerated in the definition of "innovative drug".

The RMOD must identify whether or not the medicinal ingredient in the drug under consideration is a variation of a previously approved medicinal ingredient.

This is done by comparing the structure of the medicinal ingredient under consideration with previously approved medicinal ingredients that have similar structures. The group of previously approved medicinal ingredients is identified using the mechanism of action of the medicinal ingredient under consideration and the therapeutic class of drugs to which it belongs.

Once the group of previously approved medicinal ingredients with possible structural similarities has been identified, side-by-side comparisons are performed to look at the structures of the medicinal ingredient under consideration and the previously approved medicinal ingredients. Differences due to salt appendages or ester appendages are identified at this point. While the synthetic pathway used to produce a salt or ester variation can aid in the analysis, it is not in itself determinative. There is a concern that, if the test for a variation depends on the synthetic pathway, it may be possible to design and utilize a different route of synthesis in order to circumvent the regulatory intent of protecting new chemical entities.

Enantiomers, solvates and polymorphs are typically identified by comparing the name of the medicinal ingredient under consideration with the names of the previously approved medicinal ingredients.

If an arguable variation is identified, an assessment will be made as to whether or not approval is being sought primarily on the basis of previously submitted clinical data.

2.2.2 Considerable effort

Once it has been established that the drug contains a medicinal ingredient not previously approved in a drug by the Minister and that the medicinal ingredient is not a variation of a previously approved medicinal ingredient, it is necessary to assess the nature and extent of the data contained in the drug submission to ensure that approval is being sought on the basis of new and significant data (i.e. the product of considerable effort). This determination is also performed where a drug is found to contain a medicinal ingredient that is an arguable variation. New and significant data is characterized as that which provides the evidence to determine the safety, efficacy, properties, and conditions of use of the drug (e.g. pivotal clinical trials). However, drugs approved on the basis of literature references (e.g. articles published in peer-

reviewed journals, study reports of trials not conducted or sponsored by the submission applicant, books, consensus guidelines from professional bodies, etc.) and/or market experience (e.g. information concerning the product's safety profile from domestic and/or foreign markets, details of adverse reactions from foreign authorities, etc.) would not be considered eligible for data protection.

2.2.3 Conclusion

If a drug contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph, and approval is sought on the basis of data, the origination of which involved considerable effort, the drug will be considered eligible for data protection.

2.3 Product-line extensions and drugs containing the same medicinal ingredient as an innovative drug

In some cases a drug may contain one or more medicinal ingredient(s) that is/are the same as the medicinal ingredient(s) found in an innovative drug for which a data protection period is still in effect. Consistent with the intent of section C.08.004.1 to protect new chemical entities, these drugs will benefit from the same period of data protection as the innovative drug. The brand name of the drug(s) benefitting from the same period of protection as the innovative drug will be included on the Register of Innovative Drugs. In order to benefit from the data protection term, there must be a relationship to the innovative drug. This does not apply to subsequent-entry drugs which are typically considered "generic".

Combinations of previously approved medicinal ingredients are not eligible for data protection. The following scenarios are provided as examples:

> Drug 'A' is an innovative drug that qualifies for an eight-year period of data protection ending January 1, 2022.
>
> Drug 'B' is an innovative drug that qualifies for an eight-year period of data protection ending June 1, 2023.
>
> Drugs 'C' and 'D' were each previously approved in Canada.
>
> Example 1:
>
> A new drug that includes the medicinal ingredients found in Drug 'A' and in Drug 'C' in combination is approved before the expiry of the original period of data protection for Drug 'A'. Data protection for Drug 'A' will also protect the combination until the expiry of the original data protection period for Drug 'A' on January 1, 2022.
>
> Example 2:
>
> A new combination drug containing the medicinal ingredients found in Drugs 'C' and 'D' is approved. However, it is not eligible for data protection.
>
> Example 3:
>
> A new combination drug containing the medicinal ingredient found in Drugs 'A' and 'B' will benefit from the terms of data protection for Drugs 'A' and 'B'. In this example, protection would extend to the expiry of the data protection period for Drug 'B' on June

1, 2023. The brand name of the new combination drug will be included on the Register of Innovative Drugs under the listing for both Drugs ‘A’ and ‘B’.

Example 4:

Drug ‘E’ containing the same medicinal ingredient found in Drug ‘A’ is approved, manufactured by the same company as Drug ‘A’. Drug ‘E’ will benefit from the same period of data protection as Drug ‘A’, but is not eligible for its own period of data protection.

Example 5:

Drug ‘F’ is a combination drug containing the same medicinal ingredient as Drug ‘B’ in combination with another previously approved medicinal ingredient. The drug submission for Drug ‘F’ cross-references data from the Drug ‘B’ submission, however Drug ‘F’ is manufactured by a different brand-name company than Drug ‘B’. As there is a relationship between the two drugs, Drug ‘F’ will benefit from the same period of data protection as Drug ‘B’.

2.4 Process

A manufacturer that believes that its drug qualifies as an innovative drug may submit any supporting information in module 1.2.4.2 - Data Protection Information, in accordance with the electronic Common Technical Document (eCTD) format or the non-eCTD electronic-only format. Please consult the Guidance Document: Preparation of Drug Regulatory Activities in the Electronic Common Technical Document Format, Frequently Asked Questions - Common Electronic Submissions Gateway, the CESG Health Canada Reference Guide, and the Guidance Document: Preparation of Drug Regulatory Activities in the “Non-eCTD Electronic-Only” Format for more information.

The RMOD will prepare a preliminary assessment while the submission is under review to determine if the drug qualifies for data protection. The manufacturer will be notified of the assessment in writing. The result of the assessment will also be entered into the Drug Submission Tracking System. Manufacturers may access information about their own submission via the Drug Submission Tracking System - Industry Access. Where a dispute arises, a manufacturer will have the opportunity to provide representations in writing. In order to facilitate and ensure proper processing, representations must be submitted in eCTD or non-eCTD electronic-only format, as appropriate. The RMOD will consider the representations before a further assessment is made. Prior to the issuance of the NOC, only a preliminary acceptance can be given as the drug in question must remain the first to be approved with the specific medicinal ingredient. Should there be two manufacturers with products containing the same medicinal ingredient, only the first drug issued an NOC could qualify for the protection. Manufacturers are encouraged to consult the Submissions Under Review List to determine whether or not another submission for a particular medicinal ingredient is under review.

2.5 Requirement for marketing in Canada

As per subsection C.08.004.1(5) of the Food and Drug Regulations, protection for an innovative drug is only available where the innovative drug has received an NOC and is marketed in Canada. Where the drug is withdrawn by the innovative drug manufacturer from the market,

no protection will be offered. This is to prevent the situation where the marketed version of an innovative drug is withdrawn from the Canadian market by the innovative drug manufacturer, but no equivalent generic drug is allowed on the Canadian market until the data protection period has expired. The inactivation of a DIN in accordance with paragraph C.01.014.6(1)(a) will be accepted as an indication that the drug is no longer being marketed in Canada. The marketing status of the DIN will be confirmed by consulting the Drug Product Database. It is recognized that a drug may not be notified as per section C.01.014.3 of the Food and Drug Regulations immediately following the issuance of the NOC. Where there is insufficient evidence as to the marketing status of the drug, the innovative drug manufacturer will be contacted to confirm the status of the drug.

In the case of a DIN newly-issued due to a change in the manufacturer, data protection will continue to be provided for what remains of the period as long as the new product is marketed by the new manufacturer.

An innovative drug that is re-introduced to the market will receive protection from any subsequent entry submissions for the remainder of the original data protection term. However, if a manufacturer files a subsequent entry submission when the innovative drug is not marketed, the submission will proceed and be issued an NOC even if the innovative drug is later marketed and the period of protection is restored. If the manufacturer of the subsequent entry drug seeks approval on the basis of additional direct or indirect comparisons to the innovative drug, e.g. introduces new information, after the innovative drug is marketed, the data protection period will apply.

Drugs that benefit from the same period of data protection as an innovative drug (section 2.3 of this document) will only be protected while the innovative drug is marketed.

2.6 Register of Innovative Drugs

A Register of Innovative Drugs will be maintained in accordance with subsection C.08.004.1(9) of the Food and Drug Regulations. The Register of Innovative Drugs is intended to provide a measure of transparency.

The Register of Innovative Drugs, updated on a weekly basis, is posted on the Health Canada website at: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/register-innovative-drugs.html.

Innovative drugs are added to the Register of Innovative Drugs after the issuance of the NOC. When an NOC issues for an administrative submission to change the manufacturer's name of an innovative drug, the RMOD will update the Register of Innovative Drugs with the new manufacturer name. If manufacturers have concerns over the listing of the innovative drug or the information provided on the Register of Innovative Drugs, please notify the RMOD.

2.7 Period of protection

The data protection period is eight years from the date of issuance of the first NOC for the innovative drug. Where the drug has qualified for a six-month pediatric extension, the period is extended to eight years and six months. See section 2.8 of this document for information on the six-month pediatric extension.

Within the protection period, a manufacturer seeking an NOC on the basis of a direct or indirect comparison to an innovative drug will be prevented from filing its drug submission for the first six years of the eight-year period.

2.8 Pediatric extension

In addition to the eight-year period of data protection, an additional six-month pediatric extension will be applied if an innovative drug manufacturer includes, in its NDS, or any SNDS filed within the first five years of the eight-year data protection period, results of clinical trials which were designed and conducted for the purpose of increasing knowledge about the use of the drug in pediatric populations and which will lead to a health benefit for children. To qualify, the drug must be an innovative drug and be eligible for the eight-year period of data protection.

Submission of clinical trial data

The threshold requirement provided in paragraph C.08.004.1(4)(a) of the Food and Drug Regulations is that the innovator must provide the Minister with the description and results of clinical trials relating to the use of the innovative drug in relevant pediatric populations in its first NDS for the innovative drug or in any SNDS that is filed within five years after the issuance of the first NOC for that innovative drug.

"Clinical trial" is defined in Division 5 of the Food and Drug Regulations as "an investigation in respect of the drug for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the drug, identify any adverse events in respect of the drug, study the absorption, distribution, metabolism and excretion of the drug, or ascertain the safety or efficacy of the drug". For the purposes of the six-month pediatric extension, the clinical trials must have been conducted in at least one of the three groups set out in the definition of "pediatric populations" in subsection C.08.004.1(1).

Designed and conducted to increase knowledge that provides a health benefit

The next requirement, provided in paragraph C.08.004.1(4)(b) of the Food and Drug Regulations, is whether the clinical trials were designed and conducted for the purpose of increasing knowledge of the use of the innovative drug in pediatric populations and this knowledge would thereby provide a health benefit to members of those populations.

This design and conduct requirement can be broken into two elements:

1) Knowledge
2) Health benefit

Knowledge

The extension of data protection for submitting the results of pediatric studies is intended to encourage sponsors to submit clinical trial data pertaining to the use of the drug in pediatric populations in order to maximize the information available for the benefit of children.

The study hypothesis, objectives, design and conduct will be used to determine if the clinical trial was developed and conducted for the purpose of increasing knowledge of the use of the drug in pediatric populations.

In addition, studies must result in increased knowledge about the behaviour of the drug in pediatric populations in order to assist health professionals, parents, caregivers, and patients in making informed choices about drug therapy. In such cases, the knowledge is considered to be of the type that, once made available, can provide a health benefit to pediatric patients.

The knowledge requirement for the six-month pediatric extension does not contemplate knowledge that can only be used for the purpose of designing a future study.

Health benefit

Provided that the knowledge requirement is met, a determination will be made as to whether or not that knowledge is available to provide a health benefit. At minimum, the knowledge must be available to the public, e.g. through the approved labelling or Product Monograph. It is not necessary that the published information leads to a pediatric indication. Where the clinical studies demonstrate that the drug should not be used in pediatric populations, the addition of contraindications and/or other warning statements in the labelling of the drug may be sufficient to warrant granting of the six-month pediatric extension. The nature of information needed to satisfy the requirement will be assessed on a case-by-case basis.

2.8.1 Process

The cover letter accompanying a submission should indicate when a manufacturer believes that its submission is eligible for the six-month pediatric extension. Supporting information may be placed in module 1.2.4.2 - Data Protection Information of the submission.

When an NDS for a drug that is eligible for data protection includes pediatric data, or when an SNDS that contains pediatric data for an innovative drug is filed, the RMOD will enter the document “Dataprotect Pediatr Check” in the Drug Submission Tracking System. Manufacturers may access information about their own submission via the Drug Submission Tracking System - Industry Access. A letter will not be sent to the manufacturer at the time of filing the submission to acknowledge the consideration of the six-month pediatric extension.

The determination of whether the drug is eligible for the six-month pediatric extension will be made following the review of the submission. If the determination is made that the drug is eligible for the six-month pediatric extension, the Register of Innovative Drugs will be updated accordingly. If the determination is made that the drug is not eligible for the six-month pediatric extension, a preliminary decision letter will be sent to the manufacturer and the manufacturer will be provided with an opportunity to make representations. If, after consideration of the representations received, the RMOD remains of the position that the drug is not eligible for the six-month pediatric extension, the manufacturer will be informed in writing. If the determination is to extend the data protection period by six months, the Register of Innovative Drugs will be updated accordingly.

In accordance with paragraph C.08.004.1(4)(b) of the Food and Drug Regulations, the Minister is required to make a determination whether the drug is eligible for the six-month pediatric extension before the end of six years after the day on which the first NOC was issued for the innovative drug.

Where the pediatric data is submitted by way of an SNDS, the review of the SNDS may not be complete within the six-year period, for example, if a Notice of Non-Compliance is issued for

the submission. In such cases, the RMOD will be required to assess the information available at that time to determine whether the drug is eligible for the six-month pediatric extension. If the RMOD determines preliminarily that the innovative drug is eligible for the six-month pediatric extension, the Register of Innovative Drugs will be updated to reflect the extension before the completion of the drug submission review in order to provide a measure of transparency for subsequent entry manufacturers. However, the RMOD will verify whether the submission has received an NOC by the end of the eight-year period of data protection to ensure that the health benefit requirement has been met. If the submission has not received an NOC, the eligibility for the six-month pediatric extension will be re-evaluated, and if the requirements of paragraph C.08.004.1(4)(b) have not been met, the six-month pediatric extension will be removed from the Register of Innovative Drugs.

3. Submissions comparing to innovative drugs

3.1 Prevention from filing

In accordance with paragraph C.08.004.1(3)(a) of the Food and Drug Regulations, a manufacturer seeking an NOC on the basis of a direct or indirect comparison to an innovative drug may not file a submission for six years from the date of issuance of the first NOC for the innovative drug. This language is intended to capture ANDSs and supplements to an abbreviated new drug submission (SANDSs), where the innovative drug is the Canadian Reference Product.

However, this paragraph is also intended to include NDSs and SNDSs seeking an NOC for a drug on the basis of a comparison to an innovative drug, including biosimilar drug submissions and submissions relying on third-party data.

A biosimiliar must be subsequent to a biologic drug that is approved in Canada and to which a reference is made. Sponsors may use a non-Canadian sourced version as a proxy for the Canadian drug in the comparative studies. If the Canadian drug is an innovative drug, comparative submissions are considered to contain a comparison between the biosimilar and the innovative drug. These submissions will not be accepted for filing within the six-year period from the date of issuance of the NOC for the innovative drug.

NDSs which are based on independent clinical trials and not on a comparison to an innovative drug are not captured by subsection C.08.004.1(3). In addition, submissions that do not result in a subsequent entry version of the innovative drug are not captured by this subsection. For example, a submission for a drug indicated for use in combination with an innovative drug will not be prevented from filing.

3.2 Prevention from approval

In accordance with paragraph C.08.004.1(3)(b) of the Food and Drug Regulations, a manufacturer seeking an NOC on the basis of a direct or indirect comparison to an innovative drug will not be issued an NOC before the end of the period of eight years after the day on which the first NOC was issued for the innovative drug. The period will be lengthened to eight years and six months where the innovative drug qualifies for the six-month pediatric extension. Once the examination of the submission is complete, the manufacturer will be notified and an

invoice for the review of the submission will be issued, where applicable. The submission will be placed on Intellectual Property (IP) Hold as of that date. If the innovative drug is also listed on the Patent Register, upon expiration of the data protection period the submission will remain on IP Hold until the requirements of the Patented Medicines (Notice of Compliance) Regulations (PM(NOC) Regulations) are met.

3.3 Consent to file a submission

In accordance with subsection C.08.004.1(6) of the Food and Drug Regulations, an innovative drug manufacturer may consent to the filing of a submission during the six-year no-filing period. A letter of consent to file the submission within the data protection period signed by the innovative drug manufacturer must be submitted with the submission.

3.4 Consent to the issuance of a Notice of Compliance

An innovative drug manufacturer may consent to the issuance of an NOC during the data protection period, per subsection C.08.004.1(8) of the Food and Drug Regulations. A letter of consent signed by the innovative drug manufacturer may be submitted with the submission of the authorized manufacturer or provided at a later time in eCTD or non-eCTD electronic-only format, as appropriate. The innovative drug manufacturer may provide consent to both the filing of a submission and the issuance of the NOC in the same letter.

3.5 Exemption under Canada's Access to Medicines Regime

An exemption from the six-year no-filing period has been created to allow a manufacturer to file a submission under Canada's Access to Medicines Regime under subsection C.08.004.1(7) of the Food and Drug Regulations.

Canada's Access to Medicines Regime provides a framework within which eligible countries can import less expensive generic versions of patented drugs and medical devices. Notwithstanding that a manufacturer may receive authorization to export a given drug under a compulsory license granted by the Commissioner of Patents, Health Canada will not grant an NOC providing Canadian market authorization unless the requirements for both data protection under section C.08.004.1 of the Food and Drug Regulations and the PM(NOC) Regulations have been met.

The introduction of the six-year no-filing period requires an exception to allow for the filing of drug submissions within the framework of Canada's Access to Medicines Regime. As a result, subsection C.08.004.1(7) provides an exemption where an application is filed pursuant to section C.07.003 of the Food and Drug Regulations.

Where second person submissions are filed within the six-year period, the date of filing for the purpose of the PM(NOC) Regulations is deemed to be six years after the date of issuance of the first person's NOC. Please see Health Canada's Guidance Document: Patented Medicines (Notice of Compliance) Regulations for details.

3.6 Process

When it appears that the filing of a submission is prevented, the manufacturer will be provided with a written preliminary decision and an opportunity to make representations in response. If, following consideration of the representations, the RMOD remains of the view that the submission cannot be filed, the manufacturer will be notified and the submission will not be

processed further. In order to facilitate and ensure proper processing, representations or other information must be submitted in eCTD or non-eCTD electronic-only format, as appropriate. Please consult the Guidance Document: Preparation of Drug Regulatory Activities in the Electronic Common Technical Document Format, the Frequently Asked Questions - Common Electronic Submissions Gateway, the CESG Health Canada Reference Guide, and the Guidance Document: Preparation of Drug Regulatory Activities in the "Non-eCTD Electronic-Only" Format for more information.

4. Inquiries

Inquiries regarding a particular listing on the Register of Innovative Drugs should be sent to the RMOD at the address below.

The RMOD will endeavour to respond to inquiries by providing, whenever possible, information that is in the public domain. Confidential submission information, however, will not be provided.

As discussed in section 2 in this document, a drug is eligible for data protection if it meets the definition of an innovative drug. Data protection for the innovative drug applies only where an innovative drug has received an NOC and is marketed in Canada.

Letters challenging the innovative drug's status will be provided to the manufacturer of the innovative drug. Therefore, inquiries cannot be accepted if marked 'confidential'. In order to ensure a transparent process, the RMOD will provide its response to the inquiry to both the inquirer and the innovative drug manufacturer, with an opportunity to make representations prior to a final decision.

All inquiries, including on electronic media, should be sent to the OPML within the Office of Submissions and Intellectual Property (https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch/resource-management-operations-directorate.html#a4).

Appendices

Appendix 1 - Acronyms

ANDS	Abbreviated New Drug Submission
CAMR	Canada's Access to Medicines Regime
DIN	Drug Identification Number
HPFB	Health Products and Food Branch
NAFTA	North American Free Trade Agreement
NDS	New Drug Submission
OPML	Office of Patented Medicines and Liaison
RMOD	Resource Management and Operations Directorate
SANDS	Supplement to an Abbreviated New Drug Submission
SNDS	Supplement to a New Drug Submission
TRIPS	Trade Related Aspects of Intellectual Property Rights Agreement
WTO	World Trade Organization

[1] Veterinary products that fall under the *Health of Animals Act* S.C. 1990, c.21 are not within the scope of this Guidance.

Exhibit “J4”

This is Exhibit “J4” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.
Arash Rouhi

Health Canada Santé Canada

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Medicinal Ingredient(s)*	Submission Number	Innovative Drug	Manufacturer	Drug(s) Containing the Medicinal Ingredient / Variations	Notice of Compliance Date yyyy-mm-dd	6 Year "No File" Date	Pediatric Extension Yes / No	Data Protection Ends
abemaciclib	215268	Verzenio	Eli Lilly Canada Inc.	N/A	2019-04-05	2025-04-05	N/A	2027-04-05
abrocitinib	245854	Cibinqo	Pfizer Canada ULC	N/A	2022-06-29	2028-06-29	Yes	2030-12-29
acalabrutinib	214504	Calquence	AstraZeneca Canada Inc.	Calquence (acalabrutinib maleate)	2019-08-23	2025-08-23	N/A	2027-08-23
ad26.COV2.S (recombinant)	253702	Jcovden	Janssen Inc.	N/A	2021-11-23	2027-11-23	N/A	2029-11-23
alectinib hydrochloride	189442	Alecensaro	Hoffmann-La Roche Limited	N/A	2016-09-29	2022-09-29	N/A	2024-09-29
alirocumab	183116	Praluent	Sanofi-Aventis Canada Inc.	N/A	2016-04-11	2022-04-11	Yes	2024-10-11
alpelisib	226941	Piqray	Novartis Pharmaceuticals Canada Inc.	N/A	2020-03-11	2026-03-11	N/A	2028-03-11
amifampridine (supplied as amifampridine phosphate)	232685	Firdapse	Kye Pharmaceuticals Inc.	N/A	2020-07-31	2026-07-31	N/A	2028-07-31
amivantamab	254440	Rybrevant	Janssen Inc.	N/A	2022-03-30	2028-03-30	N/A	2030-03-30
andexanet alfa	266464	Ondexxya	AstraZeneca Canada Inc.	N/A	2023-06-16	2029-06-16	N/A	2031-06-16
andusomeran	275936	Spikevax XBB.1.5	Moderna Biopharma Canada Corporation	N/A	2023-09-12	2029-09-12	Yes	2032-03-12
anifrolumab	246187	Saphnelo	AstraZeneca Canada Inc.	N/A	2021-11-30	2027-11-30	N/A	2029-11-30
anthrax antigen filtrate	212387	Biothrax	Emergent Biodefense Operations Lansing LLC	N/A	2018-12-13	2024-12-13	N/A	2026-12-13
anthrax immune globulin (human)	200446	Anthrasil	Emergent BioSolutions Canada Inc.	N/A	2017-11-06	2023-11-06	Yes	2026-05-06
antihemophilic factor (recombinant), pegylated	189709	Adynovate	Takeda Canada Inc.	N/A	2016-11-17	2022-11-17	Yes	2025-05-17

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antihemophilic factor (recombinant, B-domain deleted, pegylated) (also known as damoctocog alfa pegol)	210935	Jivi	Bayer Inc.	N/A	2018-10-18	2024-10-18	Yes	2027-04-18
antihemophilic factor VIII (recombinant), singlechain (also known as lonoctocog alfa)	190891	Afstyla	CSL Behring Canada Inc.	N/A	2016-12-12	2022-12-12	Yes	2025-06-12
antihemophilic factor VIII (recombinant, B-domain truncated), PEGylated (turoctocog alfa pegol)	218531	Esperoct	Novo Nordisk Canada Inc.	N/A	2019-07-04	2025-07-04	Yes	2028-01-04
apalutamide	211942	Erleada	Janssen Inc.	N/A	2018-07-03	2024-07-03	N/A	2026-07-03
asciminib hydrochloride	255700	Scemblix	Novartis Pharmaceuticals Canada Inc.	N/A	2022-06-23	2028-06-23	N/A	2030-06-23
atezolizumab	196843	Tecentriq	Hoffmann-La Roche Limited	N/A	2017-04-12	2023-04-12	Yes	2025-10-12
atogepant	253186	Qulipta	Abbvie Corporation	N/A	2022-12-22	2028-12-22	N/A	2030-12-22
avacopan	248255	Tavneos	Vifor Fresenius Medical Care Renal Pharma Ltd.	N/A	2022-04-14	2028-04-14	N/A	2030-04-14
avalglucosidase alfa	245680	Nexviazyme	Sanofi-Aventis Canada Inc.	N/A	2021-11-12	2027-11-12	Yes	2030-05-12
avatrombopag maleate	251688	Doptelet	Swedish Orphan Biovitrum AB (publ)	N/A	2023-11-03	2029-11-03	N/A	2031-11-03
avelumab	204052	Bavencio	EMD Serono, a Division of EMD Inc., Canada	N/A	2017-12-18	2023-12-18	Yes	2026-06-18
axicabtagene ciloleucel	218389	Yescarta	Gilead Sciences Canada Inc	N/A	2019-02-13	2025-02-13	N/A	2027-02-13
baloxavir marboxil	227361	Xofluza	Hoffmann-La Roche Limited	N/A	2020-02-19	2026-02-19	Yes	2028-08-19
baricitinib	193687	Olumiant	Eli Lilly Canada Inc.	N/A	2018-08-17	2024-08-17	N/A	2026-08-17

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belumosudil mesylate	245791	Rezurock	Sanofi-Aventis Canada Inc.	N/A	2022-03-23	2028-03-23	N/A	2030-03-23
belzutifan	254495	Welireg	Merck Canada Inc.	N/A	2022-07-11	2028-07-11	N/A	2030-07-11
benralizumab	204008	Fasenra	AstraZeneca Canada Inc.	N/A	2018-02-22	2024-02-22	Yes	2026-08-22
bepotastine besilate	179294	Bepreve	Bausch and Lomb Incorporated	N/A	2016-07-27	2022-07-27	Yes	2025-01-27
berotralstat (supplied as berotralstat hydrochloride)	252301	Orladeyo	BioCryst Pharmaceuticals, Inc.	N/A	2022-06-02	2028-06-02	Yes	2030-12-02
bictegravir	203718	Biktarvy	Gilead Sciences Canada, Inc.	N/A	2018-07-10	2024-07-10	Yes	2027-01-10
bilastine	184231	Blexten	Aralez Pharmaceutials Canada Inc.	N/A	2016-04-21	2022-04-21	Yes	2024-10-21
bimekizumab	238499	Bimzelx	UCB Canada Inc.	N/A	2022-02-14	2028-02-14	N/A	2030-02-14
binimetinib	237410	Mektovi	Pfizer Canada ULC	N/A	2021-03-02	2027-03-02	N/A	2029-03-02
botulism antitoxin heptavalent C/ D/F/ G – (equine)	190645	Bat	Emergent BioSolutions Inc.	N/A	2016-12-08	2022-12-08	Yes	2025-06-08
brexpiprazole	192684	Rexulti	Otsuka Pharmaceutical Co. Ltd.	N/A	2017-02-16	2023-02-16	Yes	2025-08-16
brexucabtagene autoleucel	246355	Tecartus	Gilead Sciences Canada, Inc.	N/A	2021-06-08	2027-06-08	N/A	2029-06-08
brigatinib	210369	Alunbrig	Takeda Canada Incorporated	N/A	2018-07-26	2024-07-26	N/A	2026-07-26
brivaracetam	183355	Brivlera	UCB Canada Incorporated	N/A	2016-03-09	2022-03-09	Yes	2024-09-09
brodalumab	195317	Siliq	Bausch Health, Canada Inc.	N/A	2018-03-06	2024-03-06	N/A	2026-03-06
brolucizumab	226224	Beovu	Novartis Pharmaceuticals Canada Inc.	N/A	2020-03-12	2026-03-12	N/A	2028-03-12

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burosumab	216239	Crysvita	Kyowa Kirin Inc.	N/A	2018-12-05	2024-12-05	Yes	2027-06-05
cabotegravir	227315	Cabenuva	ViiV Healthcare ULC	Apretude	2020-03-18	2026-03-18	Yes	2028-09-18
cabotegravir sodium	227315	Vocabria	ViiV Healthcare ULC	Apretude	2020-03-18	2026-03-18	Yes	2028-09-18
cabozantinib (supplied as cabozantinib (S)-malate)	206230	Cabometyx	Ipsen Biopharmaceuticals Canada Inc.	N/A	2018-09-14	2024-09-14	N/A	2026-09-14
calaspargase pegol	268282	Asparlas	Servier Canada Inc.	N/A	2023-11-08	2029-11-08	Yes	2032-05-08
calcifediol	205392	Rayaldee	Eirgen Pharma Ltd.	N/A	2018-07-10	2024-07-10	N/A	2026-07-10
cangrelor tetrasodium	255032	Kengrexal	Chiesi Farmaceutici S.p.A	N/A	2023-01-20	2029-01-20	N/A	2031-01-20
capivasertib	274859	Truqap	AstraZeneca Canada Inc.	N/A	2024-01-26	2030-01-26	N/A	2032-01-26
caplacizumab	230001	Cablivi	Sanofi-Aventis Canada Inc.	N/A	2020-02-28	2026-02-28	N/A	2028-02-28
capmatinib hydrochloride	255972	Tabrecta	Novartis Pharmaceuticals Canada Inc.	N/A	2022-05-26	2028-05-26	N/A	2030-05-26
cariprazine hydrochloride	249774	Vraylar	AbbVie Corporation	N/A	2022-04-22	2028-04-22	N/A	2030-04-22
cedazuridine	234610	Inqovi	Otsuka Pharmaceutical Co., Ltd.	NA	2020-07-07	2026-07-07	N/A	2028-07-07
cemiplimab	218718	Libtayo	Sanofi-Aventis Canada Inc.	N/A	2019-04-10	2025-04-10	N/A	2027-04-10
cenegermin	218145	Oxervate	Dompé farmaceutici S.p.A.	N/A	2019-02-08	2025-02-08	N/A	2027-02-08
cenobamate	261689	Xcopri	Endo Operations Ltd.	N/A	2023-06-12	2029-06-12	N/A	2031-06-12
cerliponase alfa	216539	Brineura	Biomarin International Limited	N/A	2018-12-19	2024-12-19	Yes	2027-06-19

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chAdOx1-S [recombinant]	253700	Vaxzevria	AstraZeneca Canada Inc.	N/A	2021-11-19	2027-11-19	N/A	2029-11-19
chikungunya virus live-attenuated	275762	Ixchiq	Valneva Austria GmbH	N/A	2024-06-20	2030-06-20	N/A	2032-06-20
ciltacabtagene autoleucel	262122	Carvykti	Janssen Inc.	N/A	2023-02-09	2029-02-09	N/A	2031-02-09
clascoterone	265619	Winlevi	Sun Pharmaceutical Industries Limited	N/A	2023-06-15	2029-06-15	Yes	2031-12-15
coagulation factor IX (recombinant), albumin fusion protein (rIX-FP)	180793	Idelvion	CSL Behring Canada Inc.	N/A	2016-01-26	2022-01-26	Yes	2024-07-26
coagulation factor IX (recombinant), pegylated (nonacog beta pegol)	201114	Rebinyn	Novo Nordisk Canada Inc.	N/A	2017-11-29	2023-11-29	Yes	2026-05-29
concizumab	267120	Alhemo	Novo Nordisk Canada Inc.	N/A	2023-03-10	2029-03-10	Yes	2031-09-10
crisaborole	206906	Eucrisa	Pfizer Canada Inc.	N/A	2018-06-07	2024-06-07	Yes	2026-12-07
cysteamine bitartrate	191347	Procysbi	Horizon Pharma Ireland Ltd.	N/A	2017-06-13	2023-06-13	Yes	2025-12-13
daclizumab beta	190458	Zinbryta	Biogen Canada Inc.	N/A	2016-12-08	2022-12-08	N/A	2024-12-08
dacomitinib	214572	Vizimpro	Pfizer Canada Inc.	N/A	2019-02-26	2025-02-26	N/A	2027-02-26
dalbavancin (supplied as dalbavancin hydrochloride)	212390	Xydalba	Endo Ventures Ltd.	N/A	2018-09-04	2024-09-04	N/A	2026-09-04
daridorexant hydrochloride	255507	Quviviq	Idorsia Pharmaceuticals Ltd.	N/A	2023-04-28	2029-04-28	N/A	2031-04-28
darolutamide	226146	Nubeqa	Bayer Inc.	N/A	2020-02-20	2026-02-20	N/A	2028-02-20
davesomeran	267589	Spikevax Bivalent (Original/Omicron BA.4/5)	Moderna Biopharma Canada Corporation	N/A	2022-11-03	2028-11-03	Yes	2031-05-03

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defibrotide sodium	200808	Defitelio	Jazz Pharmaceuticals Ireland Limited	N/A	2017-07-10	2023-07-10	Yes	2026-01-10
deucravacitinib	259397	Sotyktu	Bristol-Myers Squibb Canada	N/A	2022-11-24	2028-11-24	N/A	2030-11-24
difelikefalin (supplied as difelikefalin acetate)	254548	Korsuva	Vifor Fresenius Medical Care Renal Pharma Ltd.	N/A	2022-08-16	2028-08-16	N/A	2030-08-16
dinutuximab	212066	Unituxin	United Therapeutics Corporation	N/A	2018-11-28	2024-11-28	Yes	2027-05-28
doravirine	211293	Pifeltro	Merck Canada Inc.	Delstrigo	2018-10-12	2024-10-12	Yes	2027-04-12
dostarlimab	251105	Jemperli	GlaxoSmithKline Inc.	N/A	2021-12-23	2027-12-23	N/A	2029-12-23
dupilumab	201285	Dupixent	Sanofi-Aventis Canada Inc.	N/A	2017-11-30	2023-11-30	Yes	2026-05-30
durvalumab	202953	Imfinzi	AstraZeneca Canada Inc.	N/A	2017-11-03	2023-11-03	N/A	2025-11-03
ebola zaire vaccine (rVSVΔG-ZEBOV-GP, live)	256568	Ervebo	Merck Canada Inc.	N/A	2022-11-09	2028-11-09	N/A	2030-11-09
edaravone	214391	Radicava	Mitsubishi Tanabe Pharma Corporation	N/A	2018-10-03	2024-10-03	N/A	2026-10-03
edoxaban	187363	Lixiana	Servier Canada Inc.	N/A	2016-11-04	2022-11-04	Yes	2025-05-04
efgartigimod alfa	267438	Vyvgart	Argenx BV	N/A	2023-09-19	2029-09-19	N/A	2031-09-19
elagolix	209513	Orilissa	AbbVie Corporation	N/A	2018-10-05	2024-10-05	N/A	2026-10-05
elasomeran	252733	Spikevax	Moderna Biopharma Canada Corporation	Spikevax Bivalent Spikevax Bivalent (Original/Omicron BA.4/5)	2021-09-16	2027-09-16	Yes	2030-03-16

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elexacaftor	246955	Trikafta	Vertex Pharmaceuticals (Canada) Incorporated	N/A	2021-06-18	2027-06-18	Yes	2029-12-18
eliglustat tartrate	183050	Cerdelga	Sanofi-Aventis Canada Inc.	N/A	2017-04-21	2023-04-21	N/A	2025-04-21
elranatamab	273519	Elrexfio	Pfizer Canada ULC	N/A	2023-12-06	2029-12-06	N/A	2031-12-06
eluxadoline	190162	Viberzi	AbbVie Corporation	N/A	2017-01-26	2023-01-26	N/A	2025-01-26
emicizumab	212635	Hemlibra	Hoffmann-La Roche Limited	N/A	2018-08-02	2024-08-02	Yes	2027-02-02
enasidenib mesylate	217033	Idhifa	Celgene Inc.	N/A	2019-02-06	2025-02-06	N/A	2027-02-06
encorafenib	237413	Braftovi	Pfizer Canada ULC	N/A	2021-03-02	2027-03-02	N/A	2029-03-02
enfortumab vedotin	251438	Padcev	Seagen Inc.	N/A	2021-10-29	2027-10-29	N/A	2029-10-29
entrectinib	227517	Rozlytrek	Hoffmann-La Roche Limited	N/A	2020-02-10	2026-02-10	Yes	2028-08-10
epcoritamab	271331	Epkinly	AbbVie Corporation	N/A	2023-10-13	2029-10-13	N/A	2031-10-13
eplontersen sodium	274598	Wainua	AstraZeneca Canada Inc.	N/A	2024-06-19	2030-06-19	N/A	2032-06-19
eptinezumab	233288	Vyepti	Lundbeck Canada Inc.	N/A	2021-01-11	2027-01-11	N/A	2029-01-11
erdafitinib	224529	Balversa	Janssen Inc.	N/A	2019-10-25	2025-10-25	N/A	2027-10-25
erenumab	208607	Aimovig	Novartis Pharmaceuticals Canada Inc.	N/A	2018-08-01	2024-08-01	N/A	2026-08-01
ertugliflozin	204724	Steglatro	Merck Canada Inc.	Steglujan Segluromet	2018-05-09	2024-05-09	N/A	2026-05-09
estetrol monohydrate	236197	Nextstellis	Searchlight Pharma Inc.	N/A	2021-03-05	2027-03-05	N/A	2029-03-05
etranacogene dezaparvovec	273721	Hemgenix	CSL Behring Canada Inc.	N/A	2023-10-23	2029-10-23	N/A	2031-10-23

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etrasimod L-arginine	271038	Velsipity	Pfizer Canada ULC	N/A	2024-01-31	2030-01-31	N/A	2032-01-31
evinacumab	272688	Evkeeza	Ultragenyx Pharmaceutical Inc.	N/A	2023-09-22	2029-09-22	Yes	2032-03-22
famtozinameran	267502	Comirnaty Original & Omicron BA.4/BA.5	BioNTech Manufacturing GmbH	N/A	2022-10-07	2028-10-07	Yes	2031-04-07
faricimab	253904	Vabysmo	Hoffmann-La Roche Limited	N/A	2022-05-27	2028-05-27	N/A	2030-05-27
fedratinib (supplied as fedratinib hydrochloride)	229866	Inrebic	Bristol-Myers Squibb Canada	N/A	2020-07-27	2026-07-27	N/A	2028-07-27
ferric carboxymaltose	272960	Ferinject	Vifor (International) Inc.	N/A	2024-03-11	2030-03-11	Yes	2032-09-11
ferric derisomaltose	193890	Monoferric	Pharmacosmos A/S	N/A	2018-06-22	2024-06-22	Yes	2026-12-22
ferric pyrophosphate citrate	239850	Triferic Avnu	Rockwell Medical Inc.	N/A	2021-04-22	2027-04-22	Yes	2029-10-22
fidanacogene elaparvovec	275853	Beqvez	Pfizer Canada ULC	N/A	2023-12-27	2029-12-27	N/A	2031-12-27
finafloxacin	172450	Xtoro	MerLion Pharmaceuticals GmbH	N/A	2016-03-11	2022-03-11	Yes	2024-09-11
finerenone	258231	Kerendia	Bayer Inc.	N/A	2022-10-14	2028-10-14	N/A	2030-10-14
flibanserin	189352	Addyi	Searchlight Pharma Inc.	N/A	2018-02-27	2024-02-27	N/A	2026-02-27
florbetaben (18F)	193105	Neuraceq	Isologic Innovative Radiopharmaceuticals Ltd.	N/A	2017-02-22	2023-02-22	N/A	2025-02-22
follitropin delta	188743	Rekovelle	Ferring Inc.	N/A	2018-03-22	2024-03-22	N/A	2026-03-22
fostamatinib (supplied as fostamatinib disodium)	232078	Tavalisse	Medison Pharma Canada Inc.	N/A	2020-11-19	2026-11-19	N/A	2028-11-19

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fostemsavir (supplied as fostemsavir tromethamine)	250213	Rukobia	ViiV Healthcare ULC	N/A	2021-10-01	2027-10-01	N/A	2029-10-01
fremanezumab	226828	Ajovy	Teva Canada Limited	N/A	2020-04-09	2026-04-09	N/A	2028-04-09
gadoterate meglumine	186333	Dotarem	Guerbet	N/A	2016-11-26	2022-11-26	Yes	2025-05-26
galcanezumab	219521	Emgality	Eli Lilly Canada Inc.	N/A	2019-07-30	2025-07-30	N/A	2027-07-30
gemtuzumab ozogamicin	223091	Mylotarg	Pfizer Canada ULC	N/A	2019-11-28	2025-11-28	Yes	2028-05-28
gilteritinib fumarate	227918	Xospata	Astellas Pharma Canada Inc.	N/A	2019-12-23	2025-12-23	N/A	2027-12-23
givosiran (supplied as givosiran sodium)	237194	Givlaari	Alnylam Netherlands B.V.	N/A	2020-10-09	2026-10-09	N/A	2028-10-09
glasdegib	225793	Daurismo	Pfizer Canada ULC	N/A	2020-04-28	2026-04-28	N/A	2028-04-28
glecaprevir, pibrentasvir	202233	Maviret	AbbVie Corporation	N/A	2017-08-16	2023-08-16	Yes	2026-02-16
glofitamab	265517	Columvi	Hoffmann-La Roche Limited	N/A	2023-03-24	2029-03-24	N/A	2031-03-24
glycerol phenylbutyrate	174219	Ravicti	Horizon Pharma Ireland Ltd.	N/A	2016-03-18	2022-03-18	Yes	2024-09-18
guselkumab	200590	Tremfya	Janssen Inc.	N/A	2017-11-10	2023-11-10	N/A	2025-11-10
hemin	212276	Panhematin	Recordati Rare Diseases Canada Inc.	N/A	2018-07-13	2024-07-13	N/A	2026-07-13
hepatitis B surface antigen (recombinant)	259302	Prehevbrio	VBI Vaccines Inc.	N/A	2022-12-06	2028-12-06	N/A	2030-12-06
icosapent ethyl	227235	Vascepa	HLS Therapeutics Inc.	N/A	2019-12-30	2025-12-30	N/A	2027-12-30
idecabtagene vicleucel	244266	Abecma	Celgene Inc.	N/A	2021-05-26	2027-05-26	N/A	2029-05-26

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imelasomeran	265656	Spikevax Bivalent	Moderna Biopharma Canada Corporation	N/A	2022-09-01	2028-09-01	Yes	2031-03-01
inclisiran sodium	243470	Leqvio	Novartis Pharmaceuticals Canada Inc.	N/A	2021-07-26	2027-07-26	N/A	2029-07-26
inebilizumab	271065	Uplizna	Horizon Therapeutics Ireland DAC	N/A	2023-12-15	2029-12-15	N/A	2031-12-15
infigratinib (supplied as infigratinib phosphate)	246904	Truseltiq	QED Therapeutics, Inc.	N/A	2021-09-27	2027-09-27	N/A	2029-09-27
inotersen sodium	214274	Tegsedi	Akcea Therapeutics Inc.	N/A	2018-10-03	2024-10-03	N/A	2026-10-03
inotuzumab ozogamicin	204077	Besponsa	Pfizer Canada Inc.	N/A	2018-03-15	2024-03-15	N/A	2026-03-15
insulin degludec	198124	Tresiba	Novo Nordisk Canada Inc.	Xultophy	2017-08-25	2023-08-25	Yes	2026-02-25
insulin icodec	273850	Awiqli	Novo Nordisk Canada Inc.	N/A	2024-03-12	2030-03-12	N/A	2032-03-12
ioflupane (^{123}I)	201481	Datscan	GE Healthcare Canada Inc.	N/A	2017-12-07	2023-12-07	N/A	2025-12-07
isatuximab	229245	Sarclisa	Sanofi-Aventis Canada Inc.	N/A	2020-04-29	2026-04-29	N/A	2028-04-29
isavuconazole (supplied as isavuconazonium sulfate)	208919	Cresemba	Avir Pharma Inc.	N/A	2018-12-19	2024-12-19	N/A	2026-12-19
ivabradine hydrochloride	166949	Lancora	Servier Canada Inc.	N/A	2016-12-23	2022-12-23	Yes	2025-06-23
ixazomib (supplied as ixazomib citrate)	190498	Ninlaro	Takeda Canada Inc.	N/A	2016-08-04	2022-08-04	N/A	2024-08-04
ixekizumab	184993	Taltz	Eli Lilly Canada Inc.	N/A	2016-05-25	2022-05-25	Yes	2024-11-25
lanadelumab	213920	Takhzyro	Takeda Canada Inc.	N/A	2018-09-19	2024-09-19	Yes	2027-03-19
larotrectinib (supplied as larotrectinib sulfate)	219998	Vitrakvi	Bayer Inc.	N/A	2019-07-10	2025-07-10	Yes	2028-01-10

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latanoprostene bunod	211732	Vyzulta	Bausch & Lomb Incorporated	N/A	2018-12-27	2024-12-27	N/A	2026-12-27
lebrikizumab	272660	Ebglyss	Eli Lilly Canada Inc.	N/A	2024-06-24	2030-06-24	Yes	2032-12-24
lefamulin acetate	233292	Xenleta	Sunovion Pharmaceuticals Canada Inc.	N/A	2020-07-10	2026-07-10	N/A	2028-07-10
lemborexant	231286	Dayvigo	Eisai Limited	N/A	2020-11-04	2026-11-04	N/A	2028-11-04
lenacapavir (supplied as lenacapavir sodium)	262999	Sunlenca	Gilead Sciences Canada, Inc.	N/A	2022-11-02	2028-11-02	N/A	2030-11-02
letermovir	204165	Prevymis	Merck Canada Inc.	N/A	2017-11-01	2023-11-01	N/A	2025-11-01
lifitegrast	199810	Xiidra	Novartis Pharmaceuticals Canada Inc.	N/A	2017-12-22	2023-12-22	N/A	2025-12-22
lisocabtagene maraleucel	247562	Breyanzi	Bristol-Myers Squibb Canada	N/A	2022-05-06	2028-05-06	N/A	2030-05-06
lixisenatide	193862	Adlyxine	Sanofi-Aventis Canada Inc.	Soliqua	2017-05-25	2023-05-25	N/A	2025-05-25
lorlatinib	215733	Lorbrena	Pfizer Canada ULC	N/A	2019-02-22	2025-02-22	N/A	2027-02-22
lumacaftor	181715	Orkambi	Vertex Pharmaceuticals (Canada) Incorporated	N/A	2016-01-26	2022-01-26	Yes	2024-07-26
lumasiran (supplied as lumasiran sodium)	254883	Oxlumo	Alnylam Netherlands B.V.	N/A	2022-03-07	2028-03-07	Yes	2030-09-07
lurbinectedin	247485	Zepzelca	Jazz Pharmaceuticals Ireland Limited	N/A	2021-09-29	2027-09-29	N/A	2029-09-29
luspatercept	236441	Reblozyl	Celgene Inc.	N/A	2020-09-25	2026-09-25	N/A	2028-09-25
lutetium (^{177}Lu) oxodotreotide	217184	Lutathera	Novartis Pharmaceuticals Canada Inc.	N/A	2019-01-09	2025-01-09	N/A	2027-01-09
lutetium (^{177}Lu) vipivotide tetraxetan	260951	Pluvicto	Novartis Pharmaceuticals Canada Inc.	N/A	2022-08-25	2028-08-25	N/A	2030-08-25

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maralixibat chloride	271030	Livmarli	Mirum Pharmaceuticals, Inc.	N/A	2023-07-21	2029-07-21	Yes	2032-01-21
maribavir	259676	Livtencity	Takeda Canada Inc.	N/A	2022-09-15	2028-09-15	N/A	2030-09-15
mavacamten	258772	Camzyos	Bristol-Myers Squibb Canada	N/A	2022-11-08	2028-11-08	N/A	2030-11-08
mecasermin	235023	Increlex	Ipsen Biopharmaceuticals Canada Inc.	N/A	2020-12-17	2026-12-17	Yes	2029-06-17
metreleptin	273908	Myalepta	Amryt Pharmaceuticals DAC	N/A	2024-01-17	2030-01-17	Yes	2032-07-17
midostaurin	201101	Rydapt	Novartis Pharmaceuticals Canada Inc.	N/A	2017-07-21	2023-07-21	Yes	2026-01-21
migalastat hydrochloride	196956	Galafold	Amicus Therapeutics Canada Inc.	N/A	2017-09-05	2023-09-05	Yes	2026-03-05
mirikizumab	266471	Omvoh	Eli Lilly Canada Inc.	N/A	2023-07-20	2029-07-20	N/A	2031-07-20
mogamulizumab	251277	Poteligeo	Kyowa Kirin, Inc.	N/A	2022-06-02	2028-06-02	N/A	2030-06-02
necitumumab	193689	Portrazza	Eli Lilly Canada Inc.	N/A	2017-03-16	2023-03-16	N/A	2025-03-16
neisseria meningitidis serogroup B recombinant lipoprotein 2086 (rLP2086) subfamily A and Neisseria meningitidis serogroup B recombinant lipoprotein 2086 (rLP2086) subfamily B	195550	Trumenba	Pfizer Canada Inc.	N/A	2017-10-05	2023-10-05	Yes	2026-04-05
neratinib maleate	218224	Nerlynx	Knight Therapeutics Inc.	N/A	2019-07-16	2025-07-16	N/A	2027-07-16
netupitant	196495	Akynzeo	Knight Therapeutics Inc.	N/A	2017-09-28	2023-09-28	N/A	2025-09-28
niraparib	216792	Zejula	GlaxoSmithKline Inc.	Akeega	2019-06-27	2025-06-27	N/A	2027-06-27

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nirmatrelvir	259186	Paxlovid	Pfizer Canada ULC	N/A	2022-01-17	2028-01-17	N/A	2030-01-17
nirsevimab	269388	Beyfortus	AstraZeneca Canada Inc.	N/A	2023-04-19	2029-04-19	Yes	2031-10-19
nusinersen	200070	Spinraza	Biogen Canada Inc.	N/A	2017-06-29	2023-06-29	Yes	2025-12-29
obeticholic acid	198418	Ocaliva	Advanz Pharma Canada Inc.	N/A	2017-05-24	2023-05-24	Yes	2025-11-24
obiltoxaximab	230825	Anthim	Elusys Therapeutics, Inc.	N/A	2020-07-30	2026-07-30	N/A	2028-07-30
ocrelizumab	198094	Ocrevus	Hoffmann-La Roche Limited	N/A	2017-08-14	2023-08-14	N/A	2025-08-14
odevixibat	273741	Bylvay	Medison Pharma Canada Inc.	N/A	2023-10-30	2029-10-30	Yes	2032-04-30
olaratumab	203478	Lartruvo	Eli Lilly Canada Inc.	N/A	2017-11-23	2023-11-23	N/A	2025-11-23
olipudase alfa	275236	Xenpozyme	Sanofi-Aventis Canada Inc.	N/A	2024-02-28	2030-02-28	Yes	2032-08-28
onasemnogene abeparvovec	239719	Zolgensma	Novartis Pharmaceuticals Canada Inc.	N/A	2020-12-15	2026-12-15	Yes	2029-06-15
ospemifene	222001	Osphena	Duchesnay Inc.	N/A	2021-07-16	2027-07-16	N/A	2029-07-16
ozanimod (supplied as ozanimod hydrochloride)	232761	Zeposia	Bristol-Myers Squibb Canada Co.	N/A	2020-10-02	2026-10-02	N/A	2028-10-02
ozenoxacin	192925	Ozanex	Ferrer Internacional, S.A.	N/A	2017-05-01	2023-05-01	Yes	2025-11-01
palbociclib	182048	Ibrance	Pfizer Canada Inc.	N/A	2016-03-16	2022-03-16	Yes	2024-09-16
palovarotene	252065	Sohonos	Ipsen Biopharmaceuticals Canada Inc.	N/A	2022-01-21	2028-01-21	Yes	2030-07-21
patiromer sorbitex calcium	210368	Veltassa	Vifor Fresenius Medical Care Renal Pharma Ltd.	N/A	2018-10-03	2024-10-03	N/A	2026-10-03
patisiran (as patisiran sodium)	221896	Onpattro	Alnylam Netherlands B.V.	N/A	2019-06-07	2025-06-07	N/A	2027-06-07

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pegcetacoplan	263432	Empaveli	Swedish Orphan Biovitrium AB (publ)	N/A	2022-12-08	2028-12-08	N/A	2030-12-08
pegvaliase	251687	Palynziq	BioMarin International Limited	N/A	2022-03-30	2028-03-30	Yes	2030-09-30
pemigatinib	242569	Pemazyre	Incyte Corporation	N/A	2021-09-17	2027-09-17	N/A	2029-09-17
peramivir	191280	Rapivab	BioCryst Pharmaceuticals Inc.	N/A	2017-01-05	2023-01-05	N/A	2025-01-05
pitolisant hydrochloride	238175	Wakix	Endo Ventures Ltd.	N/A	2021-05-25	2027-05-25	Yes	2029-11-25
plecanatide	215288	Trulance	Bausch Health, Canada Inc.	N/A	2019-10-10	2025-10-10	N/A	2027-10-10
pneumococcal polysaccharide serotypes 22F and 33F conjugated to CRM-197.	247042	Vaxneuvance	Merk Canada Inc.	N/A	2021-11-16	2027-11-16	Yes	2030-05-16
pneumococcal polysaccharide serotypes 8, 10A, 11A, 12F and 15B individually conjugated to CRM197 protein	253111	Prevnar 20	Pfizer Canada ULC	N/A	2022-05-09	2028-05-09	Yes	2030-11-09
polatuzumab vedotin	232303	Polivy	Hoffmann-La Roche Limited	N/A	2020-07-09	2026-07-09	N/A	2028-07-09
ponesimod	239537	Ponvory	Janssen Inc.	N/A	2021-04-28	2027-04-28	N/A	2029-04-28
pralatrexate	207545	Folotyn	Servier Canada Inc.	N/A	2018-10-26	2024-10-26	N/A	2026-10-26
pralsetinib	243731	Gavreto	Hoffmann-La Roche Limited	N/A	2021-06-30	2027-06-30	N/A	2029-06-30
prasterone	198822	Intrarosa	Cosette Pharmaceuticals, Inc.	N/A	2019-11-01	2025-11-01	N/A	2027-11-01
propiverine hydrochloride	188323	Mictoryl / Mictoryl Pediatric	Duchesnay Inc.	N/A	2017-01-05	2023-01-05	Yes	2025-07-05
ravulizumab	217955	Ultomiris	Alexion Pharma GmbH	N/A	2019-08-28	2025-08-28	Yes	2028-02-28

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raxtozinameran	276302	Comirnaty Omicron XBB.1.5	BioNTech Manufacturing GmbH	N/A	2023-09-28	2029-09-28	N/A	2031-09-28
recombinant haemagglutinin protein-strain A (H1N1) recombinant haemagglutinin protein-strain A (H3N2) recombinant haemagglutinin protein-strain B (Victoria) recombinant haemagglutinin protein-strain B (Yamagata)	235672	Supemtek	Sanofi Pasteur Limited	N/A	2021-01-14	2027-01-14	N/A	2029-01-14
recombinant human hyaluronidase	247727	Hyqvia	Takeda Canada Inc.	N/A	2022-01-14	2028-01-14	Yes	2030-07-14
relatlimab	256629	Opdualag	Bristol-Myers Squibb Canada	N/A	2023-09-13	2029-09-13	Yes	2032-03-13
relugolix	267148	Myfembree	Sumitomo Pharma Switzerland GmbH	Orgovyx	2023-09-22	2029-09-22	N/A	2031-09-22
remdesivir	240551	Veklury	Gilead Sciences Canada, Inc.	N/A	2020-07-27	2026-07-27	Yes	2029-01-27
reslizumab	185873	Cinqair	Teva Canada Limited	N/A	2016-07-20	2022-07-20	Yes	2025-01-20
respiratory syncytial virus prefusion F protein (RSVPreF3)	269021	Arexvy	GlaxoSmithKline Inc.	N/A	2023-08-04	2029-08-04	N/A	2031-08-04
ribociclib (supplied as ribociclib succinate)	203884	Kisqali	Novartis Pharmaceuticals Canada Inc.	N/A	2018-03-02	2024-03-02	N/A	2026-03-02
riltozinameran	266189	Comirnaty Original / Omicron BA.1	BioNTech Manufacturing GmbH	N/A	2022-10-21	2028-10-21	Yes	2031-04-21
rimegepant	268384	Nurtec ODT	Pfizer Canada ULC	N/A	2023-12-01	2029-12-01	N/A	2031-12-01
ripretinib	234688	Qinlock	Deciphera Pharmaceuticals, LLC	N/A	2020-06-19	2026-06-19	N/A	2028-06-19

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risankizumab	215753	Skyrizi	AbbVie Corporation	N/A	2019-04-17	2025-04-17	Yes	2027-10-17
risdiplam	242373	Evrysdi	Hoffman-La Roche Limited	N/A	2021-04-14	2027-04-14	Yes	2029-10-14
ritlecitinib tosylate	268723	Litfulo	Pfizer Canada ULC	N/A	2023-11-29	2029-11-29	Yes	2032-05-29
romosozumab	197713	Evenity	Amgen Canada Inc.	N/A	2019-06-17	2025-06-17	N/A	2027-06-17
RSV subgroup A stabilized prefusion F protein and RSV subgroup B stabilized prefusion F protein	272785	Abrysvo	Pfizer Canada ULC	N/A	2023-12-21	2029-12-21	Yes	2032-06-21
rupatadine (supplied as rupatadine fumarate)	186488	Rupall	Medexus Inc.	N/A	2016-07-20	2022-07-20	Yes	2025-01-20
sacituzumab govitecan	248753	Trodelvy	Gilead Sciences Canada, Inc.	N/A	2021-09-24	2027-09-24	N/A	2029-09-24
safinamide (as safinamide mesylate)	207115	Onstryv	Valeo Pharma Inc.	N/A	2019-01-10	2025-01-10	N/A	2027-01-10
sarilumab	191745	Kevzara	Sanofi-Aventis Canada Inc.	N/A	2017-01-12	2023-01-12	N/A	2025-01-12
sars-cov-2 recombinant spike protein	255370	Nuvaxovid	Novavax Inc.	N/A	2022-02-17	2028-02-17	Yes	2030-08-17
sars-cov-2 recombinant spike protein (omicron XBB.1.5)	278519	Nuvaxovid XBB.1.5	Novavax Inc.	N/A	2023-12-05	2029-12-05	N/A	2031-12-05
satralizumab	233642	Enspryng	Hoffmann-La Roche Limited	N/A	2020-06-01	2026-06-01	Yes	2028-12-01
sebelipase alfa	204085	Kanuma	Alexion Pharma GmbH	N/A	2017-12-15	2023-12-15	Yes	2026-06-15
selexipag	182114	Uptravi	Janssen Inc.	N/A	2016-01-20	2022-01-20	Yes	2024-07-20
selinexor	253182	Xpovio	FORUS Therapeutics Inc.	N/A	2022-05-31	2028-05-31	N/A	2030-05-31
selpercatinib	243748	Retevmo	Loxo Oncology Inc.	N/A	2021-06-15	2027-06-15	Yes	2029-12-15

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selumetinib sulfate	243733	Koselugo	Alexion Pharma GmbH	N/A	2022-08-31	2028-08-31	Yes	2031-03-03
semaglutide	202059	Ozempic	Novo Nordisk Canada Inc.	Rybelsus Wegovy	2018-01-04	2024-01-04	N/A	2026-01-04
setmelanotide acetate	268412	Imcivree	Rhythm Pharmaceuticals, Inc.	N/A	2023-05-05	2029-05-05	Yes	2031-11-05
siponimod	223225	Mayzent	Novartis Pharmaceuticals Canada Inc.	N/A	2020-02-20	2026-02-20	N/A	2028-02-20
sodium zirconium cyclosilicate	218799	Lokelma	AstraZeneca Canada Inc.	N/A	2019-07-25	2025-07-25	N/A	2027-07-25
solriamfetol hydrochloride	237511	Sunosi	Axsome Malta Ltd.	N/A	2021-05-13	2027-05-13	N/A	2029-11-13
somapacitan	267443	Sogroya	Novo Nordisk Canada Inc.	N/A	2023-07-26	2029-07-26	Yes	2032-01-26
somatrogon	246729	Ngenla	Pfizer Canada ULC	N/A	2021-10-26	2027-10-26	Yes	2030-04-26
sonidegib phosphate	229407	Odomzo	Sun Pharmaceutical Industries Ltd.	N/A	2020-06-12	2026-06-12	N/A	2028-06-12
sotorasib	248435	Lumakras	Amgen Canada Inc.	N/A	2021-09-10	2027-09-10	N/A	2029-09-10
spesolimab	267362	Spevigo	Boehringer Ingelheim (Canada) Ltd.	N/A	2023-03-22	2029-03-22	N/A	2031-03-22
sucroferric oxyhydroxide	201492	Velphoro	Vifor Fresenius Medical Care Renal Pharma Ltd.	N/A	2018-01-05	2024-01-05	N/A	2026-01-05
sugammadex sodium	180385	Bridion	Merck Canada Inc.	N/A	2016-02-05	2022-02-05	Yes	2024-08-05
suvorexant	196367	Belsomra	Merck Canada Inc.	N/A	2018-11-29	2024-11-29	N/A	2026-11-29
tafamidis meglumine	228368	Vyndaqel	Pfizer Canada ULC	Vyndamax	2020-01-20	2026-01-20	N/A	2028-01-20
tafasitamab	247025	Minjuvi	Incyte Corporation	N/A	2021-08-19	2027-08-19	N/A	2029-08-19

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talazoparib (supplied as talazoparib tosylate)	220584	Talzenna	Pfizer Canada ULC	N/A	2019-09-06	2025-09-06	N/A	2027-09-06
talquetamab	278277	Talvey	Janssen Inc.	N/A	2024-04-30	2030-04-30	N/A	2032-04-30
tebentafusp	258717	Kimmtrak	Immunocore Ireland Limited	N/A	2022-06-07	2028-06-07	N/A	2030-06-07
teclistamab	269369	Tecvayli	Janssen Inc.	N/A	2023-07-26	2029-07-26	N/A	2031-07-26
tecovirimat monohydrate	247561	Tpoxx	Siga Technologies, Inc.	N/A	2021-11-29	2027-11-29	Yes	2030-05-29
telotristat ethyl (as telotristat etiprate)	208730	Xermelo	SERB SAS	N/A	2018-10-10	2024-10-10	N/A	2026-10-10
tenapanor hydrochloride	224850	Ibsrela	Knight Therapeutics Inc.	N/A	2020-04-15	2026-04-15	N/A	2028-04-15
tepotinib (supplied as tepotinib hydrochloride)	242300	Tepmetko	EMD Serono, a Division of EMD Inc., Canada	N/A	2021-05-27	2027-05-27	N/A	2029-05-27
tezacaftor	211292	Symdeko	Vertex Pharmaceuticals (Canada) Incorporated	Trikafta	2018-06-27	2024-06-27	Yes	2026-12-27
tezepelumab	256188	Tezspire	AstraZeneca Canada Inc.	N/A	2022-07-28	2028-07-28	Yes	2031-01-28
tildrakizumab	224036	Ilumya	Sun Pharmaceutical Industries Ltd.	N/A	2021-05-19	2027-05-19	N/A	2029-05-19
tipiracil hydrochloride	205852	Lonsurf	Taiho Pharma Canada Inc.	N/A	2018-01-25	2024-01-25	N/A	2026-01-25
tirbanibulin	262080	Onakta	AVIR Pharma Inc.	N/A	2023-05-12	2029-05-12	N/A	2031-05-12
tirzepatide	259103	Mounjaro	Eli Lilly Canada Inc.	N/A	2022-11-24	2028-11-24	N/A	2030-11-24
tisagenlecleucel	213547 / 213698	Kymriah	Novartis Pharmaceuticals Canada Inc.	N/A	2018-09-05	2024-09-05	Yes	2027-03-05
tixagevimab / cilgavimab	258295	Evusheld	AstraZeneca Canada Inc.	N/A	2022-04-14	2028-04-14	N/A	2030-04-14

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tozinameran	252736	Comirnaty	BioNTech Manufacturing GmbH	Comirnaty Original & Omicron BA.4/BA.5 Comirnaty Original/Omicron BA.1	2021-09-16	2027-09-16	Yes	2030-03-16
tralokinumab	245877	Adtralza	LEO Pharma Inc.	N/A	2021-10-13	2027-10-13	Yes	2030-04-13
trastuzumab deruxtecan	242104	Enhertu	AstraZeneca Canada Inc.	N/A	2021-04-15	2027-04-15	N/A	2029-04-15
tremelimumab	262740	Imjudo	AstraZeneca Canada Inc.	N/A	2023-08-31	2029-08-31	N/A	2031-08-31
trifarotene	221945	Aklief	Galderma Canada Inc.	N/A	2019-11-25	2025-11-25	Yes	2028-05-25
triheptanoin	242196	Dojolvi	Ultragenyx Pharmaceutical Inc.	N/A	2021-02-15	2027-02-15	Yes	2029-08-15
tucatinib	235295	Tukysa	Seagen Inc.	N/A	2020-06-05	2026-06-05	N/A	2028-06-05
ubrogepant	256191	Ubrelvy	AbbVie Corporation	N/A	2022-11-10	2028-11-10	N/A	2030-11-10
upadacitinib	223734	Rinvoq	AbbVie Corporation	N/A	2019-12-23	2025-12-23	Yes	2028-06-23
ursodoxicoltaurine	253502	Albrioza	Amylyx Pharmaceuticals Inc.	N/A	2022-06-10	2028-06-10	N/A	2030-06-10
varicella-zoster virus glycoprotein E (gE)	200244	Shingrix	GlaxoSmithKline Inc.	N/A	2017-10-13	2023-10-13	N/A	2025-10-13
velpatasvir	190521	Epclusa	Gilead Sciences Canada Inc.	Vosevi	2016-07-11	2022-07-11	Yes	2025-01-11
venetoclax	190761	Venclexta	AbbVie Corporation	N/A	2016-09-30	2022-09-30	N/A	2024-09-30
vericiguat	240862	Verquvo	Bayer Inc.	N/A	2023-04-28	2029-04-28	N/A	2031-04-28

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vernakalant hydrochloride	190817	Brinavess	Cipher Pharmaceuticals Inc.	N/A	2017-03-13	2023-03-13	N/A	2025-03-13
virus-like particles (VLP) of sars-cov-2 spike protein	254598	Covifenz	Medicago Inc.	N/A	2022-02-24	2028-02-24	N/A	2030-02-24
von willebrand factor (recombinant) (vonicog alfa)	213188	Vonvendi	Takeda Canada Inc.	N/A	2019-01-10	2025-01-10	N/A	2027-01-10
voretigene neparvovec	233097	Luxturna	Novartis Pharmaceuticals Canada Inc.	N/A	2020-10-13	2026-10-13	Yes	2029-04-13
voxilaprevir	202324	Vosevi	Gilead Sciences Canada Inc.	N/A	2017-08-16	2023-08-16	N/A	2025-08-16
vutrisiran sodium	267923	Amvuttra	Alnylam Netherlands B.V.	N/A	2023-10-18	2029-10-18	N/A	2031-10-18
zanubrutinib	242748	Brukinsa	BeiGene Switzerland GmbH	N/A	2021-03-01	2027-03-01	N/A	2029-03-01

*The medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient (subsection C.08.004.1(1) of the *Food and Drug Regulations*).

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abatacept	098531	Orencia	Bristol-Myers Squibb Canada	N/A	2006-06-29	2012-06-29	Yes	2014-12-29
abiraterone acetate	138343	Zytiga	Janssen Inc.	N/A	2011-07-27	2017-07-27	N/A	2019-07-27
acamprosate calcium	103287	Campral	Mylan Pharmaceuticals ULC	N/A	2007-03-16	2013-03-16	N/A	2015-03-16
aclidinium bromide	157598	Tudorza Genuair	AstraZeneca Canada Inc.	Duaklir Genuair	2013-07-29	2019-07-29	N/A	2021-07-29
afatinib dimaleate	158730	Giotrif	Boehringer Ingelheim (Canada) Ltd.	N/A	2013-11-01	2019-11-01	N/A	2021-11-01
aflibercept	149321	Eylea	Bayer Inc.	N/A	2013-11-08	2019-11-08	N/A	2021-11-08
albiglutide	165145	Eperzan	GlaxoSmithKline Inc.	N/A	2015-07-15	2021-07-15	N/A	2023-07-15
alglucosidase alfa	103381	Myozyme	Genzyme Canada Inc.	N/A	2006-08-14	2012-08-14	Yes	2015-02-14
aliskiren hemifumarate	105388	Rasilez	Novartis Pharmaceuticals Canada Inc.	Rasilez HCT Rasilamlo	2007-11-14	2013-11-14	N/A	2015-11-14
alogliptin benzoate	158335	Nesina	Takeda Canada Inc.	Kazano Oseni	2013-11-27	2019-11-27	N/A	2021-11-27
ambrisentan	113287	Volibris	GlaxoSmithKline Inc.	N/A	2008-03-20	2014-03-20	N/A	2016-03-20
anidulafungin	110202	Eraxis	Pfizer Canada Inc.	N/A	2007-11-14	2013-11-14	Yes	2016-05-14
antihemophilic factor (recombinant BDD), Fc fusion protein	163447	Eloctate	Sanofi-Aventis Canada Inc.	N/A	2014-08-22	2020-08-22	Yes	2023-02-22

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antihemophilic factor (recombinant, B-domain deleted) (also known as simoctocog alfa)	169551	Nuwiq	Octapharma Pharmazeutika Produktionsges.m.b.H	N/A	2014-10-23	2020-10-23	Yes	2023-04-23
apixaban	141873	Eliquis	Bristol-Myers Squibb Canada	N/A	2011-12-16	2017-12-16	Yes	2020-06-16
apremilast	169862	Otezla	Amgen Canada Inc.	N/A	2014-11-12	2020-11-12	N/A	2022-11-12
aprepitant	108483	Emend	Merck Frosst Canada Ltd.	Emend Tri-Pack Emend IV	2007-08-24	2013-08-24	N/A	2015-08-24
aripiprazole	120192	Abilify	Bristol-Myers Squibb Canada	Abilify Maintena	2009-07-09	2015-07-09	Yes	2018-01-09
asenapine maleate	127427	Saphris	Merck Canada Inc.	N/A	2011-10-07	2017-10-07	Yes	2020-04-07
asfotase alfa	179340	Strensiq	Alexion Pharma International Sàrl	N/A	2015-08-14	2021-08-14	Yes	2024-02-14
asunaprevir	172617	Sunvepra	Bristol-Myers Squibb Canada	N/A	2016-03-09	2022-03-09	N/A	2024-03-09
axitinib	144404	Inlyta	Pfizer Canada Inc.	N/A	2012-07-12	2018-07-12	Yes	2021-01-12
azacitidine	127108	Vidaza	Celgene	N/A	2009-10-23	2015-10-23	N/A	2017-10-23
azelastine hydrochloride	169604	Dymista	BGP Pharma ULC	N/A	2014-10-23	2020-10-23	Yes	2023-04-23
azilsartan medoxomil potassium	145305	Edarbi	Valeant Canada LP	Edarbyclor	2012-03-08	2018-03-08	N/A	2020-03-08
bazedoxifene acetate	160681	Duavive	Pfizer Canada Inc.	N/A	2014-10-23	2020-10-23	N/A	2022-10-23

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belimumab	137699	Benlysta	GlaxoSmithKline Inc.	N/A	2011-07-06	2017-07-06	N/A	2019-07-06
bendamustine hydrochloride	149814	Treanda	Teva Canada Limited	N/A	2012-08-24	2018-08-24	Yes	2021-02-24
besifloxacin	123400	Besivance	Bausch & Lomb Inc.	N/A	2009-10-23	2015-10-23	Yes	2018-04-23
blinatumomab	181723	Blincyto	Amgen Canada Incorporated	N/A	2015-12-22	2021-12-22	Yes	2024-06-22
boceprevir	141556	Victrelis	Merck Canada Inc.	Victrelis Triple	2011-07-29	2017-07-29	N/A	2019-07-29
bosutinib	152211	Bosulif	Pfizer Canada Inc.	N/A	2014-03-07	2020-03-07	N/A	2022-03-07
brentuximab vedotin	154851	Adcetris	Seattle Genetics Inc.	N/A	2013-02-01	2019-02-01	N/A	2021-02-01
bromfenac sodium sesquihydrate	171657	Prolensa	Bausch & Lomb Incorporated	N/A	2015-03-26	2021-03-26	N/A	2023-03-26
cabazitaxel	137421	Jevtana	Sanofi-aventis Canada Inc.	N/A	2011-06-16	2017-06-16	Yes	2019-12-16
canagliflozin	157505	Invokana	Janssen Inc.	Invokamet Invokamet XR	2014-05-23	2020-05-23	N/A	2022-05-23
canakinumab	131009	Ilaris	Novartis Pharmaceuticals Canada Inc.	N/A	2010-02-26	2016-02-26	Yes	2018-08-26
carfilzomib	184479	Kyprolis	Amgen Canada Inc.	N/A	2016-01-15	2022-01-15	N/A	2024-01-15
carglumic acid	171358	Carbaglu	Recordati Rare Diseases	N/A	2015-04-10	2021-04-10	Yes	2023-10-10
catridecacog	152228	Tretten	Novo Nordisk Canada Inc.	N/A	2012-07-19	2018-07-19	Yes	2021-01-19

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catumaxomab	142629	Removab	Fresenius Biotech GmbH	N/A	2012-05-11	2018-05-11	N/A	2020-05-11
ceftobiprole medocaril	112752	Zeftera	Janssen Inc.	N/A	2008-06-26	2014-06-26	N/A	2016-06-26
ceftolozane	178006	Zerbaxa	Merck Canada Inc.	N/A	2015-09-30	2021-09-30	N/A	2023-09-30
ceritinib	175702	Zykadia	Novartis Pharmaceuticals Canada Inc.	N/A	2015-03-27	2021-03-27	N/A	2023-03-27
certolizumab pegol	120296	Cimzia	UCB Canada Inc.	N/A	2009-08-12	2015-08-12	N/A	2017-08-12
ciclesonide	101419	Alvesco	Takeda Canada Inc.	Omnaris Omnaris HFA	2006-09-11	2012-09-11	Yes	2015-03-11
clevidipine	125287	Cleviprex	Chiesi Farmaceutici S.p.A.	N/A	2011-04-15	2017-04-15	N/A	2019-04-15
clofarabine	121874	Clolar	Sanofi-aventis Canada Inc.	N/A	2009-07-16	2015-07-16	Yes	2018-01-16
coagulation factor IX, Fc fusion protein	163614	Alprolix	Sanofi-Aventis Canada Inc.	N/A	2014-03-20	2020-03-20	Yes	2022-09-20
cobimetinib	182788	Cotellic	Hoffmann-La Roche Limited	N/A	2016-02-22	2022-02-22	N/A	2024-02-22
colesevelam hydrochloride	133463	Lodalis	Valeant Canada LP / Valeant Canada S.E.C.	N/A	2011-09-22	2017-09-22	N/A	2019-09-22
collagenase clostridium histolyticum	147788	Xiaflex	Endo Ventures Ltd.	N/A	2012-07-05	2018-07-05	N/A	2020-07-05
crizotinib	145155	Xalkori	Pfizer Canada Inc.	N/A	2012-04-25	2018-04-25	Yes	2020-10-25
dabigatran etexilate mesilate	114887	Pradaxa	Boehringer Ingelheim (Canada) Ltd.	N/A	2008-06-10	2014-06-10	N/A	2016-06-10

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dabrafenib mesylate	157590	Tafinlar	Novartis Pharmaceuticals Canada Inc.	N/A	2013-07-16	2019-07-16	N/A	2021-07-16
daclatasvir	172616	Daklinza	Bristol-Myers Squibb Canada	N/A	2015-08-13	2021-08-13	N/A	2023-08-13
dapagliflozin propanediol	160877	Forxiga	AstraZeneca Canada Inc.	Xigduo Qtern	2014-12-12	2020-12-12	N/A	2022-12-12
daptomycin	102320	Cubicin	Cubist Pharmaceuticals, Incorporated	N/A	2007-09-24	2013-09-24	Yes	2016-03-24
daratumumab	187648	Darzalex	Janssen Inc.	Darzalex SC	2016-06-29	2022-06-29	N/A	2024-06-29
darunavir ethanolate	103324	Prezista	Janssen Inc.	N/A	2006-07-28	2012-07-28	Yes	2015-01-28
dasatinib monohydrate	104993	Sprycel	Bristol-Myers Squibb Canada	N/A	2007-03-26	2013-03-26	N/A	2015-03-26
deferasirox	099621	Exjade	Novartis Pharmaceuticals Canada Inc.	N/A	2006-10-18	2012-10-18	Yes	2015-04-18
deferiprone	162924	Ferriprox	Chiesi Canada Corp.	N/A	2015-02-13	2021-02-13	Yes	2023-08-13
degarelix acetate	120421	Firmagon	Ferring Inc.	N/A	2009-11-16	2015-11-16	N/A	2017-11-16
denosumab	121139	Prolia	Amgen Canada Inc.	Xgeva	2010-08-06	2016-08-06	N/A	2018-08-06
desvenlafaxine succinate	115439	Pristiq	Pfizer Canada Inc.	N/A	2009-02-04	2015-02-04	Yes	2017-08-04
dexmedetomidine hydrochloride	126931	Precedex	Pfizer Canada Inc.	N/A	2009-12-09	2015-12-09	Yes	2018-06-09
dienogest	132174	Visanne	Bayer Inc.	Natazia	2011-10-12	2017-10-12	Yes	2020-04-12
difluprednate	154517	Durezol	Novartis Pharmaceuticals Canada Inc.	N/A	2013-11-04	2019-11-04	Yes	2022-05-04

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dimethyl fumarate	154776	Tecfidera	Biogen Idec Canada Inc.	N/A	2013-04-03	2019-04-03	Yes	2021-10-03
dolutegravir sodium	161084	Tivicay	ViiV Healthcare ULC	Triumeq Juluca Dovato	2013-10-31	2019-10-31	Yes	2022-05-01
doripenem monohydrate	113640	Doribax	Janssen Inc.	N/A	2009-09-02	2015-09-02	N/A	2017-09-02
dronedarone hydrochloride	121065	Multaq	Sanofi-aventis Canada Inc.	N/A	2009-08-11	2015-08-11	N/A	2017-08-11
dulaglutide	168671	Trulicity	Eli Lilly Canada Inc.	N/A	2015-11-10	2021-11-10	N/A	2023-11-10
duloxetine hydrochloride	110028	Cymbalta	Eli Lilly Canada Inc.	N/A	2007-11-01	2013-11-01	Yes	2016-05-01
eculizumab	122467	Soliris	Alexion Pharma International Sàrl	N/A	2009-01-28	2015-01-28	Yes	2017-07-28
efinaconazole	159416	Jublia	Bausch Health, Canada Inc.	N/A	2013-10-02	2019-10-02	N/A	2021-10-02
elosulfase alfa	170340	Vimizim	Biomarin International Limited	N/A	2014-07-02	2020-07-02	Yes	2023-01-02
elotuzumab	188144	Empliciti	Bristol-Myers Squibb Canada	N/A	2016-06-21	2022-06-21	N/A	2024-06-21
eltrombopag olamine	123984	Revolade	Novartis Pharmaceuticals Canada Inc.	N/A	2011-01-12	2017-01-12	Yes	2019-07-12
elvitegravir, cobicistat	152198	Stribild	Gilead Sciences Canada Inc.	Tybost Vitekta Prezcobix Evotaz Genvoya Symtuza	2012-11-26	2018-11-26	N/A	2020-11-26

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empagliflozin	162552	Jardiance	Boehringer Ingelheim (Canada) Ltd.	Synjardy Glyxambi	2015-07-23	2021-07-23	N/A	2023-07-23
enzalutamide	159678	Xtandi	Astellas Pharma Canada Inc.	N/A	2013-05-29	2019-05-29	N/A	2021-05-29
eplerenone	120440	Inspra	Pfizer Canada Inc.	N/A	2009-02-26	2015-02-26	Yes	2017-08-26
eribulin mesylate	141946	Halaven	Eisai Limited	N/A	2011-12-14	2017-12-14	N/A	2019-12-14
eslicarbazepine acetate	165665	Aptiom	Sunovion Pharmaceuticals Canada Inc.	N/A	2014-07-08	2020-07-08	Yes	2023-01-08
etravirine	113100	Intelence	Janssen Inc.	N/A	2008-03-27	2014-03-27	Yes	2016-09-27
everolimus	125809	Afinitor	Novartis Pharmaceuticals Canada Inc.	Certican	2009-12-14	2015-12-14	Yes	2018-06-14
evolocumab	178234	Repatha	Amgen Canada Inc.	N/A	2015-09-10	2021-09-10	Yes	2024-03-10
exenatide	128932	Byetta	AstraZeneca Canada Inc.	Bydureon	2011-01-13	2017-01-13	N/A	2019-01-13
ezogabine	134659	Potiga	GlaxoSmithKline Inc.	N/A	2012-10-18	2018-10-18	N/A	2020-10-18
fampridine	132859	Fampyra	Biogen Idec Canada Inc.	N/A	2012-02-10	2018-02-10	N/A	2020-02-10
febuxostat	129969	Uloric	Takeda Canada Inc.	N/A	2010-09-22	2016-09-22	N/A	2018-09-22
ferumoxytol	133250	Feraheme	AMAG Pharmaceuticals Inc.	N/A	2011-12-08	2017-12-08	N/A	2019-12-08
fesoterodine fumarate	142326	Toviaz	Pfizer Canada Inc.	N/A	2012-02-09	2018-02-09	Yes	2020-08-09
fidaxomicin	151086	Dificid	Merck Canada Inc.	N/A	2012-06-07	2018-06-07	N/A	2020-06-07

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fingolimod hydrochloride	137516	Gilenya	Novartis Pharmaceuticals Canada Inc.	N/A	2011-03-09	2017-03-09	N/A	2019-03-09
fludeoxyglucose 18F	091404	Cantrace	Ipet Pharmaceuticals Inc.	N/A	2006-07-27	2012-07-27	N/A	2014-07-27
fluticasone furoate	107372	Avamys	GlaxoSmithKline Inc.	N/A	2007-08-14	2013-08-14	Yes	2016-02-14
gadofosveset trisodium	096420	Vasovist	Berlex Canada Inc.	N/A	2006-10-31	2012-10-31	N/A	2014-10-31
gadoxetate disodium	127609	Primovist	Bayer Inc.	N/A	2010-01-14	2016-01-14	N/A	2018-01-14
galsulfase	159020	Naglazyme	BioMarin Pharmaceutical Inc.	N/A	2013-09-16	2019-09-16	Yes	2022-03-16
golimumab	120525	Simponi	Janssen Inc.	N/A	2009-04-07	2015-04-07	N/A	2017-04-07
grazoprevir, elbasvir	185866	Zepatier	Merck Canada Inc.	N/A	2016-01-19	2022-01-19	N/A	2024-01-19
guanfacine hydrochloride	150741	Intuniv XR	Takeda Canada Inc.	N/A	2013-07-05	2019-07-05	Yes	2022-01-05
haemagglutinin strain A (H5N1)	115398	Arepanrix H5N1	ID Biomedical Corporation of Quebec	N/A	2013-02-13	2019-02-13	Yes	2021-08-13
human C1 esterase inhibitor	121221	Berinert	CSL Behring Canada Inc.	Haegarda	2010-05-31	2016-05-31	N/A	2018-05-31
ibrutinib	174029	Imbruvica	Janssen Inc.	N/A	2014-11-17	2020-11-17	Yes	2023-05-17
icatibant acetate	162918	Firazyr	Takeda Canada Inc.	N/A	2014-06-04	2020-06-04	Yes	2022-12-04
idarucizumab	182503	Praxbind	Boehringer Ingelheim (Canada) Ltd	N/A	2016-04-29	2022-04-29	N/A	2024-04-29
idebenone	117672	Catena	Santhera Pharmaceuticals Ltd.	N/A	2008-07-23	2014-07-23	Yes	2017-01-23

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idelalisib	172652	Zydelig	Gilead Sciences Canada Inc.	N/A	2015-03-27	2021-03-27	N/A	2023-03-27
idursulfase	109857	Elaprase	Shire Human Genetic Therapies, Inc.	N/A	2007-06-13	2013-06-13	Yes	2015-12-13
indacaterol maleate	143984	Onbrez Breezhaler	Novartis Pharmaceuticals Canada Inc.	Ultibro Breezhaler	2011-12-06	2017-12-06	N/A	2019-12-06
influenza virus type A (H1N1), influenza virus type A (H3N2), influenza virus type B	129379	FluMist	AstraZeneca Canada Incorporated	FluMist Quadrivalent	2010-06-22	2016-06-22	Yes	2018-12-22
ingenol mebutate	153285	Picato	Leo Pharma Inc.	N/A	2013-01-30	2019-01-30	N/A	2021-01-30
ipilimumab	138178	Yervoy	Bristol-Myers Squibb Canada	N/A	2012-02-01	2018-02-01	Yes	2020-08-01
ivacaftor	155318	Kalydeco	Vertex Pharmaceuticals (Canada) Inc.	Orkambi Symdeko	2012-11-26	2018-11-26	Yes	2021-05-26
ivermectin	172733	Rosiver	Galderma Canada Inc.	N/A	2015-04-22	2021-04-22	N/A	2023-04-22
lacosamide	116632	Vimpat	UCB Canada Inc.	N/A	2010-09-30	2016-09-30	N/A	2018-09-30
lanreotide	098949	Somatuline Autogel	Ipsen Biopharm Limited	N/A	2006-07-17	2012-07-17	N/A	2014-07-17
lanthanum carbonate	102240	Fosrenol	Shire BioChem Inc.	N/A	2006-10-17	2012-10-17	N/A	2014-10-17
lapatinib ditosylate	110294	Tykerb	Novartis Pharmaceuticals Canada Inc.	N/A	2009-05-15	2015-05-15	N/A	2017-05-15
ledipasvir	173180	Harvoni	Gilead Sciences Canada Inc.	N/A	2014-10-15	2020-10-15	Yes	2023-04-15
lenalidomide	111952	Revlimid	Celgene	N/A	2008-01-17	2014-01-17	N/A	2016-01-17

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lenvatinib mesylate	180877	Lenvima	Eisai Limited	N/A	2015-12-22	2021-12-22	Yes	2024-06-22
levomilnacipran hydrochloride	167319	Fetzima	Abbvie Corporation	N/A	2015-05-08	2021-05-08	N/A	2023-05-08
linaclotide	161056	Constella	Forest Laboratories Canada Inc.	N/A	2013-12-02	2019-12-02	N/A	2021-12-02
linagliptin	140881	Trajenta	Boehringer Ingelheim (Canada) Ltd.	Jentadueto Glyxambi	2011-07-28	2017-07-28	N/A	2019-07-28
liraglutide	119928	Victoza	Novo Nordisk Canada Inc.	Saxenda Xultophy	2010-05-21	2016-05-21	N/A	2018-05-21
lisdexamfetamine dimesylate	120534	Vyvanse	Shire Pharma Canada ULC.	N/A	2009-02-19	2015-02-19	Yes	2017-08-19
lomitapide mesylate	160385	Juxtapid	Aegerion Pharmaceuticals Canada Ltd.	N/A	2014-02-04	2020-02-04	N/A	2022-02-04
loteprednol etabonate	117199	Alrex	Bausch & Lomb Inc.	Lotemax Lotemax Ointment Lotemax Gel	2008-12-23	2014-12-23	N/A	2016-12-23
lubiprostone	179333	Amitiza	Sucampo Pharma Americas LLC	N/A	2015-10-14	2021-10-14	N/A	2023-10-14
lumiracoxib	102465	Prexige	Novartis Pharmaceuticals Canada Inc.	N/A	2006-11-02	2012-11-02	N/A	2014-11-02
lurasidone hydrochloride	145406	Latuda	Sunovion Pharmaceuticals Canada Inc.	N/A	2012-06-13	2018-06-13	Yes	2020-12-13
macitentan	161372	Opsumit	Janssen Inc.	Opsynvi	2013-11-06	2019-11-06	Yes	2022-05-06
maraviroc	112435	Celsentri	ViiV Healthcare ULC	N/A	2007-09-21	2013-09-21	N/A	2015-09-21
mepolizumab	179850	Nucala	GlaxoSmithKline Inc.	N/A	2015-12-03	2021-12-03	Yes	2024-06-03

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methoxy polyethylene gycol epoetin beta	106461	Mircera	Hoffmann-La Roche Ltd.	N/A	2008-03-31	2014-03-31	N/A	2016-03-31
methylnaltrexone bromide	114266	Relistor	Salix Pharmaceuticals, Inc.	N/A	2008-03-28	2014-03-28	N/A	2016-03-28
micafungin sodium	078577	Mycamine	Astellas Pharma Canada, Inc.	N/A	2007-05-22	2013-05-22	N/A	2015-05-22
mifepristone	160063	Mifegymiso	Linepharma International Limited	N/A	2015-07-29	2021-07-29	Yes	2024-01-29
mirabegron	153806	Myrbetriq	Astellas Pharma Canada Inc.	N/A	2013-03-06	2019-03-06	N/A	2021-03-06
modified vaccinia virus (ankara-bavarian nordic)	144762	Imvamune	Bavarian Nordic A/S	N/A	2013-11-21	2019-11-21	N/A	2021-11-21
naloxegol oxalate	167790	Movantik	Knight Therapeutics Inc.	N/A	2015-06-02	2021-06-02	N/A	2023-06-02
natalizumab	093001	Tysabri	Biogen Idec Canada Inc.	N/A	2006-09-28	2012-09-28	N/A	2014-09-28
nebivolol hydrochloride	152353	Bystolic	Allergan Inc.	N/A	2012-12-21	2018-12-21	N/A	2020-12-21
neisseria meningitidis serogroup A polysaccharide, neisseria meningitidis serogroup C polysaccharide, neisseria meningitidis serogroup W-135 polysaccharide, neisseria meningitidis serogroup Y polysaccharide, conjugated to tetanus toxoid carrier protein	154290	Nimenrix	Pfizer Canada Inc.	N/A	2013-03-05	2019-03-05	Yes	2021-09-05
nelarabine	099994	Atriance	Novartis Pharmaceuticals Canada Inc.	N/A	2007-09-22	2013-09-22	Yes	2016-03-22

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nepafenac	114004	Nevanac	Alcon Canada Inc.	Ilevro	2008-04-17	2014-04-17	N/A	2016-04-17
nesiritide	111760	Natrecor	Janssen Inc.	N/A	2007-11-08	2013-11-08	N/A	2015-11-08
nilotinib hydrochloride monohydrate	110305	Tasigna	Novartis Pharmaceuticals Canada Inc.	N/A	2008-09-09	2014-09-09	N/A	2016-09-09
nintedanib (supplied as nintedanib esilate)	176043	Ofev	Boehringer Ingelheim (Canada) Ltd	N/A	2015-06-25	2021-06-25	N/A	2023-06-25
nivolumab	180828	Opdivo	Bristol-Myers-Squibb Canada	Opdualag	2015-09-25	2021-09-25	Yes	2024-03-25
obinutuzumab	168227	Gazyva	Hoffmann-La Roche Limited	N/A	2014-11-25	2020-11-25	N/A	2022-11-25
ocriplasmin	161356	Jetrea	ThromboGenics N.V.	N/A	2013-08-13	2019-08-13	N/A	2021-08-13
ofatumumab	128188	Arzerra	Novartis Pharmaceuticals Canada Inc.	N/A	2012-03-09	2018-03-09	N/A	2020-03-09
olaparib	182823	Lynparza	AstraZeneca Canada Inc.	N/A	2016-04-29	2022-04-29	N/A	2024-04-29
olmesartan medoxomil	115991	Olmetec	Merck Canada Inc.	Olmetec Plus	2008-10-28	2014-10-28	Yes	2017-04-28
olodaterol hydrochloride	155649	Striverdi Respimat	Boehringer Ingelheim (Canada) Ltd.	Inspiolto Respimat	2013-06-11	2019-06-11	N/A	2021-06-11
ombitasvir, paritaprevir, dasabuvir sodium	174739	Holkira Pak	Abbvie Corporation	Technivie	2014-12-22	2020-12-22	N/A	2022-12-22
osimertinib mesylate	188171	Tagrisso	AstraZeneca Canada Inc.	N/A	2016-07-05	2022-07-05	N/A	2024-07-05
oxaliplatin	109965	Eloxatin	Sanofi-aventis Canada Inc.	N/A	2007-06-15	2013-06-15	Yes	2015-12-15

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paliperidone	108748	Invega	Janssen Inc.	Invega Sustenna	2007-09-26	2013-09-26	Yes	2016-03-26
palonosetron hydrochloride	145491	Aloxi	Purdue Pharma	Akynzeo	2012-03-14	2018-03-14	N/A	2020-03-14
panitumumab	105601	Vectibix	Amgen Canada Inc.	N/A	2008-04-03	2014-04-03	N/A	2016-04-03
pasireotide diaspartate	145005	Signifor	Novartis Pharmaceuticals Canada Inc.	Signifor Lar	2013-09-23	2019-09-23	N/A	2021-09-23
pazopanib hydrochloride	128332	Votrient	Novartis Pharmaceuticals Canada Inc.	N/A	2010-05-27	2016-05-27	N/A	2018-05-27
peginterferon beta-1a	166974	Plegridy	Biogen Idec Canada Inc.	N/A	2015-08-10	2021-08-10	N/A	2023-08-10
pembrolizumab	175884	Keytruda	Merck Canada Inc.	N/A	2015-05-19	2021-05-19	Yes	2023-11-19
perampanel	153747	Fycompa	Eisai Limited	N/A	2013-04-04	2019-04-04	Yes	2021-10-04
pertuzumab	158419	Perjeta	Hoffmann-La Roche Limited	Perjeta-Herceptin Combo Pack Phesgo	2013-04-12	2019-04-12	N/A	2021-04-12
pirfenidone	153849	Esbriet	Hoffmann-La Roche Limited	N/A	2012-10-01	2018-10-01	N/A	2020-10-01
plerixafor	142638	Mozobil	Sanofi-aventis Canada Inc.	N/A	2011-12-08	2017-12-08	N/A	2019-12-08
pneumococcal polysaccharide serotype 1, 3, 5, 6A, 7F, 19A conjugated to diphtheria CRM197 protein	122881	Prevnar 13	Pfizer Canada Inc.	N/A	2009-12-21	2015-12-21	Yes	2018-06-21

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pneumococcal polysaccharide serotype 1, 4, 5, 6B, 7F, 9V, 14, 23F conjugated to protein D carrier protein; serotype 18C conjugated to tetanus toxoid carrier protein; serotype 19F conjugated to diphtheria toxoid carrier protein	119056	Synflorix	GlaxoSmithKline Inc.	N/A	2008-12-11	2014-12-11	Yes	2017-06-11
polidocanol	177359	Varithena	Provensis Ltd.	N/A	2015-08-04	2021-08-04	N/A	2023-08-04
pomalidomide	165891	Pomalyst	Celgene Inc.	N/A	2014-01-20	2020-01-20	Yes	2022-07-20
ponatinib hydrochloride	165121	Iclusig	Ariad Pharmaceuticals Inc.	N/A	2015-04-02	2021-04-02	N/A	2023-04-02
posaconazole	108193	Posanol	Merck Canada Inc.	N/A	2007-03-26	2013-03-26	Yes	2015-09-26
prasugrel hydrochloride	121143	Effient	Eli Lilly Canada Inc.	N/A	2010-04-16	2016-04-16	Yes	2018-10-16
prucalopride succinate	141157	Resotran	Janssen Inc.	N/A	2011-12-07	2017-12-07	N/A	2019-12-07
radium - 223 dichloride	161312	Xofigo	Bayer Inc.	N/A	2013-12-12	2019-12-12	N/A	2021-12-12
raltegravir potassium	113408	Isentress	Merck Frosst Canada Inc.	N/A	2007-11-27	2013-11-27	Yes	2016-05-27
ramucirumab	176810	Cyramza	Eli Lilly Canada Inc.	N/A	2015-07-16	2021-07-16	N/A	2023-07-16
ranibizumab	110233	Lucentis	Novartis Opthalmics, Novartis Pharmaceuticals	N/A	2007-06-26	2013-06-26	N/A	2015-06-26
rasagiline mesylate	101846	Azilect	Teva Pharmaceuticals Industries Ltd.	N/A	2006-08-17	2012-08-17	N/A	2014-08-17

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recombinant human papillomavirus type 11 L1, type 16 L1, type 18 L1, type 6 L1 protein	102682	Gardasil	Merck Frosst Canada Ltd.	N/A	2006-07-10	2012-07-10	Yes	2015-01-10
recombinant human papillomavirus types 31, 33, 45, 52 and 58	170006	Gardasil 9	Merck Canada Inc.	N/A	2015-02-05	2021-02-05	Yes	2023-08-05
recombinant neisseria meningitidis group B NHBA fusion protein, recombinant neisseria meningitidis group B NadA protein, recombinant neisseria meningitidis group B FHBP fusion protein, outer membrane vesicle (neisseria meningitidis group B NZ98/254 strain)	147275	Bexsero	GlaxoSmithKline Inc.	N/A	2013-12-06	2019-12-06	Yes	2022-06-06
recombinant porcine factor VIII (antihemophilic factor (recombinant), porcine sequence)	177290	Obizur	Takeda Canada Inc.	N/A	2015-10-14	2021-10-14	N/A	2023-10-14
regorafenib monohydrate	157970	Stivarga	Bayer Inc.	N/A	2013-03-11	2019-03-11	Yes	2021-09-11
remestemcel-L	150026	Prochymal	Osiris Therapeutics Inc.	N/A	2012-05-17	2018-05-17	Yes	2020-11-17
retapamulin	109037	Altargo	GlaxoSmithKline Inc.	N/A	2008-03-19	2014-03-19	Yes	2016-09-19
rifaximin	161256	Zaxine	Salix Pharmaceuticals Inc.	N/A	2013-08-13	2019-08-13	N/A	2021-08-13

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rilpivirine hydrochloride	137484	Edurant	Janssen Inc.	Complera Odefsey Juluca	2011-07-21	2017-07-21	Yes	2020-01-21
riociguat	162761	Adempas	Bayer Inc.	N/A	2013-09-19	2019-09-19	N/A	2021-09-19
rivaroxaban	119111	Xarelto	Bayer Healthcare	N/A	2008-09-15	2014-09-15	N/A	2016-09-15
roflumilast	127683	Daxas	Takeda Canada Inc.	N/A	2010-11-23	2016-11-23	N/A	2018-11-23
romidepsin	152293	Istodax	Celgene Inc.	N/A	2013-10-16	2019-10-16	N/A	2021-10-16
romiplostim	117327	Nplate	Amgen Canada Inc.	N/A	2009-02-19	2015-02-19	Yes	2017-08-19
rotavirus RIX4414 strain, live, attenuated (human)	109624	Rotarix	GlaxoSmithKline Inc.	N/A	2007-10-09	2013-10-09	Yes	2016-04-09
rotavirus vaccine, live, oral type G1, type G2, type G3, type G4, type P1(8) (human)	100399	Rotateq	Merck Frosst Canada Ltd.	N/A	2006-08-01	2012-08-01	Yes	2015-02-01
rotigotine	145523	Neupro	UCB Canada Inc.	N/A	2013-03-21	2019-03-21	N/A	2021-03-21
rubidium 82 chloride	138823	Ruby-Fill	Jubilant Draximage Inc.	N/A	2011-09-20	2017-09-20	N/A	2019-09-20
rufinamide	139913	Banzel	Eisai Limited	N/A	2011-06-22	2017-06-22	Yes	2019-12-22
ruxolitinib phosphate	151723	Jakavi	Novartis Pharmaceuticals Canada Inc.	N/A	2012-06-19	2018-06-19	N/A	2020-06-19
sacubitril	182734	Entresto	Novartis Pharmaceuticals Canada Inc.	N/A	2015-10-02	2021-10-02	Yes	2024-04-02
sapropterin dihydrochloride	128151	Kuvan	BioMarin Pharmaceutical Inc.	N/A	2010-04-30	2016-04-30	Yes	2018-10-30

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saxagliptin hydrochloride	123854	Onglyza	AstraZeneca Canada Inc.	Komboglyze Qtern	2009-09-14	2015-09-14	N/A	2017-09-14
secukinumab	170732	Cosentyx	Novartis Pharmaceuticals Canada Inc.	N/A	2015-02-27	2021-02-27	Yes	2023-08-27
silodosin	121740	Rapaflo	Purdue Pharma	N/A	2011-01-11	2017-01-11	N/A	2019-01-11
siltuximab	174291	Sylvant	EUSA Pharma (UK) Limited	N/A	2014-12-03	2020-12-03	N/A	2022-12-03
simeprevir	164021	Galexos	Janssen Inc.	N/A	2013-11-18	2019-11-18	N/A	2021-11-18
sitagliptin phosphate	103039	Januvia	Merck Frosst Canada Ltd.	Janumet Janumet XR	2007-12-14	2013-12-14	N/A	2015-12-14
sitaxsentan sodium	101934	Thelin	Pfizer Canada Inc.	N/A	2007-05-30	2013-05-30	N/A	2015-05-30
sodium fluoride 18F	145561	NaF Plus	Isologic Innovative Radiopharmaceuticals Ltd.	N/A	2013-02-11	2019-02-11	N/A	2021-02-11
sofosbuvir	165043	Sovaldi	Gilead Sciences Canada Inc.	Harvoni Epclusa Vosevi	2013-12-13	2019-12-13	N/A	2021-12-13
sorafenib	102070	Nexavar	Bayer Inc.	N/A	2006-07-28	2012-07-28	N/A	2014-07-28
stiripentol	142417	Diacomit	Biocodex SA	N/A	2012-12-21	2018-12-21	Yes	2021-06-21
tafluprost	165596	Saflutan	Purdue Pharma	N/A	2014-05-26	2020-05-26	N/A	2022-05-26
taliglucerase alfa	140854	Elelyso	Pfizer Canada Inc.	N/A	2014-05-29	2020-05-29	Yes	2022-11-29

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tapentadol hydrochloride	133167	Nucynta CR	Janssen Inc.	Nucynta IR Nucynta Extended Release	2010-12-02	2016-12-02	N/A	2018-12-02
tedizolid phosphate	173603	Sivextro	Merck Canada Inc.	N/A	2015-03-17	2021-03-17	N/A	2023-03-17
teduglutide	180223	Revestive	Takeda Canada Inc.	N/A	2015-09-04	2021-09-04	Yes	2024-03-04
telaprevir	142482	Incivek	Vertex Pharmaceuticals (Canada) Inc.	N/A	2011-08-16	2017-08-16	N/A	2019-08-10
telavancin hydrochloride	107792	Vibativ	Pendopharm Division of de Pharmascience Inc.	N/A	2009-09-29	2015-09-29	N/A	2017-09-29
telbivudine	104469	Sebivo	Novartis Pharmaceuticals Canada Inc.	N/A	2006-11-28	2012-11-28	N/A	2014-11-28
temsirolimus	109201	Torisel	Pfizer Canada Inc.	N/A	2007-12-21	2013-12-21	Yes	2016-06-21
tenofovir alafenamide hemifumarate	181399	Genvoya	Gilead Sciences Canada Inc.	Descovy Odefsey Vemlidy Symtuza Biktarvy	2015-11-27	2021-11-27	Yes	2024-05-27
teriflunomide	160646	Aubagio	Genzyme Canada a division of Sanofi-aventis Canada Inc.	N/A	2013-11-14	2019-11-14	Yes	2022-05-14
tesamorelin	131836	Egrifta	Theratechnologies Inc.	N/A	2014-04-29	2020-04-29	N/A	2022-04-29
ticagrelor	132218	Brilinta	AstraZeneca Canada Incorporated	N/A	2011-05-30	2017-05-30	N/A	2019-05-30
tigecycline	094870	Tygacil	Pfizer Canada Inc.	N/A	2006-09-14	2012-09-14	N/A	2014-09-14

Register Of Innovative Drugs

Products for Human Use - Expired Data Protection Period

Medicinal Ingredient(s)*	Submission Number	Innovative Drug	Manufacturer	Drug(s) Containing the Medicinal Ingredient / Variations	Notice of Compliance Date yyyy-mm-dd	6 Year "No File" Date	Pediatric Extension Yes / No	Data Protection Ends
tocilizumab	121089	Actemra	Hoffmann-La Roche Ltd.	N/A	2010-04-30	2016-04-30	Yes	2018-10-30
tofacitinib	154642	Xeljanz	Pfizer Canada Inc.	N/A	2014-04-17	2020-04-17	Yes	2022-10-17
tolvaptan	139413	Samsca	Otsuka Pharmaceutical Co. Ltd.	Jinarc	2011-07-25	2017-07-25	N/A	2019-07-25
trabectedin	124729	Yondelis	Janssen Inc.	N/A	2010-05-13	2016-05-13	N/A	2018-05-13
trametinib	157665	Mekinist	Novartis Pharmaceuticals Canada Inc.	N/A	2013-07-18	2019-07-18	N/A	2021-07-18
trastuzumab emtansine	162414	Kadcyla	Hoffmann-La Roche Limited	N/A	2013-09-11	2019-09-11	N/A	2021-09-11
turoctocog alfa	170796	Zonovate	Novo Nordisk Canada Inc.	N/A	2014-12-08	2020-12-08	Yes	2023-06-08
ulipristal acetate	156861	Fibristal	Allergan Inc.	N/A	2013-06-24	2019-06-24	N/A	2021-06-24
umeclidinium bromide	161585	Anoro Ellipta	GlaxoSmithKline Inc.	Incruse Ellipta	2013-12-23	2019-12-23	N/A	2021-12-23
ustekinumab	114272	Stelara	Janssen Inc.	N/A	2008-12-12	2014-12-12	N/A	2016-12-12
vandetanib	126822	Caprelsa	Genzyme Canada, a division of Sanofi-aventis Canada Inc.	N/A	2012-01-12	2018-01-12	N/A	2020-01-12
varenicline tartrate	104007	Champix	Pfizer Canada Inc.	N/A	2007-01-24	2013-01-24	Yes	2015-07-24
vedolizumab	169414	Entyvio	Takeda Canada Inc.	N/A	2015-01-29	2021-01-29	Yes	2023-07-29
velaglucerase alfa	132604	Vpriv	Shire Human Genetic Therapies, Inc.	N/A	2010-10-01	2016-10-01	Yes	2019-04-01
vemurafenib	148693	Zelboraf	Hoffmann-La Roche Ltd.	N/A	2012-02-15	2018-02-15	N/A	2020-02-15

Register Of Innovative Drugs

Products for Human Use - Expired Data Protection Period

Medicinal Ingredient(s)*	Submission Number	Innovative Drug	Manufacturer	Drug(s) Containing the Medicinal Ingredient / Variations	Notice of Compliance Date yyyy-mm-dd	6 Year "No File" Date	Pediatric Extension Yes / No	Data Protection Ends
vilanterol trifenatate	157301	Breo Ellipta	GlaxoSmithKline Inc.	Anoro Ellipta Trelegy Ellipta	2013-07-03	2019-07-03	Yes	2022-01-03
vilazodone hydrochloride	176820	Viibryd	AbbVie Corporation	N/A	2015-07-16	2021-07-16	Yes	2024-01-16
vismodegib	154608	Erivedge	Hoffmann-La Roche Ltd.	N/A	2013-07-12	2019-07-12	N/A	2021-07-12
vorapaxar sulfate	179320	Zontivity	Xspire Pharma, LLC	N/A	2016-05-13	2022-05-13	N/A	2024-05-13
vorinostat	104562	Zolinza	Merck Frosst Canada Ltd.	N/A	2009-06-11	2015-06-11	N/A	2017-06-11
vortioxetine hydrobromide	159019	Trintellix	Lundbeck Canada Inc.	N/A	2014-10-22	2020-10-22	Yes	2023-04-22
ziprasidone hydrochloride monohydrate	078188	Zeldox	Pfizer Canada Inc.	N/A	2007-08-27	2013-08-27	Yes	2016-02-27
zucapsaicin	121952	Zuacta	Sanofi-aventis Canada Inc.	N/A	2010-07-15	2016-07-15	N/A	2018-07-15

*The medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient (subsection C.08.004.1(1) of the *Food and Drug Regulations*).

Register Of Innovative Drugs

Products for Veterinary Use - Active Data Protection Period

Medicinal Ingredient(s)*	Submission Number	Innovative Drug	Manufacturer	Drug(s) Containing the Medicinal Ingredient / Variations	Notice of Compliance Date yyyy-mm-dd	6 Year "No File" Date	Data Protection Ends
amlodipine besilate	218786	Amodip Flavoured Tablets	Ceva Animal Health Inc.	N/A	2020-03-25	2026-03-25	2028-03-25
bedinvetmab	237723	Librela	Zoetis Canada Inc.	N/A	2021-02-01	2027-02-01	2029-02-01
bupivacaine hydrochloride	254222	Tri-Solfen	Dechra Ltd.	N/A	2022-06-21	2028-06-21	2030-06-21
capromorelin tartrate	259520	Elura	Elanco Canada Limited	N/A	2024-06-03	2030-06-03	2032-06-03
ciclesonide	200882	Aservo Equihaler	Boehringer Ingelheim Animal Health Canada Inc.	N/A	2020-04-30	2026-04-30	2028-04-30
frunevetmab	242879	Solensia	Zoetis Canada Inc.	N/A	2021-07-27	2027-07-27	2029-07-27
gonadorelin[6-D-Phe] acetate	256977	Gonavet	Modern Veterinary Therapeutics LLC	N/A	2022-10-20	2028-10-20	2030-10-20
grapiprant	211760	Galliprant	Elanco Canada Limited	N/A	2019-01-08	2025-01-08	2027-01-08
isoeugenol	252779	Aqui-S	AQUI-S New Zealand Ltd.	N/A	2023-07-31	2029-07-31	2031-07-31
lotilaner	193712	Credelio	Elanco Canada Limited	Credelio Plus Credelio Cat	2017-12-29	2023-12-29	2025-12-29
lubabegron	166199	Experior 10	Elanco Canada Limited	Experior 50	2018-11-07	2024-11-07	2026-11-07
methadone hydrochloride	226217	Comfortan	Eurovet Animal Health B.V.	N/A	2020-02-25	2026-02-25	2028-02-25
midazolam	230770	Dormazolam	Dechra Regulatory BV	N/A	2021-06-29	2027-06-29	2029-06-29

Register Of Innovative Drugs

Products for Veterinary Use - Active Data Protection Period

Medicinal Ingredient(s)*	Submission Number	Innovative Drug	Manufacturer	Drug(s) Containing the Medicinal Ingredient / Variations	Notice of Compliance Date yyyy-mm-dd	6 Year "No File" Date	Data Protection Ends
mirtazapine	232197	Mirataz	Dechra Ltd.	N/A	2020-09-08	2026-09-08	2028-09-08
peforelin	190986	Maprelin XP-10	Modern Veterinary Therapeutics LLC	N/A	2017-06-19	2023-06-19	2025-06-19
spironolactone	263787	Cardalis	Ceva Animal Health Inc.	N/A	2023-10-11	2029-10-11	2031-10-11
tetracosactide	228462	Cosacthen	Dechra Ltd.	N/A	2020-04-27	2026-04-27	2028-04-27
vatinoxan hydrochloride	256567	Zenalpha	Dechra Veterinary Products Inc.	N/A	2023-05-01	2029-05-01	2031-05-01
velagliflozin L-proline monohydrate	265785	Senvelgo	Boehringer Ingelheim Animal Health Canada Inc.	N/A	2023-11-28	2029-11-28	2031-11-28

*The medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient (subsection C.08.004.1(1) of the *Food and Drug Regulations*).

Register Of Innovative Drugs

Products for Veterinary Use - Expired Data Protection Period

Medicinal Ingredient(s)*	Submission Number	Innovative Drug	Manufacturer	Drug(s) Containing the Medicinal Ingredient / Variations	Notice of Compliance Date yyyy-mm-dd	6 Year "No File" Date	Data Protection Ends
acetaminophen	110139	Pracetam 20% O.S.	Ceva Animal Health Inc.	N/A	2009-03-05	2015-03-05	2017-03-05
afoxolaner	163768	Nexgard	Boehringer Ingelheim Animal Health Canada Inc.	Nexgard Spectra Nexgard Combo	2014-07-08	2020-07-08	2022-07-08
avilamycin	156949	Surmax 100 Premix	Elanco Canada Limited	Surmax 200 Premix	2014-02-18	2020-02-18	2022-02-18
buprenorphine hydrochloride	126077	Vetergesic Multidose	Sogeval UK Limited	N/A	2010-02-03	2016-02-03	2018-02-03
cefovecin sodium	110061	Convenia	Zoetis Canada Inc.	N/A	2007-05-30	2013-05-30	2015-05-30
cefpodoxime proxetil	149164	Simplicef	Zoetis Canada Inc.	N/A	2012-12-06	2018-12-06	2020-12-06
cephalexin monohydrate	126970	Vetolexin	Vétoquinol N.-A Inc.	Cefaseptin	2010-06-24	2016-06-24	2018-06-24
clodronate disodium tetrahydrate	172789	Osphos Injection	Dechra Ltd.	N/A	2015-05-06	2021-05-06	2023-05-06
closantel sodium	180678	Flukiver	Elanco Division Eli Lilly Canada Inc	N/A	2015-11-24	2021-11-24	2023-11-24
derquantel	184844	Startect	Zoetis Canada Inc.	N/A	2016-04-27	2022-04-27	2024-04-27
dibotermin alfa (rhBMP-2)	148153	Truscient	Zoetis Canada Inc.	N/A	2012-11-20	2018-11-20	2020-11-20
dirlotapide	110110	Slentrol	Zoetis Canada Inc.	N/A	2008-08-14	2014-08-14	2016-08-14
emamectin benzoate	109976	Slice	Intervet Canada Ltd.	N/A	2009-06-29	2015-06-29	2017-06-29

Register Of Innovative Drugs

Products for Veterinary Use - Expired Data Protection Period

Medicinal Ingredient(s)*	Submission Number	Innovative Drug	Manufacturer	Drug(s) Containing the Medicinal Ingredient / Variations	Notice of Compliance Date yyyy-mm-dd	6 Year "No File" Date	Data Protection Ends
emodepside	112103 / 112106 / 112107	Profender	Bayer Healthcare, Animal Health Division	N/A	2008-08-28	2014-08-28	2016-08-28
firocoxib	110661 / 110379	Previcox	Merial Canada Inc.	N/A	2007-09-28	2013-09-28	2015-09-28
fluoxetine hydrochloride	109825 / 109826 / 110429	Reconcile	Elanco, Division Eli Lilly Canada Inc.	N/A	2008-03-28	2014-03-28	2016-03-28
fluralaner	166320	Bravecto	Intervet Canada Corp.	Vitrecto Bravecto One	2014-05-23	2020-05-23	2022-05-23
gamithromycin	125823	Zactran	Merial Canada Inc.	N/A	2010-03-29	2016-03-29	2018-03-29
gonadotropin releasing factor analogue - protein conjugate	140525	Improvest	Zoetis Canada Inc.	N/A	2011-06-22	2017-06-22	2019-06-22
ibafloxacin	110655 / 110657	Ibaflin gel	Intervet Canada Ltd.	N/A	2008-01-15	2014-01-15	2016-01-15
imidapril hydrochloride	110445 / 110450 / 110476	Prilium	Vétoquinol N.-A Inc.	N/A	2007-07-12	2013-07-12	2015-07-12
insulin human (recombinant)	150211	Prozinc	Boehringer Ingelheim Animal Health Canada	N/A	2013-04-24	2019-04-24	2021-04-24
itraconazole	109769	Itrafungol	Elanco, Division Eli Lilly Canada Inc.	N/A	2008-09-23	2014-09-23	2016-09-23

Register Of Innovative Drugs

Products for Veterinary Use - Expired Data Protection Period

Medicinal Ingredient(s)*	Submission Number	Innovative Drug	Manufacturer	Drug(s) Containing the Medicinal Ingredient / Variations	Notice of Compliance Date yyyy-mm-dd	6 Year "No File" Date	Data Protection Ends
maropitant	110342 / 110344 / 110347 / 110348	Cerenia	Zoetis Canada Inc.	N/A	2007-09-20	2013-09-20	2015-09-20
mitratapide	111600	Yarvitan	Janssen Pharmaceutica N.V.	N/A	2009-02-20	2015-02-20	2017-02-20
mometasone furoate monohydrate	110289	Mometamax	Intervet Canada Corp.	N/A	2010-02-22	2016-02-22	2018-02-22
oclacitinib maleate	159090	Apoquel	Zoetis Canada Inc.	N/A	2014-07-15	2020-07-15	2022-07-15
pegbovigrastim	148171	Imrestor	Elanco Division Eli Lilly Canada Inc.	N/A	2016-03-09	2022-03-09	2024-03-09
pergolide mesylate	158770	Prascend	Boehringer Ingelheim Animal Health Canada Inc.	N/A	2013-09-05	2019-09-05	2021-09-05
permethrin	133818	Oridermyl	Vétoquinol N.- A Inc.	N/A	2011-02-18	2017-02-18	2019-02-18
phenobarbital	142445	Epiphen	Vétoquinol N.- A Inc.	N/A	2012-04-04	2018-04-04	2020-04-04
pradofloxacin	161227	Veraflox	Elanco Canada Limited	N/A	2015-01-29	2021-01-29	2023-01-29
ramipril	110296 / 110297 / 110298	Vasotop	Intervet Canada Ltd.	N/A	2008-09-05	2014-09-05	2016-09-05
robenacoxib	128703	Onsior	Elanco Canada Limited	N/A	2011-10-03	2017-10-03	2019-10-03

Register Of Innovative Drugs

Products for Veterinary Use - Expired Data Protection Period

Medicinal Ingredient(s)*	Submission Number	Innovative Drug	Manufacturer	Drug(s) Containing the Medicinal Ingredient / Variations	Notice of Compliance Date yyyy-mm-dd	6 Year "No File" Date	Data Protection Ends
sarolaner	177679	Simparica	Zoetis Canada Inc.	Revolution Plus Simparica Trio	2016-02-11	2022-02-11	2024-02-11
sevoflurane	110109	Sevoflo	Zoetis Canada Inc.	N/A	2008-03-28	2014-03-28	2016-03-28
spinosad	112198 / 112199 / 112202 / 112203 / 112204	Comfortis	Elanco, Division Eli Lilly Canada Inc.	Trifexis	2009-08-24	2015-08-24	2017-08-24
telmisartan	158760	Semintra	Boehringer Ingelheim Animal Health Canada Inc.	N/A	2013-12-12	2019-12-12	2021-12-12
tepoxalin	109950 / 109956 / 109963	Zubrin	Schering Plough Canada Inc.	N/A	2007-10-01	2013-10-01	2015-10-01
terbinafine	170344	Osurnia	Dechra Ltd.	N/A	2015-03-26	2021-03-26	2023-03-26
thiamazole	125706	Felimazole	Dechra Ltd.	N/A	2009-08-25	2015-08-25	2017-08-25
tildipirosin	148052	Zuprevo	Intervet Canada Corp.	N/A	2012-06-13	2018-06-13	2020-06-13
tiludronic acid (as tiludronate disodium)	171467	Tildren	CEVA Animal Health	N/A	2014-12-22	2020-12-22	2022-12-22
toceranib phosphate	123643	Palladia	Zoetis Canada Inc.	N/A	2009-12-01	2015-12-01	2017-12-01

Register Of Innovative Drugs

Products for Veterinary Use - Expired Data Protection Period

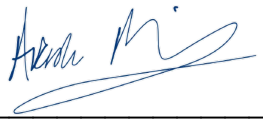
Medicinal Ingredient(s)*	Submission Number	Innovative Drug	Manufacturer	Drug(s) Containing the Medicinal Ingredient / Variations	Notice of Compliance Date yyyy-mm-dd	6 Year "No File" Date	Data Protection Ends
toltrazuril	122525	Baycox	Bayer Inc., Bayer Healthcare Animal Health Division	N/A	2010-08-20	2016-08-20	2018-08-20
trilostane	110023 / 110025 / 110221 / 113566	Vetoryl	Dechra Ltd.	N/A	2009-01-30	2015-01-30	2017-01-30
triptorelin (as triptorelin acetate)	161303	Ovugel	United-AH II, LLC	N/A	2014-04-25	2020-04-25	2022-04-25
tulathromycin	112161	Draxxin	Pfizer Canada Inc., Animal Health Group	N/A	2006-08-31	2012-08-31	2014-08-31
zilpaterol hydrochloride	110019	Zilmax	Intervet Canada Ltd.	N/A	2009-03-18	2015-03-18	2017-03-18

*The medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient (subsection C.08.004.1(1) of the *Food and Drug Regulations*).

The Minister of Health maintains a register of innovative drugs pursuant to sub-section C.08.004.1(9) of the *Food and Drug Regulations*.

Exhibit “J5”

This is Exhibit “J5” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.



A Commissioner for Taking Affidavits, etc.
Arash Rouhi

Guidance Document

Patented Medicines (Notice of Compliance) Regulations

Date Adopted: 2000/02/14
Revised Date: 2021/04/08
Effective Date: 2021/05/11

Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

Également disponible en français sous le titre :
Ligne directrice : Règlement sur les médicaments brevetés (avis de conformité)

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Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

Document change log

Date	Change	Location (section, paragraph)	Nature of and/or reason for change
2018/04/05	Updated in accordance with the September 21, 2017 amendments to the Patented Medicines (Notice of Compliance) Regulations.	All	The updates to the Guidance Document are being made following the amendments to the Patented Medicines (Notice of Compliance) Regulations, which came into force on September 21, 2017. The updates also reflect current administrative practices (e.g. update of terminology from “patent hold” to “Intellectual Property Hold”).
2021/04/08	Updated in accordance with the new Health Products and Food Branch organizational structure	Throughout	Change in Health Products and Food Branch organizational structure

Table of Contents

1. Introduction

1.1 Policy objectives

In accordance with the Regulatory Impact Analysis Statement (RIAS) published in the Canada Gazette, Part II on October 18, 2006,[1] Canada's pharmaceutical patent policy objective is to "balance the effective patent enforcement over new and innovative drugs with the timely entry of their lower priced generic competitors". The Patented Medicines (Notice of Compliance) Regulations (PM(NOC) Regulations) were introduced originally by Industry Canada (now known as Innovation, Science and Economic Development Canada) under the Patent Act. The PM(NOC) Regulations intersect with drug approval under the Food and Drugs Act and Division 8 of the Food and Drug Regulations.

1.2 Policy statements

The early working exception of subsection 55.2(1) of the Patent Act allows a subsequent manufacturer to use a patented invention for the purpose of seeking regulatory approval of that product. The provision, therefore, provides an exception from infringement. The PM(NOC) Regulations provide the balance, through a patent enforcement mechanism, to ensure that the early working exception is not abused by linking the regulatory approval of a generic drug to the patent status of the innovative product.

1.3 Scope and application

This guidance document provides information regarding the administration of the PM(NOC) Regulations by the Office of Patented Medicines and Liaison (OPML) within the Office of Submissions and Intellectual Property (OSIP), Resource Management and Operations Directorate (RMOD), Health Canada. It is applicable to drugs that receive a notice of compliance (NOC), including pharmaceutical, biological, radiopharmaceutical and veterinary drugs.

1.4 Background

The PM(NOC) Regulations were originally enacted in 1993, and have undergone various amendments. The most recent amendment came into force on September 21, 2017. Under the pre-2017 version of the PM(NOC) Regulations, innovative drug companies could commence legal proceedings for an order prohibiting the Minister of Health from granting an NOC for a generic version of a patented medicine. The September 21, 2017 amendments to the PM(NOC) Regulations replaced these prohibition application proceedings with full actions resulting in final determinations of patent infringement and validity. The pre-2017 version of the PM(NOC) Regulations will continue to apply in respect of any matter that relates to a notice of allegation (NOA) served on a first person before September 21, 2017.

2. Definitions

Filing date of a submission

Refers to the date that the submission is deemed administratively complete by Health Canada (i.e. once all elements and forms required for processing are completed and

submitted to Health Canada). This date may differ from the date of original receipt should the submission be considered administratively incomplete at the time of receipt. The filing date established for a submission is not affected by subsequent screening or review activities. In the Drug Submission Tracking System - Industry Access, the filing date of a submission is indicated in the CR Date field.

Filing date of a patent

Refers to the Canadian filing date of a Canadian patent application as established by the Canadian Intellectual Property Office (CIPO).

Patent

Refers to a granted Canadian patent (not a patent application).

Biosimilar biologic drug

Refers to a biologic drug that obtains market authorization subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. A biosimilar relies in part on prior information regarding safety, efficacy and effectiveness that is deemed relevant due to the demonstration of similarity to the reference biologic drug and which influences the amount and type of original data required. Biosimilar biologic drugs were previously referred to as Subsequent Entry Biologics.

3. General information

3.1 General

The OPML within OSIP, RMOD administers the PM(NOC) Regulations. All drug submissions seeking an NOC, including those submitted to the Biologic and Radiopharmaceutical Drugs Directorate (BRDD), Natural and Non-Prescription Health Products Directorate (NNHPD) and Veterinary Drugs Directorate (VDD), are assessed to determine if they fall within the scope of the PM(NOC) Regulations. The directorates mentioned above are a part of Health Canada's Health Products and Food Branch (HPFB).

3.2 Patent Register

Pursuant to subsection 3(2) of the PM(NOC) Regulations, the RMOD is required to maintain a register of patents that have been submitted for addition to the register and certificates of supplementary protection (CSPs) in which any of those patents are set out.

The Patent Register is available online (http://pr-rdb.hc-sc.gc.ca/pr-rdb/index-eng.jsp) and is refreshed nightly. Any questions, comments or problems with the Patent Register should be directed to the OPML (opml-bmbl@hc-sc.gc.ca).

3.3 Drug Identification Number (DIN) cancellation - deletion of Patent Lists from the Patent Register

Subsection 3(3) of the PM(NOC) Regulations applies to drugs for which the drug identification number (DIN) has been cancelled under the Food and Drug Regulations. As provided for in subsection 3(3), patents added to the Patent Register in respect of a drug for which the DIN was cancelled shall be deleted from the Patent Register by the RMOD 90 days after the DIN was

cancelled. An exception to this rule exists for cancellations effected as a result of a change in manufacturer.

Form IV: Patent Lists (Form IVs) deleted as a result of a DIN cancellation will be re-added to the Patent Register upon re-activation of the DIN, i.e. receipt of a DIN Notification Form, as required by section C.01.014.3 of the Food and Drug Regulations. A first person who submits such a DIN Notification Form should also notify the OPML.

3.4 How to provide information to the RMOD

3.4.1 How to provide litigation information

As the Minister of Health will not be a party to actions for patent infringement under the PM(NOC) Regulations, litigation documents in such actions will no longer be served on the Minister. However, the RMOD must have access to relevant information to determine whether there are any barriers under the PM(NOC) Regulations that would prohibit issuance of an NOC for a second person's submission. As such, under section 6.13 of the PM(NOC) Regulations, a person who brings an action for infringement is to provide the RMOD with certain documents as soon as feasible. The RMOD may also request any information or document required to assess whether NOC issuance is prohibited under section 7 of the PM(NOC) Regulations. Requests for verification of any portion of a submission served with an NOA or produced in the course of a court action can be made under section 6.05 of the PM(NOC) Regulations.

All information related to litigation, including requests for verifications, must be submitted to the RMOD electronically and no duplicate copy should be sent in paper format. Please provide the information by email to: opml-bmbl@hc-sc.gc.ca, or on an acceptable media format, using the requirements outlined below. As with other drug submission information submitted electronically, any information received after 5:00 pm Eastern Standard Time, on a weekend, or on a Statutory Holiday will be considered received on the next business day.

By email

Litigation information should be provided via email unless it exceeds the size limit, in which case it should be provided on media.

- The sender assumes the risk of transmitting confidential or sensitive information through email.
- The maximum email size accepted by the corporate mail server is 20 megabytes. Anything larger should be sent on media.
- Documents contained in the email should not be password protected.
- Please indicate PM(NOC) Regulations, the court file number and the stakeholder name in the subject line of the email.

On media

Electronic media may be sent by courier / mail.

- The media formats acceptable when providing information are:
  - Compact Disc-Recordable (CD-R) conforming to the Joliet specification
  - Digital Versatile Disc-Random Access Memory (DVD-RAM) Universal Disc Format (UDF) standard

  - Single and dual layer Recordable Digital Versatile Discs
  - Universal Serial Bus (USB) 2.0 or 3.0 drive
- Media and files should not be password protected
- Files stored on the media should not be zipped
- All information should be provided on a single disc/drive
- Media should be scanned using current virus-scanning software and should be certified virus-free
- All media should be labelled. The label on the disc/drive should contain the following information:
  - PM(NOC) Regulations
  - Stakeholder name
  - Court file number
  - "This media has been virus-scanned and we certify that it is virus free"
- Subsequent to burning the CD/DVD or transferring data to a drive, stakeholders should ensure that all files can be opened and no files are corrupt
- Information provided on approved media formats should be sent to the attention of the OPML within the Office of Submissions and Intellectual Property (https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch/resource-management-operations-directorate.html#a4).

3.4.2 How to provide other information

As is currently required, other information related to the PM(NOC) Regulations should be submitted in either the electronic Common Technical Document (eCTD) format or the non-eCTD electronic-only format in module 1.2.4.1 - Patent Information. In accordance with Health Canada's Guidance Document: Preparation of Drug Regulatory Activities in the Electronic Common Technical Document Format, regulatory transactions accepted in the eCTD format include:

- Written correspondence related to the PM(NOC) Regulations
- NOA packages (e.g. proof of service of the NOA on the first person and a copy of the NOA) under the PM(NOC) Regulations
- Form IVs, including updates, filed in accordance with the PM(NOC) Regulations
- Form V: Declaration re: Patent Lists (Form Vs), including updates, filed in accordance with the PM(NOC) Regulations, and
- Consent letters (under the PM(NOC) Regulations)

For eCTD submissions, the regulatory transactions listed above should be submitted via the Common Electronic Submissions Gateway, as indicated in the Frequently Asked Questions - Common Electronic Submissions Gateway and the CESG Health Canada Reference Guide. For non-eCTD submissions, the above-noted information should be sent on an acceptable media format as indicated in the Guidance Document: Preparation of Drug Regulatory Activities in the 'Non-eCTD Electronic-Only' Format.

As with other drug submission information submitted electronically, any information received after 5:00 pm Eastern Standard Time, on a weekend, or on a Statutory Holiday will be considered received on the next business day.

4. Section 4 of the PM(NOC) Regulations

4.1 General

The requirements that must be met before a patent can be added to the Patent Register are provided by section 4 of the PM(NOC) Regulations. Section 4 describes (i) the timing requirements for filing patent lists; (ii) the required content of patent lists; (iii) the drug submissions for which patent lists may be filed; and (iv) eligibility requirements relating to the claims of the patent. The following sections provide more detailed guidance regarding these requirements.

A patent list must be submitted using the Form IV: Patent List template, available on the Health Canada website. Refer to Appendix A for instructions on how to complete the form. First persons are requested to complete one form per patent, per submission, per DIN.

4.2 Timing requirements

A first person wishing to file a patent list for a particular drug must meet the timing requirements set out in subsections 4(5) and 4(6) of the PM(NOC) Regulations. The timing requirements continue to apply during the reconsideration process set out in Health Canada's Guidance Document Reconsideration of Decisions Issued for Human Drug Submissions.

4.2.1 Patent Lists at time of filing a submission

Pursuant to subsection 4(5) of the PM(NOC) Regulations, a first person wishing to submit a patent list must do so at the time it files the new drug submission (NDS) or supplement to a new drug submission (SNDS) to which the patent list relates. Only patent lists that accompany the drug submission will be accepted and patent lists submitted separately will be refused as not meeting the timing requirements.

4.2.2 Patent Lists after time of filing a submission

Pursuant to subsection 4(6) of the PM(NOC) Regulations, a first person may also submit a patent list in respect of a previously filed drug submission provided that the following conditions are met:

a) the Canadian filing date of the patent precedes the drug submission filing date, and

b) the patent list is submitted to the RMOD within thirty days after the issuance of the patent.

In these circumstances, a first person must, in addition to submitting all of the information required under subsection 4(4), identify the submission number to which the newly granted patent relates.

4.3 Content requirements and prioritisation

All patent lists received by the RMOD will be evaluated for completeness against the list of required information set out in subsection 4(4) of the PM(NOC) Regulations. It should be noted, however, that the RMOD does not have a duty to make corrections or suggestions or inform first persons of any deficiencies in the content of patent lists.

In the case of a newly-issued patent, it is recommended that patent lists be submitted to the RMOD as soon as possible. Where deficiencies are identified, first persons may have an

opportunity to correct a patent list or submit additional patent lists before the end of the 30-day period. For more information on how to complete a Form IV, please consult Appendix A.

In order to expedite the evaluation by the RMOD, first persons are encouraged to include (i.e. as part of the cover letter) with their patent lists a list of eligible patent claims and a description of how such claims correspond to the drug submission in respect of which the patent list is filed, as well as page references to relevant portions of the drug submission, where applicable. The RMOD will prioritise evaluations for submissions for which an NOC has already issued.

4.4 Drug submissions eligible for filing a Patent List

In accordance with subsection 4(1) of the PM(NOC) Regulations, a patent list may be filed in relation to an NDS or an SNDS. Both "new drug submission" and "supplement to a new drug submission" are defined in subsection 3(1) of the PM(NOC) Regulations. Pursuant to these definitions and to subsections 4(2) and 4(3), only the following clearly defined submission types provide an opportunity to add a patent to the Patent Register:

- An NDS, except an NDS based solely on the change of name of the manufacturer (see definition of "new drug submission" in subsection 3(1))
- An SNDS for a change in formulation
- An SNDS for a change in dosage form
- An SNDS for a change in use of the medicinal ingredient

4.5 Product specificity requirements

In addition to the timing, content and submission requirements outlined in the previous sections, section 4 of the PM(NOC) Regulations sets out additional product-specificity requirements which are to be considered in determining the eligibility of a patent to be added to the Patent Register.

As discussed in the RIAS accompanying the October 5, 2006 amendments, in order for a patent to qualify for protection under the PM(NOC) Regulations, it must be relevant to the drug product the first person is approved to sell. The amendments entrench the concept of drug product specificity as the key consideration required of the Minister in applying the eligibility requirements under the PM(NOC) Regulations. In turn, the amended language more precisely reflects the intended link between the subject matter of a patent on a patent list and the content of the underlying submission for the NOC in relation to which it is submitted.

4.5.1. Patent List in relation to a New Drug Submission

In order to be eligible to be added to the Patent Register, the patent must contain a claim for the medicinal ingredient, a claim for the formulation containing the medicinal ingredient, a claim for the dosage form, or a claim for the use of the medicinal ingredient, which has been approved through the issuance of an NOC in respect of the submission.

The RMOD considers the following three questions when applying the requirements of section 4 of the PM(NOC) Regulations.

1. What does the patent claim?
2. What is approved in the submission?
3. Does the patent claim what is approved in the submission?

In general, the RMOD will not consider the following types of patents as being eligible to be added to the Patent Register:

- a purely process patent
- a patent for a medical device
- a patent for an intermediate used in the manufacture of the medicinal ingredient
- a patent for a metabolite of the medicinal ingredient, and
- a patent for an impurity present in the final drug product

Claim for the medicinal ingredient

As specified in the definition of "claim for the medicinal ingredient", product-by-process patents and patents claiming biological drugs are eligible to be added to the Patent Register provided that all other requirements set out in the PM(NOC) Regulations are met. This definition also clarifies that patents claiming different polymorphs of the medicinal ingredient are eligible for listing. As specified in the RIAS accompanying the October 5, 2006 amendments to the PM(NOC) Regulations, the term "polymorph" is meant to include different crystalline, amorphous, hydrated and solvated forms of the approved medicinal ingredient.

A patent claiming an enantiomer is not eligible to be added to the Patent Register in respect of a medicinal ingredient that is a racemate. In addition, a patent that claims varying ratios of enantiomers is not eligible to be added to the Patent Register with respect to a racemate of the medicinal ingredient. Similarly, a patent directed specifically to a racemic mixture or a mixture of two enantiomers in varying ratios will not be eligible to be added to the Patent Register in relation to a drug containing only one of the enantiomers.

In accordance with subsection 4(2.1), a patent that claims a medicinal ingredient is eligible to be added to the Patent Register in respect of a drug that contains that medicinal ingredient in combination with other medicinal ingredients. However, patents claiming a combination of medicinal ingredients contained in a single formulation or dosage form are not eligible to be added to the Patent Register in respect of a drug that contains only one of the claimed medicinal ingredients.

Claim for the formulation that contains the medicinal ingredient

The formulation claimed in the patent must correspond to the formulation approved in the relevant drug submission. A claim for the formulation may or may not specify non-medicinal ingredients.

Under paragraph 4(2.1)(b), a patent that contains a claim for the formulation is eligible to be added to the Patent Register if the drug contains the non-medicinal ingredients in the claim, even if the drug contains additional non-medicinal ingredients.

For example, a patent claiming a formulation that contains non-medicinal ingredient X would not be eligible to be added to the Patent Register in respect of a drug that does not contain non-medicinal ingredient X. Conversely, the same patent would be eligible to be added to the Patent Register in respect of a drug that contains non-medicinal ingredients X and Y.

Claim for the dosage form

The dosage form claimed in the patent must correspond to the dosage form approved in the relevant drug submission as noted on the NOC. This would include novel dosage forms, for example, patents that claim:

- a patch
- an extended-release tablet or capsule, and
- an implant

However, patents directed solely towards a dispenser, a container or packaging (e.g. an inhaler, an intravenous stand, or a syringe) would not be considered to contain a claim for the dosage form.

Claim for the use of the medicinal ingredient

The RMOD will refer to the indication section of the Product Monograph (PM) of the drug to determine whether or not the patent claims an approved use of the medicinal ingredient. However, it is not expected that the language in the patent will be reproduced exactly in the PM. As PMs do not exist for veterinary products, generally the labelling information and package insert will be used.

A patent containing a claim for the use of a medicinal ingredient is eligible to be added to the Patent Register in respect of a drug that contains that medicinal ingredient in combination with other medicinal ingredients, if the drug is approved for the use claimed in the patent. Patents claiming the use of a combination of medicinal ingredients will generally not be eligible to be added to the Patent Register against a drug containing only one of the medicinal ingredients in the combination. However, patents claiming the use of a medicinal ingredient in combination with one or more other medicinal ingredient(s) are eligible to be added to the Patent Register, if said combination use is found in the indication section of the drug's approved PM. However, in order to be eligible, the patent claims must not be limited to the use of the combination in a single formulation or dosage form.

For example, a patent claiming the sequential use of medicinal ingredient A in combination with medicinal ingredient B for the treatment of X could be added to the Patent Register in respect of a drug solely containing medicinal ingredient A, if the claimed use of the combination is found in the drug's approved PM.

4.5.2 Patent List in relation to a Supplement to a New Drug Submission

A new patent may only be added to the Patent Register in respect of the following three specific types of SNDSs:

- an SNDS for a change in formulation (this includes a change in strength)
- an SNDS for a change in dosage form, and
- an SNDS for a change in use of the medicinal ingredient

In addition to this requirement and in keeping with the product-specificity requirements, the patent will only be eligible to be added to the Patent Register if it contains a claim for the very change approved in the supplement. Therefore, if the supplement is for a new formulation, dosage form or use, the patent must contain a claim for the new formulation, dosage form or

use in order to be eligible to be added to the Patent Register. Subsection 4(3) of the PM(NOC) Regulations does not allow the addition of patents containing claims solely for the medicinal ingredient (including polymorphic forms).

The RMOD considers the following three questions when applying the requirements of subsection 4(3) of the PM(NOC) Regulations.

1. What does the patent claim?
2. What is the change approved in the submission?
3. Does the patent claim the very change approved in the submission?

4.5.3 Carry-forward provision

Subsection 4.1(2) of the PM(NOC) Regulations is a "carry-forward" provision. Under subsection 4.1(2), a first person who submits a patent list in relation to an NDS referred to in subsection 4(2) may, if the list is added to the Patent Register, resubmit the same list in relation to an SNDS, but may not submit a new patent list in relation to a supplement except in accordance with subsection 4(3). Similarly, a patent on a patent list that has been added to the Patent Register in respect of a supplement under subsection 4(3) may be "carried forward" in respect of a subsequently approved supplement.

The RMOD is required to give effect to the product-specificity requirements in applying the "carry-forward" provision under subsection 4.1(2). As such, patents which are already included on the Patent Register will be "carried forward" to a new DIN, provided the product-specificity requirements continue to be met (e.g. a patent that contains a claim for the medicinal ingredient will be carried forward in respect of a supplement for a new strength or dosage form).

In all cases, the RMOD will apply the same timing requirements to patent lists submitted under the "carry-forward" provision as are applied to patent lists submitted under section 4 of the PM(NOC) Regulations. When submitting a patent list with a supplement and the patent is already included on the Patent Register, the RMOD recommends that the first person submit such a patent list under the "carry forward" provision, unless the patent contains a specific claim for the changed formulation, the changed dosage form or the changed use, for which the supplement was submitted.

4.5.4 Consultation

As permitted by subsection 3(8) of the PM(NOC) Regulations, the RMOD may consult with officers or employees of the Patent Office in the CIPO regarding the claims construction of the patent. The CIPO may be consulted to verify if a patent has lapsed. The RMOD may also consult with the relevant review area within the HPFB, where necessary, regarding the information in the drug submission (e.g. regarding the approved use of the medicinal ingredient).

4.6 Process

For patent lists submitted at the time of filing of a drug submission and for newly-issued patents submitted for drug submissions under review, the RMOD will conduct a preliminary evaluation to ensure that the patents meet all eligibility requirements. If a patent is preliminarily found to be eligible, the RMOD will inform the first person in writing, indicating that the eligibility determination is subject to a final review at the time of issuance of the NOC.

The RMOD will conduct a final check of the eligibility of the patent prior to addition to the Patent Register, as what is approved may be different from what was initially submitted. This final check is to ensure that no significant changes were made to the drug submission during the review process that would affect the patent eligibility, for example, changes to the indication, dosage form, route of administration or strength of the drug. The final patent check will also ensure that there have been no changes to the jurisprudence which would affect the eligibility of the patent for addition to the Patent Register. This check does not delay the issuance of the NOC.

If the RMOD preliminarily determines a patent to be ineligible, the RMOD will notify the first person, in writing, that the patent has been found ineligible to be added to the Patent Register. The first person will then be provided with an opportunity to submit written representations as to the patent's eligibility to be added to the Patent Register. If representations are provided, they will be taken into consideration by the RMOD and a final decision regarding the patent eligibility will subsequently be communicated to the first person.

4.7 Certificates of Supplementary Protection

A CSP provides an additional period of protection, of up to 2 years, for drugs containing a new medicinal ingredient, or a combination thereof, protected by an eligible patent. For more information on CSPs, please consult the Health Canada Guidance Document Certificate of Supplementary Protection Regulations.

In accordance with subsection 4(3.1) of the PM(NOC) Regulations, a CSP is eligible to be added to the Patent Register in respect of an NDS or SNDS if two requirements are met. The first requirement is that the patent set out in the CSP must be included on the Patent Register in respect of that submission or supplement. The second requirement is that the submission or supplement relates to a drug with respect to which the CSP grants rights, privileges and liberties referred to in section 115 of the Patent Act.

Section 115 of the Patent Act provides that the scope of the CSP is the same as that of the patent, but only with respect to the making, constructing, using or selling of any drug that contains the medicinal ingredient or combination of medicinal ingredients set out in the certificate, by itself or in addition to any other medicinal ingredient.

The following scenarios are provided as examples.

Example 1a:

CSP No. 1 is issued in relation to medicinal ingredient X and the NDS for Drug A. The patent set out in CSP No. 1 is included on the Patent Register in respect of Drug A. The scope of the CSP includes Drug A because Drug A contains medicinal ingredient X. As both requirements of subsection 4(3.1) are met, CSP No. 1 is eligible to be added to the Patent Register in respect of Drug A.

Example 1b:

The patent set out in CSP No. 1 is included on the Patent Register in respect of Drug B. Drug B contains medicinal ingredient X in combination with medicinal ingredient Y. The scope of CSP No. 1 includes Drug B because Drug B contains medicinal ingredient X. As both requirements of

subsection 4(3.1) are met, CSP No. 1 is eligible to be added to the Patent Register in respect of Drug B.

Example 2:

CSP No. 2 is issued in relation to medicinal ingredient W and the NDS for Drug C. However, the patent set out in CSP No. 2 is not included on the Patent Register in respect of Drug C. Therefore, the requirement of paragraph 4(3.1)(a) is not met and CSP No. 2 is not eligible to be added to the Patent Register.

Example 3:

CSP No. 3 is issued in relation to the NDS for Drug D, containing medicinal ingredient Y.

The patent set out in CSP No. 3 is included on the Patent Register in respect of Drug D, containing medicinal ingredient Y. Drug D is within the scope of CSP No. 3 because it contains the medicinal ingredient set out in the CSP. Therefore, CSP No. 3 is eligible to be added to the Patent Register in respect of Drug D.

The patent set out in CSP No. 3 is also included on the Patent Register in respect of another drug, Drug E, containing medicinal ingredient Z. CSP No. 3 does not grant rights, privileges and liberties in respect of Drug E in accordance with section 115 of the Patent Act, as Drug E does not contain the medicinal ingredient Y or the “same” medicinal ingredient, per the Certificate of Supplementary Protection Regulations and section 105 of the Patent Act. Therefore, CSP No. 3 is not eligible to be added to the Patent Register in respect of Drug E because the requirement of paragraph 4(3.1)(b) of the PM(NOC) Regulations is not met.

4.7.1 Process

Once issued, all CSPs will be assessed by the RMOD in accordance with subsection 4(3.1) of the PM(NOC) Regulations for eligibility to be added to the Patent Register without requiring a separate form or request from the first person. To assess the eligibility of a CSP, the RMOD will first determine if the patent set out in the CSP is included on the Patent Register. If the patent is included on the Patent Register, the RMOD will assess whether the drug on the Patent Register is a drug with respect to which the CSP grants rights, privileges and liberties referred to in section 115 of the Patent Act. If the patent is not on the Patent Register, the CSP is not eligible to be added to the Patent Register, and the RMOD will not provide an assessment in writing.

For CSPs found eligible for addition to the Patent Register, the RMOD will insert the CSP number and expiry date in the office use section of the corresponding patent list(s) and will update the Patent Register. The first person will also be notified in writing. The expiry date of the CSP will be reflected in a separate field on the Patent Register from the expiry date of the patent.

If the patent set out in the CSP is included on the Patent Register, but the RMOD determines that the CSP is not eligible to be added to the Patent Register, the first person will be notified in writing. The first person will have the opportunity to provide representations. The RMOD will consider any representations before a final decision is made.

It is possible that a CSP will be added to the Patent Register before publication of the CSP issuance on the Register of Certificates of Supplementary Protection and Applications.

When completing a Form IV for a patent that is set out in a CSP, first persons should provide the information relating to the patent only. For example, enter the patent number and the expiry date of the patent in Part 3 of the form, and not the CSP number or expiry date. The RMOD will insert the information in relation to the CSP in the office use section of the form. In accordance with subsection 4(1.1) of the PM(NOC) Regulations, a patent list may include a patent that has expired if it is set out in a CSP that has taken effect. As such, if a patent has expired and the term of a CSP is in effect when submitting a Form IV with a submission, the first person should continue to enter the patent information on the form, as described above.

4.8 Addition of patent(s) and CSP(s) to the Patent Register

As provided for in subsection 3(7) of the PM(NOC) Regulations, no patent on a patent list or CSP shall be added to the Patent Register until the drug submission in respect of which the patent list was submitted receives an NOC. In addition to this requirement, the RMOD will not add any patent or CSP until it has completed a final evaluation and is satisfied that the patent or CSP meets the eligibility requirements set out in section 4, described above. The RMOD will prioritise evaluations for submissions for which an NOC has already issued.

It is recognised that certain terminology proposed by the company at the time of filing a drug submission does not become final until review and approval through the issuance of an NOC. Therefore, at the time of NOC issuance, it is possible that the information on Part 2 of the Form IV does not match the NOC, e.g. the medicinal ingredient, brand name, strength, route of administration and dosage form. If this information does not match the NOC, the first person is expected to request updates to the patent list, in accordance with the obligations set out in subsection 4(7). The RMOD will not update a patent list without written permission from the first person. Replacement Form IVs should not be provided by first persons.

Upon receipt of the written permission, the RMOD will make the requested changes to the Form IV to align the terminology on the Form IV with that approved on the NOC. Where permission is not received in a timely manner, there may be delays in adding the patent lists to the Patent Register.

4.9 Accuracy of Patent List information

Pursuant to subsection 4(7), first persons are required to keep the information on their patent lists up to date. The update of information, however, does not provide an opportunity to add a new patent. A first person should notify the RMOD in writing of any updates to the information included on the patent lists. Examples of an update include a change to the company name or address, the name and address for service of an NOA, patent lapse, or the dedication of the patent to the public interest. The onus is on the first person to ensure that the information on the patent list and the Patent Register is accurate and current. Please note that due to the complexities of corporate mergers and acquisitions, information is not automatically updated when an NOC is issued for a company name change or merger.

To ensure receipt of an NOA from a second person, the company name and address for service must be current. First persons wishing to update a patent list should forward to the RMOD a letter outlining the requested changes. First persons are requested not to provide the RMOD with new forms. The RMOD will not assume any responsibility for errors arising from the failure

of the first person to provide up-to-date information. First persons are encouraged to view the Form IVs on the Patent Register, available online, to ensure the accuracy of the information.

4.10 Re-issued patents

If a patent that is included on the Patent Register is re-issued by the CIPO, the RMOD recommends that the first person submit a new Form IV within 30 days of the date of re-issuance. The granted date entered on the patent list should be the date the patent was re-issued. The RMOD will conduct a review to determine whether the patent remains eligible to be included on the Patent Register. If the RMOD is of the view that the patent is no longer eligible, the RMOD will notify the first person, in writing, that the patent has been found ineligible for inclusion on the Patent Register. The first person will then be provided with an opportunity to submit written representations as to the patent's eligibility for inclusion on the Patent Register. If representations are provided, they will be taken into consideration by the RMOD and a final decision regarding the patent eligibility will subsequently be communicated to the first person.

5. Section 5 of the PM(NOC) Regulations

5.1 Scope and application of Section 5

In accordance with subsection 5(1), when a second person files a submission seeking an NOC for a drug and the submission directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada by a first person and in respect of which there are patents and/or CSPs included on the Patent Register, the second person must include in the submission the required statements or allegations set out in subsection 5(2.1) of the PM(NOC) Regulations.

Subsection 5(2) applies when a second person files a supplement for a change in formulation, a change in dosage form, or a change in use of the medicinal ingredient and the supplement directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada by a first person and in respect of which there are patents and/or CSPs included on the Patent Register.

While the terminology in section 5 is intended to capture abbreviated new drug submissions (ANDSs) and supplements to abbreviated new drug submissions (SANDSs), the language of section 5 of the PM(NOC) Regulations is not exclusive to ANDSs and SANDSs. It is also intended to capture NDSs and SNDSs that directly or indirectly compare the drug with, or make reference to, another drug marketed in Canada, including biosimilar drug submissions and submissions relying on third-party data.

A biosimilar must be subsequent to a biologic drug that is approved in Canada and to which a reference is made. Sponsors may use a non-Canadian sourced version as a proxy for the Canadian drug in the comparative studies. If the Canadian drug is marketed in Canada and has patents or CSPs included on the Patent Register, NDSs and SNDSs submitted in accordance with Health Canada's Guidance Document: Information and Submission Requirements for Biosimilar Biologic Drugs are considered to make a comparison or reference within the meaning of section 5. Sponsors of such submissions will be required to comply with the requirements for second persons under the PM(NOC) Regulations.

NDSs which seek approval based on independent clinical trials and not on a comparison or reference to a drug which has patents and/or CSPs included on the Patent Register are not captured by section 5. In addition, submissions that do not result in a subsequent entry version of the drug which has patents and/or CSPs included on the Patent Register are not captured by this section. For example, a submission for a drug indicated for use in combination with a drug on the Patent Register will not be required to comply with section 5 of the PM(NOC) Regulations.

5.1.1 Administrative drug submissions

When a manufacturer files a drug submission in accordance with Health Canada's Guidance Document Administrative Processing of Submissions and Applications: Human or Disinfectant Drugs, the administrative drug submission does not trigger application of section 5 of the PM(NOC) Regulations.

Rather, only the originating submission which directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada under an NOC issued to a first person, will trigger the application of section 5 of the PM(NOC) Regulations.

Subsequently filed administrative drug submissions that cross-reference the originating drug submission will not re-trigger section 5 of the PM(NOC) Regulations and should not include a Form V. An NOC will be issuable in respect of an administrative drug submission after the requirements of the Food and Drug Regulations have been met and only after the originating drug submission receives its NOC. In the case where the originating drug submission is placed on Intellectual Property (IP) Hold, the administrative drug submission will also be placed on IP Hold.

If consent is received from the patent owner under subsection 7(2) of the PM(NOC) Regulations, or subsection 7(3) of the pre-September 21, 2017 version of the PM(NOC) Regulations, and the NOC issues for the originating drug submission, the NOC for the administrative drug submission will also issue, as the requirements of the PM(NOC) Regulations have been met for the originating drug submission.

In accordance with subsection 5(4) of the PM(NOC) Regulations, the date of filing on which the Patent Register is frozen is specific to the originating drug submission. As such, any patent added to the Patent Register in respect of the first person's drug on or after the date of filing of the originating drug submission need not be addressed in respect of the administrative submission. The Patent Register is, in effect, "frozen" as of the date of filing of the originating drug submission.

Example 1:

Generic A files an ANDS for its drug X on January 2, 2018 and addresses the patents included on the Patent Register in respect of the first person's drug prior to January 2, 2018 as required by section 5 of the PM(NOC) Regulations. Subsequently, Generic A receives an NOC for its drug X.

Generic B then enters into a licensing agreement with Generic A and files an administrative ANDS for its identical drug XX, cross-referencing Generic A's ANDS. Generic A continues marketing its drug X while Generic B is assigned a distinct DIN for its drug XX after the requirements of the Food and Drug Regulations have been met.

Subsection 5(1) of the PM(NOC) Regulations is not re-triggered in respect of Generic B's administrative ANDS for its drug XX. Therefore, Generic B does not need to address the patents included on the Patent Register in respect of the first person's drug prior to receiving an NOC for its drug XX.

Example 2:

Generic C files an ANDS for its drug Y on January 2, 2018 and elects to await expiry of the patents included on the Patent Register in respect of the first person's drug prior to January 2, 2018. Subsequently, upon meeting the requirements under the Food and Drug Regulations, Generic C's ANDS for its drug Y is placed on IP Hold.

Generic D then enters into a licensing agreement with Generic C and files an administrative ANDS for its identical drug YY, cross-referencing Generic C's ANDS.

An NOC is issuable in respect of Generic D's administrative ANDS for its drug YY after the requirements of the Food and Drug Regulations have been met and only after Generic C receives an NOC for its ANDS for its drug Y. Therefore, Generic D's administrative ANDS will be placed on IP Hold until the NOC issues for Generic C's drug.

5.2 Submission of a Form V: Declaration re: Patent List

Under subsections 5(1) and 5(2) of the PM(NOC) Regulations, a second person must include in the submission or supplement the required statements or allegations set out in subsection 5(2.1) for each patent and CSP included on the Patent Register in respect of the first person's drug. The required statements and allegations are set out in the Form V. One Form V must be submitted for each patent included on the Patent Register, and for each strength of the second person's drug. Refer to Appendix B for instructions on how to complete the Form V.

Every required Form V must be a part of a drug submission. Filing of a Form V prior to the filing of a drug submission or supplement is not permitted. However, revised Form Vs are accepted by the RMOD.

A submission or supplement requiring a Form V will be considered administratively incomplete without one. It will be placed on Patent-Form V Hold and will not be transmitted to the relevant reviewing bureau/centre until the required Form V has been received by the RMOD. The filing date of the submission is as defined above in section 2 of this document.

A second person will be required to address all patents that are added to the Patent Register before the date of filing of its submission or supplement. If a second person cancels its submission or supplement and subsequently re-files, or the relevant directorate issues a rejection letter (e.g. a screening rejection letter, a notice of non-compliance-withdrawal or a notice of deficiency-withdrawal), the original date of filing is lost and the new date of filing becomes the date on which the submission or supplement is re-filed and considered administratively complete.

5.3 Freezing the Patent Register: addressing additions to the Patent Register on or after the date of filing of a second person's submission or supplement

Under subsection 5(4) of the PM(NOC) Regulations, a second person is not required to address a patent, or associated CSP setting out that patent, added to the Patent Register in respect of

the first person's drug on or after the date of filing of the second person's submission. The Patent Register is, in effect, "frozen" in respect of the patents included on the Patent Register as of the date of filing of the second person's submission.

The date of filing on which the Patent Register is frozen is specific to a second person's submission or supplement. Each second person benefits from the same freezing mechanism as of the date of filing of their respective submissions or supplements with the HPFB.

The PM(NOC) Regulations address the possible situation where a CSP is added to the Patent Register after the second person has filed its submission or supplement, but where the patent set out in the CSP was added to the Patent Register before the second person filed its submission or supplement. If this occurs, the PM(NOC) Regulations prohibit the issuance of an NOC to the second person until the expiry of the CSP, if certain conditions are met. The CSP must set out a patent in respect of which the second person was required to make a statement or allegation but did not make an allegation, or a patent in respect of which the Court has made a declaration of infringement. In addition, the CSP must be included on the Patent Register in respect of the same submission or supplement as the patent.

5.4 Certification of date of filing

When a second person's submission or supplement is considered administratively complete, the RMOD will issue to the second person an acknowledgement and certification letter to certify the date of filing of the submission. This letter will be identified by the title "Acknowledgement and Certification of Information Received".

Under subparagraph 5(3)(c)(i) of the PM(NOC) Regulations, this certification must be served with an NOA on the first person. Please note that the acknowledgement and certification is not the same as a regular acknowledgement letter, which does not have the title "Acknowledgement and Certification of Information Received". The acknowledgement letter does not certify the date of filing of the submission.

5.5 Deemed date of filing under Canada's Access to Medicines Regime

In cases where a second person has filed a submission or supplement under Canada's Access to Medicines Regime (CAMR), also known as An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa), subsection 5(5) of the PM(NOC) Regulations provides for a deemed date of filing in order to comply with the data protection provisions under section C.08.004.1 of the Food and Drug Regulations.

CAMR provides a framework within which eligible countries can import less expensive generic versions of patented drugs and medical devices. Notwithstanding that a second person may receive authorization to export a given drug under a compulsory license granted by the Commissioner of Patents, the HPFB will not grant an NOC providing Canadian market authorization unless the requirements for both data protection under section C.08.004.1 of the Food and Drug Regulations, and the PM(NOC) Regulations have been met.

Subsection C.08.004.1 of the Food and Drug Regulations provides an eight-year period of market exclusivity for innovative drugs. In addition, a subsequent-entry manufacturer is prevented from filing a submission for a copy of that innovative drug for the first six years of the eight-year period. The eight-year period may be extended by six months through a pediatric

extension. The introduction of the six-year no filing period requires an exception to allow for the filing of drug submissions within the framework of CAMR.

The addition of subsection 5(5) to the PM(NOC) Regulations provides this exception. For the purpose of subsection 5(3), which governs the service of an NOA, and subsection 5(4), which governs the freezing of the Patent Register, there is a deemed date of filing for submissions and supplements filed under CAMR, and referred to in paragraph C.07.003(b) of the Food and Drug Regulations. That date of filing is deemed to be six years after the date of issuance of the first person's NOC provided that:

1) the drug to which the second person makes a comparison or reference is an innovative drug within the meaning of subsection C.08.004.1(1) of the Food and Drug Regulations, and
2) the date that the submission or supplement is received by the HPFB is less than six years from the day on which the first NOC was issued in respect of the innovative drug.

The result is that, under subsection 5(3) of the PM(NOC) Regulations, a second person may not serve an NOA before the deemed filing date of its submission or supplement, which is six years after the date of issuance of the first person's NOC.

In addition, under subsection 5(4), the Patent Register will be frozen six years after the date of issuance of the first person's NOC. During that time, a first person may continue to add patents to the Patent Register in accordance with the PM(NOC) Regulations.

5.6 Notice of Allegation and information to be served on a First Person

5.6.1 Timing of service

Under paragraph 5(3)(a) of the PM(NOC) Regulations, a second person who makes an allegation under paragraph 5(2.1)(c) must serve on the first person an NOA relating to the submission or supplement that forms the basis of the allegation, but may not do so before the filing date of the submission or supplement.

The address for service of the first person is located on the patent list. Service by registered mail (as defined by Canada Post) is deemed to be effected on the addressee five days after mailing.

5.6.2 Contents of Notice of Allegation and documents served with a Notice of Allegation

Under subparagraph 5(3)(b)(i) of the PM(NOC) Regulations, an NOA must include a description of the medicinal ingredient, dosage form, strength, route of administration and use of the drug in respect of which the submission or supplement has been filed. The RMOD will verify that this information corresponds with that of the submission or supplement on file with the HPFB. The RMOD will also verify that the manufacturer in the submission is the same as the second person who has served the NOA. If any piece of information is missing from the NOA, or does not correspond with the information in the submission or supplement, the RMOD will notify the second person of the deficiencies identified in the NOA. As a transparency measure, the RMOD will also copy the first person on this correspondence. The second person will be required to serve an NOA reflecting all of the correct information outlined in subparagraph 5(3)(b)(i) of the PM(NOC) Regulations.

A certification of the date of filing of the submission or supplement is required to be served with the NOA. As discussed above, the certification of the date of filing of the submission or supplement is provided by the RMOD in the form of the "Acknowledgement and Certification of Information Received" letter.

5.6.3 Information to provide to the RMOD

In accordance with paragraph 5(3)(e) of the PM(NOC) Regulations, the second person must provide to the RMOD proof of service of the NOA, along with a copy of the NOA. A copy of the documents required to be served with the NOA under paragraphs 5(3)(c) and 5(3)(d) do not need to be provided to the RMOD.

It is recommended that second persons provide the proof of service and a copy of the NOA to the RMOD as soon as possible following service on the first person to allow the RMOD a period of time to review the NOA. Allowing for a period to review the NOA to ensure the information required by subparagraph 5(3)(b)(i) is included in the NOA and corresponds with the submission or supplement may provide an opportunity for second persons to address any deficiencies before an action is brought by the first person or patent owner.

5.6.4 Retraction of a Notice of Allegation

Under subsection 5(6), a second person who has served an NOA on a first person must retract that NOA and serve a notice of retraction on the first person within 90 days after either:

1) the date on which the Minister notifies the second person under paragraph C.08.004(3)(b) or C.08.004.01(3)(b) of the Food and Drug Regulations that the submission or supplement does not comply with the requirements of section C.08.002, C.08.002.01, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1, or
2) the date of the cancellation by the second person of the submission or supplement to which the allegation relates.

The types of notices requiring a retraction of an NOA include, for example, a screening rejection letter, a notice of non-compliance-withdrawal or a notice of deficiency-withdrawal.

A copy of the retraction or withdrawal of the NOA should be provided to the RMOD. The RMOD will acknowledge the retraction or withdrawal in writing, and will copy the first and second person.

5.7 Second Person company name changes prior to NOC issuance

A second person's submission may be transferred to another manufacturer prior to NOC issuance, if there is a company merger or licensing agreement. If an NOA has been served on the first person, the new second person should notify the first person of its new name in order to ensure transparency.

6. Sections 6 and 7 of the PM(NOC) Regulations

6.1 Actions

When a first person is served with an NOA, the first person or patent owner may bring an action against the second person in the Federal Court for a declaration that the making,

constructing, using or selling of the second person's drug would infringe any patent or CSP that is the subject of an allegation. The first person or patent owner has a period of 45 days after the date of service of the NOA to bring the action. If an action is brought, the Minister is prohibited from issuing the NOC to the second person for up to 24 months (the statutory stay).

6.2 Intellectual Property Hold

Once the examination of a second person's submission has been completed, the submission will be placed on IP Hold if the requirements of the PM(NOC) Regulations have not been met. The manufacturer will be notified in writing of the date on which the examination was completed and that the submission has been placed on IP Hold. An invoice for the review of the submission will also be issued, where applicable. Once the requirements of the PM(NOC) Regulations have been met, the submission may remain on IP Hold until the expiration of any data protection period for the first person's drug under section C.08.004.1 of the Food and Drug Regulations.

Where there is a notifiable change submission, it will be placed on IP Hold while the related submission is on IP Hold. The manufacturer will not be notified in writing when a notifiable change submission has been placed on IP Hold. Second persons are encouraged to view the status of their submissions in the Drug Submission Tracking System – Industry Access. The status of the notifiable change submission will be updated to IP Hold when the review of the submission is complete.

In accordance with subsection 8(2) of the PM(NOC) Regulations and paragraph 8(1)(a) of the pre-September 21, 2017 version of the PM(NOC) Regulations, the Minister may be requested to certify the date on which a NOC would have been issued to a second person in the absence of the PM(NOC) Regulations.

6.3 NOC issuance to a Second Person in the absence of an action for patent infringement

A first person or patent owner has a period of 45 days following service of an NOA to bring an action in the Federal Court. If no action is brought, the NOC may be issuable to the second person on the 46th day after the NOA was served, if the requirements of the Food and Drug Regulations have been met. As such, the RMOD will verify on day 46 whether a copy of a statement of claim has been received.

The Minister of Health is not a party to actions for patent infringement, therefore a copy of the statement of claim should not be served on the Minister. However, in accordance with section 6.13 of the PM(NOC) Regulations, a copy of the statement of claim must be provided to the RMOD as soon as feasible. Please refer to section 3.4.1 of this document for information on how to provide the statement of claim to the RMOD.

The RMOD will rely on the absence of a statement of claim to establish that no action was brought in the Federal Court. It is recommended that first persons and patent owners provide a copy of the statement of claim to the RMOD within the 45-day period to avoid any unwanted issuance of an NOC to the second person.

6.4 Verification of portions of a submission or supplement

Pre-September 21, 2017 version of the PM(NOC) Regulations

Under paragraph 6(7)(a) of the pre-September 21, 2017 PM(NOC) Regulations, a second person may be ordered by the court to produce any portion of the submission or supplement filed for an NOC that is relevant to the disposition of the issues in the prohibition proceeding. In addition, the court may order the production of any changes, as they are made, to the portion during that proceeding.

Under paragraph 6(7)(b), the RMOD may be ordered to verify that any portions of the submission or supplement produced by the second person correspond fully to the information in the submission or supplement, usually within 30 days of receipt of the productions. In such cases, the second person should produce the relevant documents directly to the first person. The first person will then direct the documents to the attention of the RMOD through counsel for the RMOD.

September 21, 2017 version of the PM(NOC) Regulations

Section 6.05 of the PM(NOC) Regulations provides that, on the request of any party to an action under the regulations, the RMOD must verify that any portion of a submission or supplement that is required to be served with an NOA, or that is produced as a result of an order, corresponds to the information in the submission or supplement. The documents to be verified shall be provided directly to the RMOD as outlined in section 3.4.1 of this guidance document. To ensure a transparent process, the RMOD recommends that the documents to be verified be provided by the first person or patent owner. Where the documents are provided by the second person, the RMOD will not produce a copy to the first person or patent owner.

6.4.1 Verification process

The RMOD is required only to verify whether the portions produced by the second person correspond with the relevant submission or supplement on file at the HPFB. The RMOD is not required to produce additional documentation, or make any statements or characterizations regarding the nature of the portions produced by the second person. In keeping with the pre-September 21, 2017 practice, the RMOD will endeavour to complete verification requests within 30 days.

To facilitate the verification process, parties are encouraged to continue to provide good quality copies of documents that are indexed using the format found in the example below, with respect to their location within the original submission or supplement.

If the productions are not formatted in a format acceptable to the RMOD, they may be rejected for verification. To this effect, productions to be verified under either version of the PM(NOC) Regulations should be formatted as follows:

Index:
The documents should be indexed and tabbed. The index should denote the location of the documents from within the production. It is important to note that providing detailed descriptions and information in the index will assist the RMOD in locating the documents and verifying the production efficiently.

Description of Item:
If multiple versions of a document were filed in respect of the relevant submission, for example a PM, add the "date of preparation" to the description (see Tab 2 of the example in Appendix C).

If multiple documents have similar titles, use a distinguishing name and/or highlight the difference(s) between the documents (see Tab 6 of the example in Appendix C).

Location:
If a document is located in a Master File, provide the Master File number and note whether the document can be found in the Unrestricted/Open or Restricted/Closed portion of the file (see Tabs 4 and 5 of the example in Appendix C).

Pages within a tab:
When only certain pages are provided for verification from a larger document, note the page numbers to be verified in the index and the complete number of pages of the document (see Tab 3 of the example in Appendix C).

Tabs:
Use a naming convention similar to "Tab–3 - [name of document]" when formatting the electronic production. If there are multiple documents contained in one tab, use one New Folder per tab (see Tab 7 of the example in Appendix C).

6.5 Consent

Under subsection 7(2) of the PM(NOC) Regulations, or subsection 7(3) of the pre-September 21, 2017 version of the PM(NOC) Regulations, the owner of the patent may provide consent to the making, constructing, using or selling of the drug in Canada by the second person.

The consent letter must be signed by the owner of the patent or by a person authorized to act on the owner's behalf. If the letter is signed by a person authorized to act on behalf of the patent owner, this must be stated in the letter. The letter should indicate the following:

- the patent and/or CSP numbers for which consent is being provided
- the second person's submission number
- the medicinal ingredient
- the second person's name, and
- a statement that for the purposes of subsection 7(2) or 7(3) of the PM(NOC) Regulations, as the case may be, the owner of the patent consents to the making, constructing, using or selling of the drug in Canada by the second person.

6.6 Renouncing the 24-month stay

Paragraph 7(1)(d) of the PM(NOC) Regulations prohibits the Minister from issuing an NOC to a second person for a 24-month period from the day on which an action is brought under subsection 6(1). However, a party who brings an action may renounce application of this 24-month period under paragraph 7(5)(b). To do so, each of the parties who bring an action must provide to the RMOD a notice that they renounce the application of the 24-month stay, at the time the action is brought.

The notice should indicate the following:

- the second person's submission number
- the patent and/or CSP numbers
- the court file number, and
- a statement that the application of paragraph 7(1)(d) of the PM(NOC) Regulations is being renounced in accordance with paragraph 7(5)(b) of the PM(NOC) Regulations.

7. Maintenance of the Patent Register

The RMOD is responsible for maintaining the Patent Register in accordance with subsection 3(2) of the PM(NOC) Regulations. The RMOD is required to add any patent on a patent list or CSP that meets the requirements for addition to the Patent Register and to refuse to add any patent or CSP that does not meet the requirements for addition to the Patent Register.

The RMOD must also delete any patents or CSPs from the Patent Register as outlined in the PM(NOC) Regulations, as follows:

- if the patent or CSP was added to the Patent Register due to an administrative error
- if the patent or CSP has been declared invalid or void under subsection 60(1) or 125(1) of the Patent Act
- if the patent or CSP has been declared under subsection 6.07(1) to be ineligible for inclusion on the Patent Register
- if the first person requests that the patent or CSP be deleted from the Patent Register
- if the patent has expired, unless a CSP in which that patent is set out is included on the Patent Register in respect of the same submission, or
- if the CSP has expired.

A patent or CSP declared ineligible for inclusion on the Patent Register will not be deleted until the period for appealing the decision to the Federal Court of Appeal ends, or until the conclusion of any appeal to the Federal Court of Appeal. This same delay does not apply to patents or CSPs declared invalid or void, which will be deleted after an initial finding. If a patent or CSP was deleted because of a finding of invalidity or ineligibility, it will be added back to the Patent Register, with a new date added, if the decision is subsequently reversed or set aside on appeal. Second persons who file submissions in the interim when the patent is not on the Patent Register will not need to address the patent. The first person will be notified in writing once a patent or CSP has been deleted from the Patent Register in accordance with paragraph 3(2)(c).

Subsection 3(2.3) provides the RMOD with discretion to review the eligibility of all the patents on the Patent Register. This may occur when, for instance, the eligibility requirements are called into question by new jurisprudence. If it is necessary to undertake a review of the Patent Register under subsection 3(2.3) of the PM(NOC) Regulations, the RMOD will notify first persons in writing if a patent or CSP has been found not to meet the requirements for inclusion on the Patent Register. If, during the course of such a review, an inquiry is received from an interested party regarding the inclusion of the patent on the Patent Register, a copy of the inquiry will be provided to the first person. As such, inquiries should not be marked confidential. The first person will then be provided with an opportunity to submit written

representations as to the patent or CSP's eligibility for inclusion on the Patent Register. If representations are provided, they will be taken into consideration by the RMOD and a final decision regarding the patent eligibility will subsequently be communicated to the first person and the inquirer. Note, however, that the mere receipt of an inquiry will not be considered as a sufficient basis to trigger a review of the entire Patent Register.

Appendices

Appendix A - How to complete a Form IV: Patent List

Please submit one Form IV per patent, per submission, per DIN.

Part 1

Select whether the patent list is being filed with the submission, or whether it is a newly issued patent for listing against a previously filed submission. The PM(NOC) Regulations require that all patents submitted for listing must be linked with a submission for an NOC. Therefore, in the case of a newly issued patent, the first person must provide the submission number. However, if the Form IV is being filed with the submission, the RMOD will insert the submission number on the form.

Select "NDS" if the Form IV is to be added to the Patent Register in accordance with subsection 4(2) of the PM(NOC) Regulations. Select "SNDS" if the Form IV is to be added to the Patent Register in accordance with subsection 4(3) of the PM(NOC) Regulations, and then select the appropriate option(s): change in formulation, change in dosage form or change in use.

Select "Carry forward, in accordance with section 4.1(2)" if the patent is already included on the Patent Register and the patent is being resubmitted in relation to the submission or supplement.

Note: When submitting a patent list with an SNDS for a change in formulation, change in dosage form or change in use of the medicinal ingredient, and the patent is already listed on the Patent Register for the same product, the RMOD recommends that the first person submit such a patent under the "carry forward" provision, unless the patent contains a specific claim for the changed formulation, dosage form or use for which the supplement was submitted.

Part 2

Enter the information about the drug as it appears, or as it is expected to appear, on the NOC.

Medicinal ingredient(s):

Enter the medicinal ingredient(s) contained in the drug as it appears, or as it is expected to appear, on the NOC.

Brand Name:

Enter the brand name under which the drug is (or will be) marketed. If the brand name has not yet been determined, it may be left blank and will be entered by the RMOD when the NOC is issued.

Human or Veterinary:

Indicate human or veterinary.

Strength per unit:

Provide the strength of the medicinal ingredient(s) (e.g. 10 mg, 100 mg, 0.5 mg/10 ml). Please note that one Form IV should be submitted per DIN. If there is more than one medicinal ingredient, list the strengths in the order that the medicinal ingredients appear in the medicinal ingredient field. Therefore, the names of the medicinal ingredients do not need to be repeated in the strength field.

Dosage Form:

Provide the physical form of the drug (e.g. tablet, capsule, solution, powder) as it appears, or as it is expected to appear, on the NOC.

Route(s) of Administration:

Provide the route of administration of the drug (e.g. oral, nasal, subcutaneous) as it appears, or as it is expected to appear, on the NOC.

DIN:

In the case of the first submission for an NOC for a drug, the DIN will not be known by the first person. Therefore, this field should be left blank and the RMOD will insert the DIN once the NOC issues. In all other cases, the DIN for the drug should be provided. Please note that one Form IV per DIN should be submitted.

Use(s) of the Medicinal Ingredient(s):

Enter the specific use(s) of the drug for which approval is being sought, or which has been approved, in the submission or supplement to which the patent list relates.

Part 3

Enter the information about the patent.

Patent Number:

Enter the Canadian patent number being submitted for addition to the Patent Register. If a CSP has issued in respect of the patent, enter the patent number only in this section. The RMOD will insert the CSP number and expiry date in the office use section, where applicable.

Code:

Indicate whether the first person is the owner of the patent, has an exclusive licence or has obtained consent from the owner of the patent to have it included on the patent list.

A: Applicant is the owner of the patent

B: Applicant has an exclusive license

C: Applicant has obtained the consent of the owner of the patent for the inclusion of the patent on the above patent list

Filing Date of Patent Application:

Indicate the Canadian patent application filing date.

Date Granted:

Enter the date on which the Canadian patent was granted by the CIPO.

Expiration Date:

Enter the date on which the patent term will expire. The term of a patent is 20 years from date of filing for patent applications filed on or after October 1, 1989. For patent applications filed before October 1, 1989, the expiry date is the later of 17 years from date of grant of the patent or 20 years from the date of filing. If a CSP has issued in respect of the patent, enter the expiration date of the patent in this section. The RMOD will insert the CSP number and expiry date in the office use section, where applicable.

Part 4

Enter the address in Canada for service, on the first person, of an NOA referred to in paragraph 5(3)(a) or the name and address for service in Canada of another person on whom service may be made with the same effect as if service were made on the first person. A post office box (P.O.) box is not an acceptable address, as it cannot accept registered mail.

The RMOD recommends using contact person titles (e.g. Director, Regulatory Affairs) rather than a name in this section to reduce the number of changes required to the form due to corporate staffing changes.

The onus is on the first person to keep this information up-to-date, in accordance with subsection 4(7) of the PM(NOC) Regulations.

Part 5

Enter the manufacturer and contact information and provide a certification that the information included on the patent list is accurate and that the patent on the list meets the eligibility requirements of subsection 4(2) or 4(3) of the PM(NOC) Regulations. The RMOD will use the contact information provided in this section to correspond with the first person regarding the patent list.

Part 6

This section is for office use only.

Appendix B - How to complete a Form V: Declaration re Patent List

Please submit one Form V per patent, per submission, per DIN.

Part 1

Select whether the form is an amendment to a previously filed Form V, or if the Form V is being filed with the submission.

Part 2

Enter the information about the second person's drug.

Medicinal ingredient(s):

Enter the medicinal ingredient(s) contained in the second person's drug as it appears, or as it is expected to appear, on the NOC.

Brand Name:

Enter the brand name of the second person's drug as it appears, or as it is expected to appear, on the NOC.

Drug Use:

Indicate human or veterinary.

Strength per unit:

Provide the strength of the medicinal ingredient (e.g. 10 mg, 100 mg, 0.5 mg/10 ml). Please note that one Form V should be submitted per DIN. If there is more than one medicinal ingredient, list the strengths in the order that the medicinal ingredients appear in the medicinal ingredient field. Therefore, the names of the medicinal ingredients do not need to be repeated in the strength field.

Dosage Form:

Provide the physical form of the drug (e.g. tablet, capsule, solution, powder) as it appears, or as it is expected to appear, on the NOC.

Route(s) of Administration:

Provide the route of administration of the drug (e.g. oral, nasal, subcutaneous) as it appears, or as it is expected to appear, on the NOC.

Use(s) of medicinal ingredient(s):

Enter the specific uses of the drug for which approval is being sought in the second person's submission.

Part 3

Enter the information about the first person's drug.

Part 3.1

Provide the Canadian patent number and expiry date of each patent included on the Patent Register for the first person's drug. Please note that one Form V should be submitted per patent, per DIN.

If there is a CSP number included on the Patent Register, enter the number and expiry date.

Part 3.2

In this section, the second person must select one of the statements or at least one of the allegations required by subsection 5(2.1) of the PM(NOC) Regulations.

Part 4

Provide the name and address of the manufacturer of the drug (the name of the company that is seeking the NOC) and contact information, which will be used by the RMOD to correspond with the second person regarding the form. Any NOA served should be from the company seeking the NOC.

Part 5

This section is for office use only.

Appendix C - Sample productions for verification

Sample Index Example

Tab	Sequence	Section	Description of Item	Location
1	0002	3.2.S.1.2	Quality - Body of Data - Drug Substance - Stability - Stability Data - Supplier Commitment	[Submission no.]
2	0005	1.3.1	Non-Annotated Product Monograph [date of preparation]	[Submission no.]
3	0004	3.2.S.3	Characterization, pp. 416-423 of 739	[Submission no.]
4	0000	1.0.4	Master File [Master File No.] - Administrative Information and Prescribing Information - Quality Overall Summary	Master File [Master File No.] - Open Portion or Closed Portion
5	The portions of [drug manufacturer name]'s Master File [Master File No.] that comprise the Productions are the following:			
	0001	3.2.S.1	General Information, pp. 6-7 of 739	Unrestricted Part or Restricted Part
6	0009	5.3.1.2	Comparative Bioavailability and Bioequivalence Study Reports: Comparative, Randomized 2-way Crossover Bioavailability Study of Tablets Under Fed Conditions, Drug Concentration by Formulation	[Submission no.]
			Comparative Bioavailability and Bioequivalence Study Reports: Comparative, Randomized 2-way Crossover Bioavailability Study of Tablets Under Fasting Conditions, Drug Concentration by Formulation	
7	0003	3.2.1.5	Drug Product - Specification(s) [drug name] - 10-mg-release-specifications	[Submission no.]
			Drug Product - Specification(s) [drug name]	[Submission no.]

Sample Index Example

Tab	Sequence	Section	Description of Item	Location
			- 15-mg-release-specifications	
			Drug Product - Specification(s) [drug name] - 20-mg-release-specifications	[Submission no.]

[1] Canada Gazette 2006.II.1510.

Exhibit “J6”

This is Exhibit “J6” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.
Arash Rouhi

Government of Canada Gouvernement du Canada

Patent register

From Health Canada

This information is provided by an organization which is not subject to the Official Languages Act and is therefore in the language used by the organization in question.

Search criteria

To search the register enter a value in **one** of the following fields:

Medicinal ingredient

Brand name

Patent number

Drug Identification Number (DIN)

Certificate of Supplementary Protection (CSP) number

Search Reset

Quick search

Search for expired patents
Search for removed patents
Search by date added to register
Search by date amended
Search by manufacturer
Search by submission number

Forms

Form IV: patent list forms
Form V: declaration re: patent list forms

Reports

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Exhibit “J7”

This is Exhibit “J7” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.
Arash Rouhi

mAbs 3:6, 535-545; November/December 2011; © 2011 Landes Bioscience

Discovery and mechanism of ustekinumab

A human monoclonal antibody targeting interleukin-12 and interleukin-23 for treatment of immune-mediated disorders

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Key words: ustekinumab, psoriasis, monoclonal antibody, interleukin-12/23p40

Abbreviations: ADCC, antibody-dependent cellular cytotoxicity; CCL, chemokine (C-C motif) ligand; CCR, C-C chemokine receptor type; CXCL, chemokine (C-X-C motif) ligand; CD, cluster of differentiation; CDC, complement-dependent cytotoxicity; CIA, collagen-induced arthritis; CNS, central nervous system; CTLA, cytotoxic T lymphocyte-associated antigen; D, domain; EAE, experimental autoimmune encephalomyelitis; Fab, fragment antigen binding; GMCSF, granulocyte macrophage stimulating factor; Hu-Ig, human immunoglobulin; IFNγ, interferon gamma; IL, interleukin; IL-12R, interleukin-12 receptor complex; IL-23R, IL-23 receptor complex; J, joining; κ, kappa; mAb, monoclonal antibody; NK, natural killer; NKT, natural killer T cells; MS, multiple sclerosis; PsA, psoriatic arthritis; RA, rheumatoid arthritis; ROR, retinoid-related orphan receptor; STAT, signal transduction and activation of transcription; Th, T-helper; TNFα, tumor necrosis factor alpha; Treg, T regulatory; V, variable

Monoclonal antibody (mAb) therapy was first established upon the approval of a mouse antibody for treatment of human acute organ rejection. However, the high incidence of immune response against the mouse mAb restricted therapeutic utility. Development of chimeric, "humanized" and human mAbs broadened therapeutic application to immune-mediated diseases requiring long-term treatment. Indeed, mAb therapeutics targeting soluble cytokines are highly effective in numerous immune-mediated disorders. A recent example is ustekinumab, a first-in-class therapeutic human immunoglobulin (Ig) G_1 kappa mAb that binds to the interleukins (IL)-12 and IL-23, cytokines that modulate lymphocyte function, including T-helper (Th) 1 and Th17 cell subsets. Ustekinumab was generated via recombinant human IL-12 immunization of human Ig (hu-Ig) transgenic mice. Ustekinumab binds to the p40 subunit common to IL-12 and IL-23 and prevents their interaction with the IL-12 receptor β1 subunit of the IL-12 and IL-23 receptor complexes. Ustekinumab is approved for treatment of moderate-to-severe plaque psoriasis and has demonstrated efficacy in Crohn disease and psoriatic arthritis. The clinical characterization of ustekinumab continues to refine our understanding of human immune pathologies and may offer a novel therapeutic option for certain immune-mediated diseases.

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Monoclonal Antibody Therapies for Immune-Mediated Disorders

The concept of antibodies as therapeutic agents was initially described by Paul Ehrlich, where he reasoned that if a compound could be designed to selectively target a disease-causing organism, then a toxin for that organism could be delivered along with the agent of selectivity.[1] Functional and structural characterization of antibodies culminated in several precedent discoveries on the generation and maturation of the humoral immune response.[2] The key scientific breakthrough that advanced the evaluation of antibodies as therapeutic modalities was the development of hybridoma technology, which afforded the ability to reliably produce sufficient quantities of "monospecific" or identical antibody moieties, i.e., monoclonal antibodies (mAbs).

The first successful clinical development of a mAb therapeutic agent was a fully mouse anti-CD3 immunoglobulin (Ig) G (muromononab-CD3) for treatment of acute organ rejection.[3] However, frequent and significant immune-mediated toxicities were associated with administration of fully mouse mAbs, particularly upon repeated administration. Advancements in genetic engineering resulted in the development of chimeric, humanized and fully human therapeutic mAbs. The reduction or elimination of non-human amino acid sequences resulted in a significant decrease in immune-mediated associated toxicities, which in turn, broadened the potential therapeutic applications.[4] Indeed, therapeutic mAbs have become an increasingly important component of pharmacotherapy. It is estimated that more than 300 mAbs are currently in development and, approximately 30 mAbs are approved by the United States Food and Drug

Administration under Biologic License Applications.[5] The majority of approved and experimental mAbs are for oncologic indications, but indications also include chronic immune-mediated, respiratory, metabolic and central nervous system (CNS) disorders.

Therapeutic mAbs targeting soluble cytokines or lymphocyte cell surface molecules have demonstrated efficacy in treating oncologic, as well as immune-mediated disorders. One mechanism of mAbs targeting cell surface receptors is depletion of a cell subtype or subtypes. Such an example is rituximab, a mouse/human IgG1 chimeric mAb that binds to the cluster of differentiation (CD)20 antigen present on certain B lymphocytes.[6] CD20 cell surface binding can lead to cell lysis via complement-dependent cytotoxicity (CDC) or antibody-dependent cellular cytotoxicity (ADCC). Rituximab is currently approved for both oncologic (i.e., non-Hodgkin's lymphoma and chronic lymphocytic leukemia) and immune-mediated disorders (i.e., rheumatoid arthritis (RA), and Wegener's granulomatosis). Alternately, mAbs or Fc-fusion proteins targeting cell surface receptors can function through blockade of ligand-mediated receptor signaling. For example, abatacept is an Fc-fusion protein of the extracellular domain of human cytotoxic T lymphocyte-associated antigen (CTLA)-4.[7] Abatacept binds to the CD80/CD86 receptor on T cells and blocks the interaction of CD80/CD86 with CD28, a costimulatory signal required for full activation of T lymphocytes. The mechanistic properties of abatacept may include inhibition of tumor necrosis factor alpha (TNFα), and interferon gamma (IFNγ) production by activated T cells. Abatacept is currently approved for the treatment of adult RA and juvenile idiopathic arthritis.

Currently, one of the largest classes of therapeutic mAbs and Fc-fusion proteins are those that bind and neutralize TNFα, a pro-inflammatory cytokine primarily produced by macrophages. TNFα induces the expression of innate cytokines interleukin (IL)-1β, IL-6 and IL-8, resulting in the rapid recruitment of neutrophils upon exposure to infection.[8] A putative mechanistic action of TNFα in immune-mediated disorders is inhibition of matrix metalloproteinase-producing neutrophils in the synovial fluid of affected joints. In addition, clinical response of TNF antagonism in RA is associated with the downregulation of peripheral blood genes associated with acute phase reactant proteins.[9] Compounds in this group include a chimeric IgG1 mAb (infliximab), human IgG1 mAbs (golimumab and adalimumab), a pegylated Fab' fragment of humanized mAb (certolizumab), and a soluble dimeric Fc-fusion protein of the extracellular ligand-binding portion of the human 75 kD (p75) TNF receptor (etanercept).[10] These TNF antagonists bind to TNFα and inhibit the interaction of soluble TNFα with its cell surface receptors, thus inhibiting biologic responses initiated or mediated by TNFα. TNFα can also exist as a cell-surface molecule. Therefore, some component of TNF antagonist mechanisms of action may include direct binding to cell surfaces. These TNF antagonists are approved for the treatment of a number of rheumatologic, gastroenterologic and dermatologic indications.

Role of Interleukin-12 and Interleukin-23 on Lymphocyte Development and Function

TNF antagonists established mAb-based cytokine targeting as an effective treatment approach for immune-mediated disease. Another cytokine thought to contribute to certain immune-mediated disorders is IL-12. IL-12 is primarily produced by phagocytic and dendritic cells in response to microbial stimulation, and drives cell-mediated immunity by inducing lymphokine-activated killer cells and activation of natural killer (NK) cells and T lymphocytes.[11] $CD4^+$ T cells can differentiate into T-helper (Th) effector lineages, which are typically classified by the environment leading to their development and the cytokine profiles they produce. The original Th lineages identified were designated Th1 and Th2.[12] IL-12 is the key inducer of Th1 cells, which are characterized by utilization of T-bet transcription factor and robust IFNγ production. Th1 responses are thought to promote cell-mediated immunity to intracellular pathogens, delayed type hypersensitivity and macrophage activation.[13] In contrast, the Th2 lineage is associated with the GATA-3 transcription factor and IL-4, IL-5 and IL-13 production. Th2 cells are thought to mediate humoral immunity, especially to extracellular pathogens. Concurrent with discovery of the Th1/Th2 lineages, animal model and clinical studies indicated abnormal Th1 responses were driving the pathology of immune-mediated disorders, whereas abnormal Th2 responses were proposed to mediate asthmatic and allergic disorders. Mouse Th1 and Th2 cells were shown to counter-regulate each other, thus establishing the Th1/Th2 paradigm.[14] A number of key aspects of the Th1/Th2 paradigm are currently under debate, one example being irreversible lineage commitment of Th cells.

The Th1/Th2 paradigm was challenged by the identification of the Th17 lineage, characterized by cell surface CD161 and C-C chemokine receptor type (CCR)6 expression, as well as IL-17A and IL-17F production.[15] Original reports in mouse systems suggested that a newly discovered cytokine, IL-23, was critical for Th17 differentiation.[16] However, more recent studies conducted on human cells suggest a cocktail of cytokines, such as IL-23 and IL-1β, are required.[15,17] Development and maintenance of the Th17 phenotype utilizes retinoid-related orphan receptor (ROR)γτ and RORα transcription factors and likely requires multiple cytokines, including IL-23. Differences exist between human and mouse Th17 cells in relation to cytokine requirements for lineage commitment and maintenance, as well as cytokine profiles.[15,16] Human Th17 cells are thought to produce several pro-inflammatory cytokines, including IL-17A and F, TNFα, IL-22, IL-26 and IFNγ.[18,19] Similar to IL-12, IL-23 can contribute to functional responses of several effector cell subtypes other than $CD4^+$ T cells, including $CD8^+$ T cells,[20] NK, NKT,[21,22] γδ T cells,[23,24] and innate lymphoid cells (**Fig. 1**).[25]

The discovery and characterization of Th17 cells and additional Th lineages such as T follicular helper, Th9, Th22 and T regulatory (Treg) cells are substantially altering our understanding of adaptive immune function and immune-mediated pathology.[26-28] There is increasing evidence of plasticity amongst certain Th subtypes, depending upon the cytokine

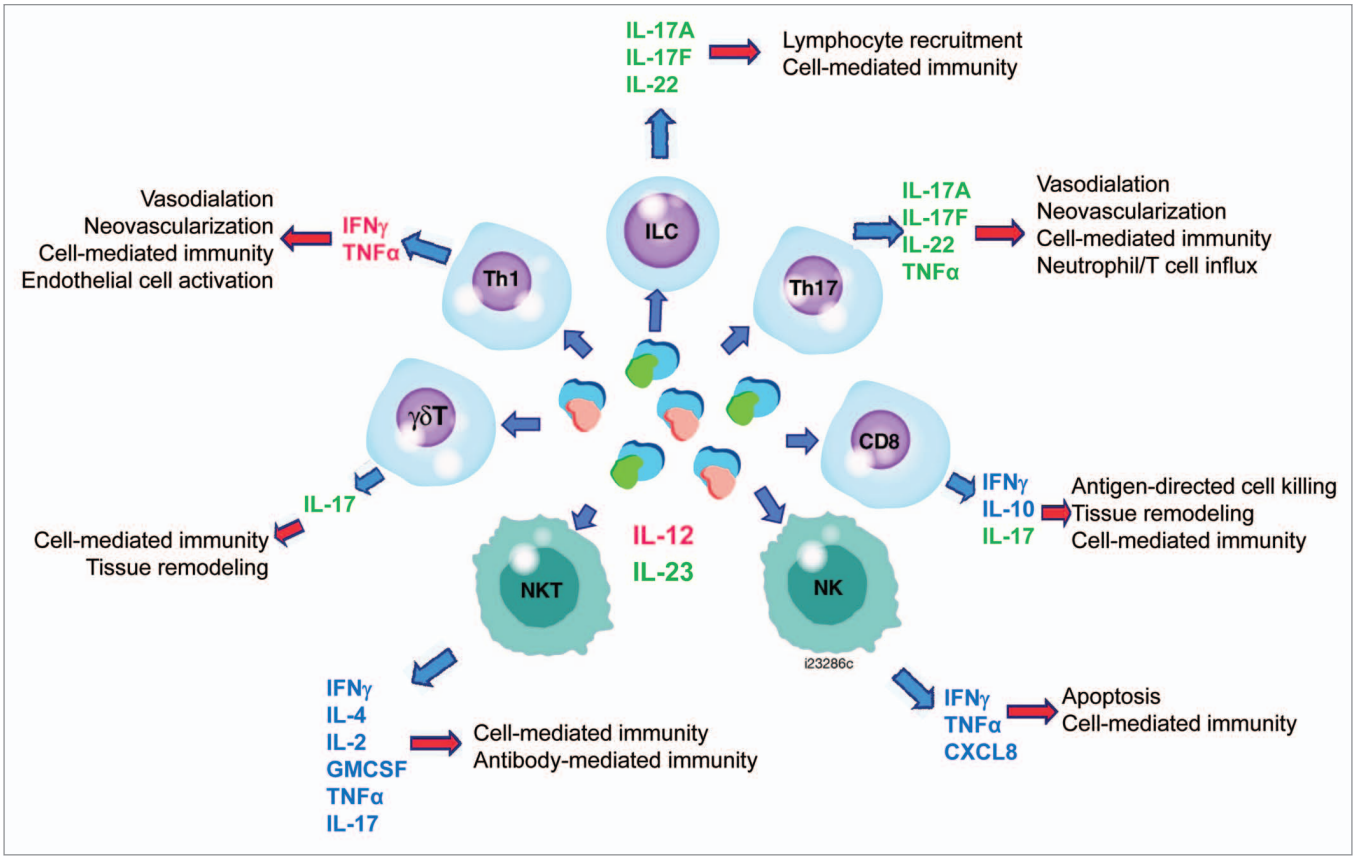

Figure 1. Function of interleukin (IL)-12 and IL-23 on effector cells. IL-12-specific specific effects are designated red; IL-23-specific effects are designated green. Properties attributed to both IL-12 and IL-23 are designated blue. CXCL, chemokine (C-X-C) motif; IFNγ, interferon gamma; GMCSF, granulocyte macrophage colony stimulating factor; NKT, natural killer cells; TNFα, tumor necrosis factor. Cited from references 12, 15, 18–21 and 23.

microenvironment.[29] For instance, Foxp3 expression by Treg cells and IL-17 by Th17 cells can be altered by changing the cytokine milieu, suggesting these phenotypes are not stable. For example, activated mouse Treg cells have the capacity to differentiate into Th17 cells in vitro in the presence of exogenous IL-6.[30] Alternately, Th17 cells can differentiate to Th1 cells in the presence of IL-12.[29] Although contributions from IL-23 were not originally appreciated, Centocor chose to develop a mAb that attenuates Th cell function by modulation of the cytokine environment and thus, initiated discovery of an anti-IL-12 therapeutic mAb.

Interleukin-12 and Interleukin-23 Antibody Discovery and Generation

Ustekinumab is a human IgG1 kappa (κ) mAb generated by Centocor Research & Development, a division of Johnson & Johnson Pharmaceutical Research and Development, LLC, using human Ig (hu-Ig) transgenic mice obtained from GenPharm, which was subsequently acquired by Medarex and is currently part of Bristol-Meyers Squibb of Princeton, New Jersey. In these mice, four distinct genetic modifications replaced the mouse Ig loci with human antibody transgenes.[31,32] The mouse antibody heavy chain joining (J) coding sequences were deleted, thereby preventing the DNA rearrangement process that is required to assemble a functional mouse antibody heavy chain gene. In addition, the mouse antibody κ light chain and constant region coding sequences were deleted, preventing expression of mouse κ light chains. The human heavy chain "minilocus" of DNA (~80,000 bases in length), which contained coding sequences for four variable (V) regions, sixteen diversity segments, six J segments, IgM constant regions and IgG1 constant regions, were cloned and inserted into the mouse genome. In addition, a human κ light chain "minilocus" of DNA (~450,000 bases in length), containing the coding sequences for at least ten V regions, five J segments and κ constant region, was inserted. These genetic modifications resulted in a mouse strain capable of producing human antibodies in response to immunizations to any antigen of interest (**Fig. 2**). The human Ig transgenic mouse technology enabled generation of diverse, high affinity, and highly specific mAbs with lower deleterious immunogenicity responses than previously developed rodent mAbs.

To elicit human anti-human IL-12 therapeutic mAbs, the transgenic mice were immunized with human IL-12 antigen. Mice that demonstrated positive serum titers for anti-IL-12 antibodies were selected for hybridoma fusion. Splenocytes, which contain antibody-producing B cells from IL-12 titer-positive mice, were fused with an immortal cell line, and the resulting

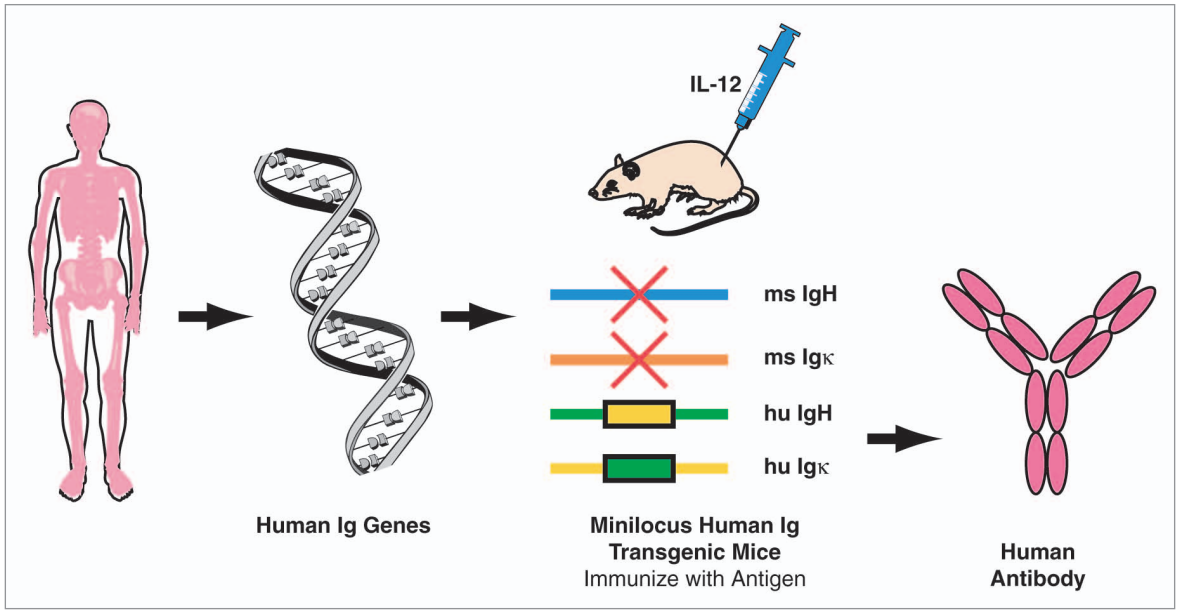

Figure 2. Human antibody transgenic mice. Human heavy and light chain genes were used by GenPharm (later known as Medarex, now part of Bristol-Meyers Squibb) to prepare minilocus human immunoglobulin (hu-Ig) transgenic mice (HC4/ KCo5). Mice were immunized with human interleukin-12 (IL-12) to produce human antibodies. H, heavy; κ, kappa; ms, mouse.

hybridoma cells were cultured under selection conditions that allowed only hybridoma cells to grow. Growth-positive hybridomas secreting IL-12-specific antibodies were selected for limited dilution subcloning (**Fig. 3**). Binding and cell-based functional assays using human T cells were utilized to select antibodies that specifically bound IL-12 and inhibited IL-12-mediated responses. A monoclonal hybridoma clone that produced a human IgG1κ antibody capable of binding to and neutralizing human and non-human primate IL-12 was thus identified. The antibody, initially named 12B75, then CNTO1275, and later ustekinumab, was chosen for further development based on its superior IL-12 binding and neutralization activity.

As a first step towards preparing a stable cell line producing high quantities of ustekinumab, DNA encoding the entire heavy and light chain genes of the ustekinumab antibody was cloned from the hybridoma cells (**Fig. 3**). Sequencing of the cloned DNA encoding ustekinumab and their subsequent translation into amino acid sequences, followed by comparison to antibody databases, confirmed that ustekinumab was a human antibody with a human IgG1 heavy chain and a κ light chain. The heavy chain IgG1 constant region sequence is of the G1m (1,3) allotype. The cloned heavy and light chain genes were then introduced into a host cell line by electroporation. Transfected cell lines producing the highest titers of ustekinumab were selected for subcloning and expansion. A single cell line was chosen to support early development. Subsequently, further changes were made to support production using perfusion bioreactors in accordance with Good Manufacturing Practice guidelines, with the resultant recombinant antibody retaining the same amino acid sequence as found in the original hybridoma cell lines. Ustekinumab is purified from the supernatant generated from the bioreactor process.

Ustekinumab Mechanism of Action

IL-12 is a heterodimeric cytokine containing two protein subunits named p40 and p35 according to their approximate molecular weight. Subunit binding analysis determined that ustekinumab binds to the IL-12p40 subunit. This was later confirmed by elucidation of the ustekinumab fragment antigen binding (Fab)/IL-12 co-crystal structure.[33] IL-12 binds to a heterodimeric receptor complex consisting of IL-12 receptor (IL-12R) β1 and IL-12Rβ2 chains expressed on the surface of T cells or NK cells (**Fig. 4**).[34] The IL-12Rβ1 chain binds to the p40 subunit, whereas IL-12p35 association with IL-12Rβ2 confers intracellular signaling. IL-12-mediated signaling includes intracellular phosphorylation of signal transduction activation of transcription (STAT)4 and STAT6 proteins, and functional responses including cell surface molecule expression, NK cell lytic activities and cytokine production, such as IFNγ.

The p40 protein subunit of IL-12 was also found to associate with a p19 subunit to form IL-23.[35] Both IL-12 and IL-23 exist only as secreted heterodimeric cytokines and neither IL-12p35 nor IL-23p19 subunits are secreted without intracellular covalent association with p40. IL-23 also utilizes the IL-12Rβ1 chain for binding to the cell surface of effector cells (**Fig. 4**). However, it is association of IL-23p19 to the second component of the IL-23 receptor complex (IL-23R) that confers IL-23-specific intracellular signaling, such as intracellular phosphorylation of STAT3 and lymphocyte activation and cytokine production, such as IL-17A (**Fig. 4**).[36] Since IL-23 also contains the IL-12p40 protein subunit, ustekinumab was characterized for binding and neutralization activity against human IL-23. Interestingly, the description of IL-23 occurred subsequent to the discovery and preclinical development of ustekinumab. The opportunities and

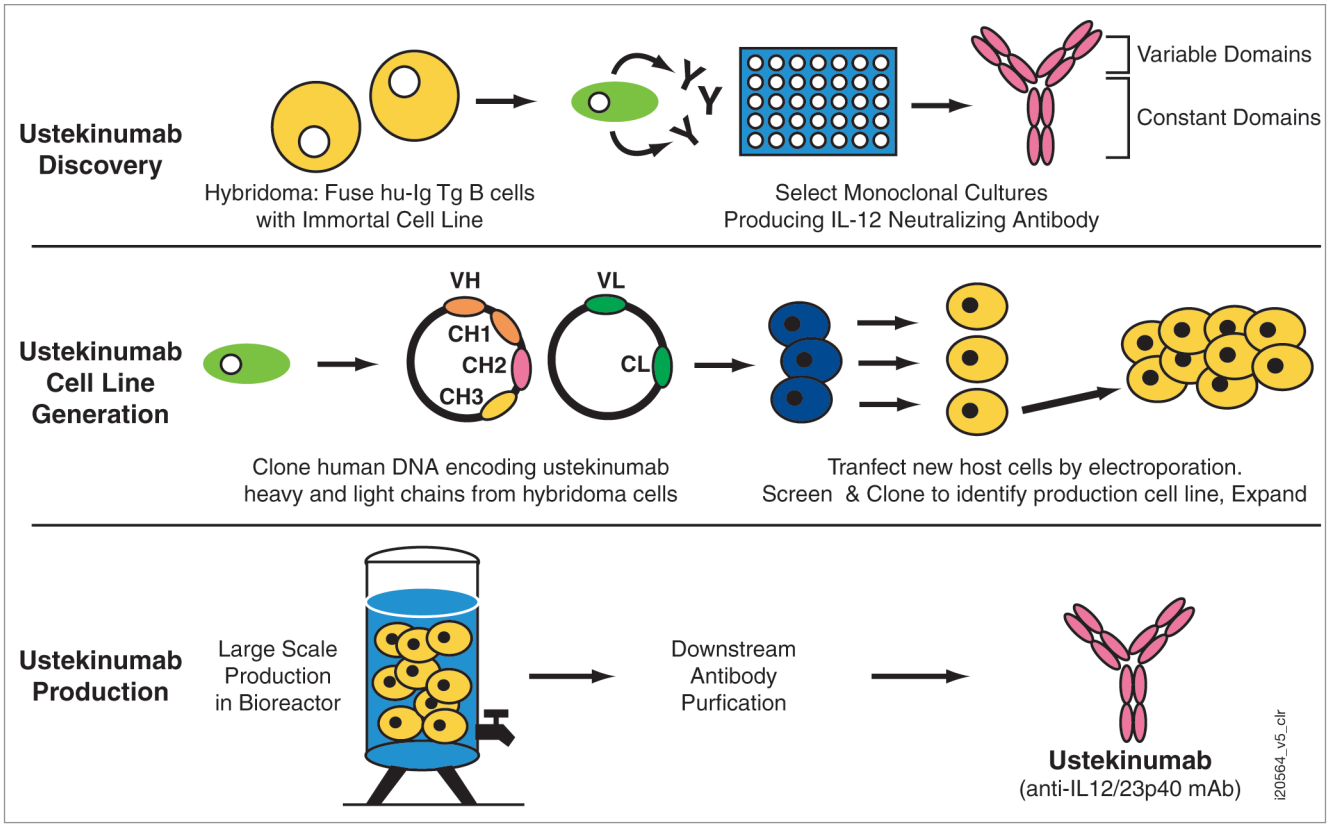

Figure 3. Ustekinumab discovery, cell line generation and antibody production. Ustekinumab is a human monoclonal antibody (mAb) discovered through the generation of hybridoma cultures from immunized human immunoglobulin (hu-Ig) transgenic (Tg) mice. Hybridomas secreting human mAbs that neutralized interleukin-12 (IL-12) were identified. Ustekinumab variable (V) and constant (C) domains were cloned from hybridoma cells and the heavy (H) and light (L) chains of the V and C domains were transfected into new host cells by electroporation. Ustekinumab is produced using perfusion fermentation culture and purified from the supernatant generated from the fermentation process.

challenges of the unique dual specificity to the clinical development of ustekinumab have recently been described in detail.[37]

The p40 subunit of human IL-12 and IL-23 is comprised of three domains (D), i.e., D1–D3, two of which (D2 and D3) are involved in binding IL-12p35 and IL-23p19.[38,39] Based on a crystal structure of ustekinumab Fab region complexed with human IL-12, the binding epitope for ustekinumab is located in the D1 domain of the p40 subunit, which is spatially distant from IL-12p35 and IL-23p19.[33] Mutational analysis confirmed amino acid residues within D1 that were required for ustekinumab binding. Through isothermal titration calorimetry analysis, ustekinumab was shown to bind IL-12 and IL-23 equally, with the expected 2:1 antigen-to-antibody stoichiometry. Furthermore, ustekinumab did not bind to structurally related proteins or rodent IL-12/23. Overall, these studies determined the precise specificity and molecular interactions between ustekinumab and IL-12/23p40.

Ustekinumab prevents human IL-12 and IL-23 from binding to the IL-12Rβ1 receptor chain of IL-12 (IL-12Rβ1/β2) and IL-23 (IL-12Rβ1/23R) receptor complexes on the surface of NK and T cells (**Fig.** 4). This defines the molecular mechanism of action of ustekinumab. Ustekinumab cannot bind to endogenous IL-12 or IL-23 that is already bound to receptor complexes. Thus, ustekinumab is unlikely to mediate Fc effector functions, such as ADCC or CDC. In vitro, ustekinumab will neutralize IL-12-mediated responses, including intracellular phosphorylation of STAT4, cell surface marker expression and IFNγ cytokine production. IL-23-mediated responses are equally inhibited, including intracellular STAT3 phosphorylation and IL-17A, IL-17F and IL-22 cytokine protein production. Collectively, these data demonstrate that by preventing IL-12 and IL-23 from binding to the IL-12Rβ1 receptor, ustekinumab can effectively neutralize human IL-12- and IL-23-mediated cell signaling, activation and cytokine production. It is important to note that while ustekinumab will effectively neutralize IL-12- and IL-23-mediated functional responses, it will not affect immune responses stimulated through other cytokines or cellular activities.

Role of Interleukin-12 and Interleukin-23 in Immune-Mediated Diseases

Studies in animal models and with human disease samples have established a strong link between dysregulation of the Th1/Th17 pathways and dermatologic, rheumatic, gastrointestinal and neurologic disorders, namely psoriasis, RA, Crohn disease and multiple sclerosis (MS). Administration of IL-12 exacerbated disease in murine psoriasis,[40] chronic colitis,[41,42] collagen-induced arthritis (CIA) models,[43] and experimental autoimmune

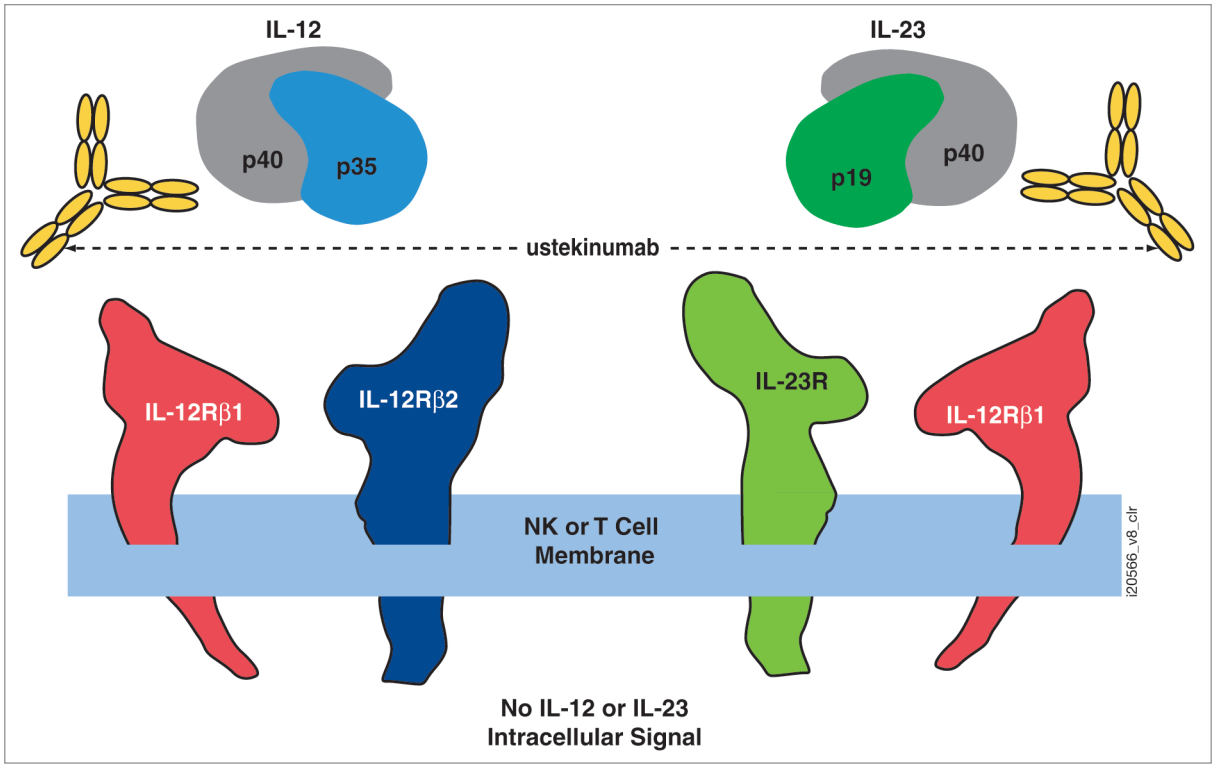

Figure 4. Ustekinumab mechanism of action. Ustekinumab binds to the p40 subunit of interleukin (IL)-12 and IL-23 and prevents their interaction with the cell surface IL-12Rβ1 receptor, subsequently inhibiting IL-12- and IL-23-mediated cell signaling, activation and cytokine production (image not drawn to scale). NK, natural killer. Adapted from Benson et al.[37]

encephalitis (EAE) models of MS,[44] whereas administration of anti-IL-12/23p40 antibodies is either protective or attenuated disease severity. Subsequent studies in mouse models of EAE and CIA revealed that IL-12/23p40 or IL-23p19 inhibition through genetic ablation or antibody treatment is either protective or attenuates disease severity. In contrast, genetic ablation of IL-12p35 was not protective. Thus, in certain mouse systems, IL-23 mediates many disease pathologies previously attributed to IL-12.[18,45-47]

Human genetic and tissue analysis indicates both IL-12 and IL-23 pathways are involved in certain immune-mediated pathologies. However, given the overlap between human Th1 and Th17 pathways and the plasticity between human Th lineages in vivo, it is difficult to distinguish between IL-12 and IL-23 biologies. For example, overexpression of IL-12 was observed systemically or within diseased tissue from a number of human autoimmune/inflammatory disorders.[48-51] In certain cases, such as MS, protein expression of the IL-12/23p40 in the serum or CNS correlated with disease severity.[52,53] In addition, gene expression levels of IL-12, IFNγ and IL-23 are elevated in psoriasis skin lesions.[54] Overexpression of both the p35 and p40 subunits of IL-12 are elevated in gastrointestinal tissue of Crohn disease patients and polymorphisms of genes that encode either IL-12/23p40 or the IL-23R are linked to psoriasis,[55,56] and Crohn disease.[57] In fact, the IL23R R381Q gene variant that protects against psoriasis, Crohn disease and ankylosing spondylitis was recently reported to exert its protective effects through selective attenuation of IL-23-induced Th17 cell effector function, without interfering with Th17 differentiation.[58] Collectively, many published studies support dysregulation of either IL-12, IL-23, or both pathways in human immune-mediated diseases.

Ustekinumab Clinical Development

As summarized previously, a strong body of pre-clinical and clinical data established an association between IL12/23p40 and a number of chronic immune-mediated disorders. Of these, psoriasis was chosen as the first-in-human population since it allowed the establishment of proof of concept early in clinical development and afforded the ability to collect and examine diseased tissue for pharmacodynamic effects via minimally invasive procedures. Psoriasis is a chronic immune-mediated skin disorder with significant co-morbidities such as psoriatic arthritis (PsA), depression, cardiovascular disease, hypertension, obesity, diabetes, metabolic syndrome and Crohn disease.[59] Plaque psoriasis is the most common form of the disease and manifests in well-demarcated erythematous lesions topped with white silver scales.[60] Plaques are pruritic, painful and often disfiguring, and a significant proportion of psoriatic patients have plaques on hands/nails, face, feet and genitalia. As such, psoriasis can impose physical and psychosocial burdens that extend beyond the physical dermatological symptoms and interfere with everyday activities. For example, psoriasis negatively impacts familial, spousal, social and work relationships,[61,62] and is associated with a higher incidence of depression and increased suicidal tendencies.[63]

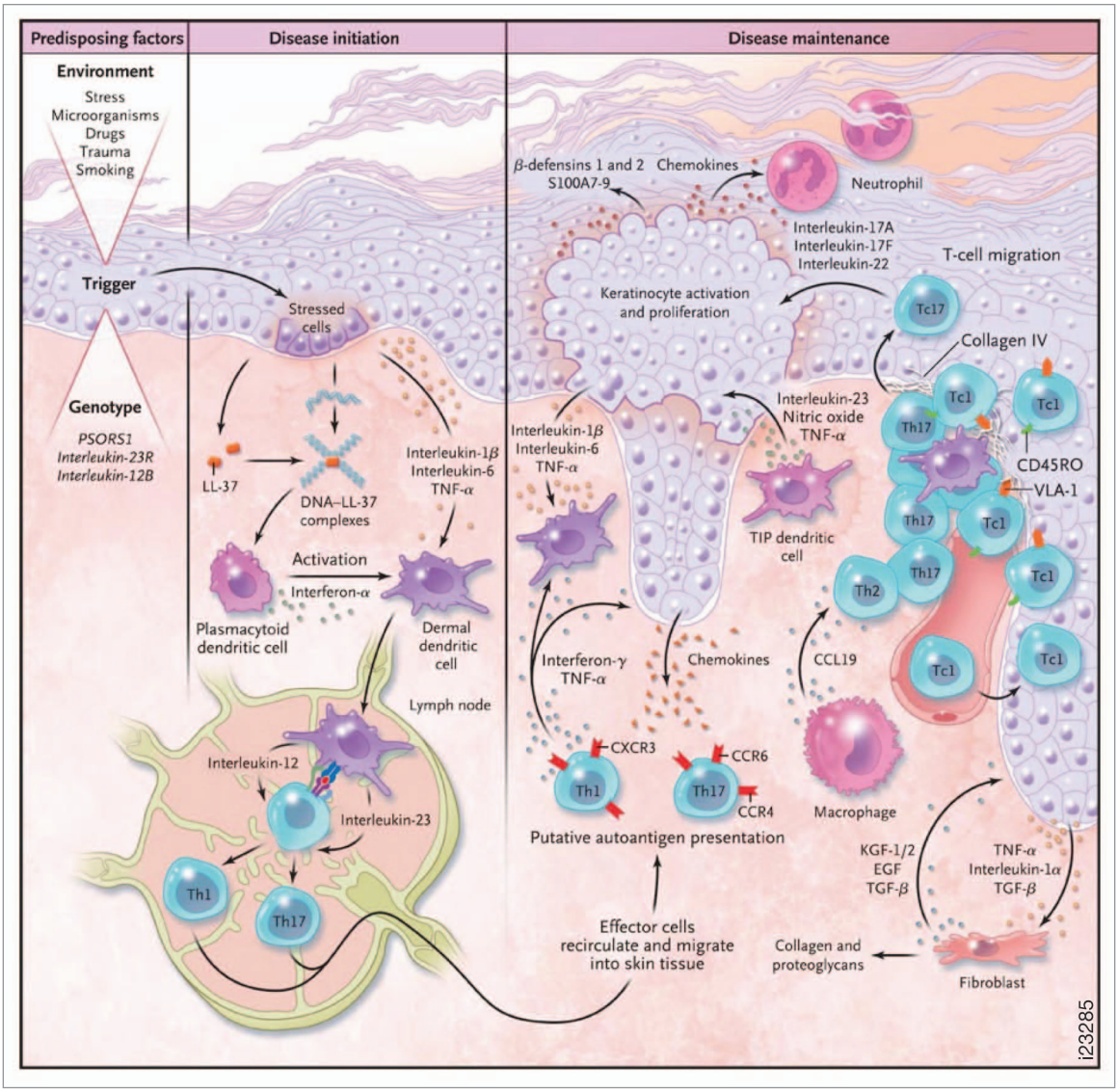

Figure 5. Proposed model for psoriasis immunopathogenesis. Activated dendritic cells (DCs) induce differentiation of naive T cells into effector cells such as T-helper (Th) 1 and Th17 cells, which then release effector cytokines that induce the production of chemokines and adhesion receptors on endothelial cells. Effector cells infiltrate the skin and contribute to keratinocyte activation and proliferation. The overall result is a continuing cycle of T cell and DC activation resulting in the maintenance of psoriatic skin inflammation and plaque formation. Reproduced with permission from Nestle et al.[82]

Histologic characterization of psoriasis lesions reveals a thickened epidermis resulting from aberrant keratinocyte proliferation and differentiation, as well as dermal infiltration and co-localization of $CD3^+$ T lymphocytes and dendritic cells (**Fig. 5**).[64] While the etiology of psoriasis is not well-defined, gene and protein analyses have shown that IL-12, IL-23 and their downstream molecules are overexpressed in psoriatic lesions,[48,65] and some may correlate with psoriasis disease severity.[66,67] Some therapies used in the treatment of psoriasis modulate IL-12 and IL-23 levels, which is speculated to contribute to their efficacy.[68] As illustrated in **Figure 5**, Th1 and Th17 cells can produce effector cytokines that induce the production of vasodilators, chemoattractants and expression of adhesion molecules on endothelial cells, which, in turn, promote monocyte and neutrophil recruitment, T cell infiltration, neovascularization and keratinocyte activation and hyperplasia. Activated keratinocytes can produce chemoattractant factors that promote neutrophil, monocyte, T cell and DC trafficking, thus establishing a cycle of inflammation and keratinocyte hyperproliferation.

Results of three Phase 3 clinical studies of ustekinumab in the treatment of moderate-to-severe plaque psoriasis have been published.[69-71] Ustekinumab administered by subcutaneous injection at weeks 0 and 4 and then once every 12 weeks exhibited rapid and sustained clinical response, as assessed by the Psoriasis Area and Severity Index, a validated efficacy tool for psoriasis. A Phase 3 study comparing ustekinumab with etanercept, a TNF antagonist, demonstrated that the efficacy of ustekinumab was superior to that of etanercept over a 12-week period in patients

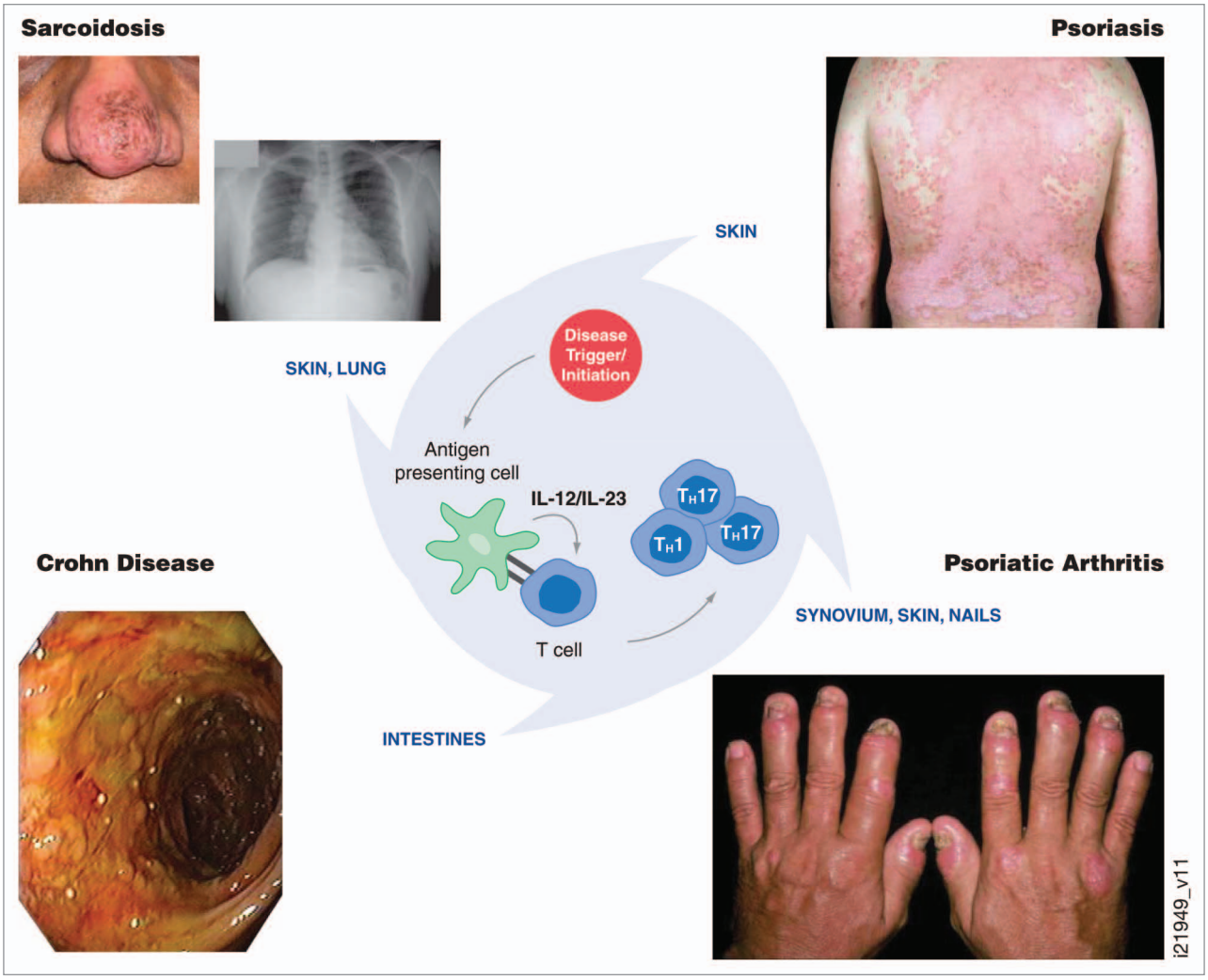

Figure 6. Proposed central role of interleukin (IL)-12/23 and T helper (Th)1/17 cells in psoriasis, psoriatic arthritis, Crohn disease and sarcoidosis pathologies. Observations to date from clinical studies with ustekinumab suggest common immune pathways between psoriasis, psoriatic arthritis and Crohn disease. The role of IL-12/23 in sarcoidosis is under evaluation.

with moderate-to-severe psoriasis.[71] In two Phase 3 clinical studies, PHOENIX I and PHOENIX II, ustekinumab exhibited a half-life of approximately 3 weeks. Immune response rates against ustekinumab ranged from 3 to 5%.[72] In addition, reported adverse events were relatively mild, with the majority of events including susceptibility to mild infections such as nasopharyngitis and upper respiratory tract infection. Rates of infection were not higher in ustekinumab-treated patients when compared with placebo-treated patients over 12 weeks of therapy; nor were they increased in association with higher, relative to lower, ustekinumab doses. Also, rates of serious infections, cardiovascular events, injection site reactions and malignancies were low.[69,70] Taken together, the clinical observations of ustekinumab in psoriasis have supported its first-in-class status and confirmed the fundamental role of IL-12 or IL-23 in psoriasis pathogenesis.

Completed ustekinumab Phase 2 studies in Crohn disease and PSA indicate that blockade of IL-12/23p40 also results in clinical response in these diseases.[73] Ustekinumab treatment resulted in significant attenuation of arthritis signs and symptoms of PsA in addition to diminishment of psoriatic plaques.[74] The safety and efficacy of ustekinumab in PsA is currently being evaluated in a Phase 3 study.[75] Ustekinumab was also recently shown to induce and maintain clinical response in patients with moderate-to-severe Crohn disease who had previously failed one or more TNF-antagonist mAbs.[76] The efficacy and safety of ustekinumab in moderate-to-severe Crohn disease are currently being further evaluated in three Phase 3 studies.[77] These clinical observations suggest that psoriasis, PsA and Crohn disease share common pathological immune pathways, which include IL-12 and IL-23 (**Fig. 6**). In contrast, a Phase 2 study of ustekinumab in patients with relapsing-remitting MS did not yield significant or clinically meaningful differences in the cumulative number of gadolinium-enhancing T-1 weighted lesions (a marker of CNS inflammation), or a reduction in the severity and duration of relapses.[78] The discordance between animal model causality and human disease association of IL-12/23 and the ustekinumab clinical trial results in MS is not well understood.

New indications for ustekinumab are also being explored. One example is sarcoidosis, which is a chronic, heterogenic and multi-systemic granulomatous disease of unknown cause. Release of cytokines such as TNFα and IL-12 during the formation of sarcoid granulomas and upregulation of IL-12 in lung tissue are reported in patients with pulmonary involvement.[79] However, the role of IL-12 or IL-23 in the development of cutaneous sarcoid lesions is not yet clearly elucidated. Genes linked with the Th1 pathway, as well as expression of IL-23 and IL-23R, are associated with cutaneous sarcoidosis.[80] In fact, gene expression of IL-12/23p40 was comparable or higher, than levels observed in psoriatic skin lesions. The effect of ustekinumab on granuloma formation in sarcoidosis is currently being assessed in a Phase 2 proof of concept study.[81] Collectively, observations to date from clinical studies with ustekinumab suggest common immune pathways between psoriasis, PSA and Crohn disease, with the role of IL-12/23 in sarcoidosis under evaluation (**Fig. 6**).

Summary

Ustekinumab is a "first-in-class" anti-IL-12/23p40 mAb approved for the treatment of moderate-to-severe plaque psoriasis and is one of the first approved therapeutic mAbs generated directly through hu-Ig mice technology with no further molecular engineering. The mAb binds to the p40 subunit of both IL-12 and IL-23, preventing the interaction of both cytokines with the IL-12Rβ1 subunit that is common to both IL-12 and IL-23 cell surface receptors. Ustekinumab prevents IL-12- and IL-23-mediated downstream signaling, gene activation and cytokine production. Ustekinumab exhibits a long biologic half-life and low immune response rate, which translates into 12-week dosing intervals for treatment of moderate-to-severe psoriasis. The positive clinical results of ustekinumab observed in psoriasis and other immune-mediated disorders, such as Crohn disease and PSA, indicate that Th1 or Th17 lineages play a critical role in the underlying pathologic processes of these immune disorders. Similar to the TNF antagonists, ustekinumab further demonstrates that mAb-directed cytokine targeting can effectively attenuate cytokine-mediated pathologic processes, presumably through altering the local cytokine environment within diseased tissues. The relative roles of IL-12 and IL-23 in immune pathologies are not clearly defined and would require further clinical evaluation with agents specifically targeting the individual cytokines.

Acknowledgments

The authors would like to thank Kim Staquet for her contributions to ustekinumab hybridoma production and Tom Nesspor for his contributions to ustekinumab cell line development. In addition, we thank Michelle Perate, M.S. and Dr. Mary Whitman of Janssen Biotech, Inc., for assistance with the preparation of the manuscript, as well as Christine Delaurentis and Ray Heslip of Janssen Biotech, Inc., for assistance with graphical displays.

We are dedicating this manuscript to the memory of Michael Brigham-Burke as a tribute to his contribution to ustekinumab analysis. Michael was dedicated to bio-molecular interactions analysis, being one of the pioneers in the area of surface plasmon resonance and a specialist in analytical ultracentrifugation analysis. He made significant scientific contributions that advanced the development of pharmaceutical sciences and several biotherapeutics, including ustekinumab.

Notes

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Exhibit “J8”

This is Exhibit “J8” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.
Arash Rouhi

Notice of Compliance Information

From Health Canada

New search

Notice of Compliance date :

2008-12-12

Manufacturer :

JANSSEN ORTHO INC

Product type:

Biologic

NOC with conditions:

No

Submission type:

New Drug Submission (NDS)

Submission class:

New Active Substance (NAS)

Therapeutic class:

SELECTIVE IMMUNOMODULATING AGENT

Brand 1 of 1 :

STELARA

Product 1 of 2 :

Drug identification number: 02320681

Dosage form(s): Solution

Route(s) of administration: Subcutaneous

Medicinal ingredient(s):

Ingredient	Strength
USTEKINUMAB	90 MG/ML

Product 2 of 2 :

Drug identification number: 02320673

Dosage form(s): Solution

Route(s) of administration: Subcutaneous

Medicinal ingredient(s):

Ingredient	Strength
USTEKINUMAB	45 MG/0.5ML

New search

Application information

- Search tips
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Related information

- Notice of Compliance listings
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- Adverse Drug Reaction - veterinary drugs
- Drug Product Database

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Date modified: 2022-11-25

Exhibit “J9”

This is Exhibit “J9” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.
Arash Rouhi

PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

Pr STELARA®
ustekinumab injection

Solution for Subcutaneous Injection

45 mg/0.5 mL
90 mg/1.0 mL

Pr STELARA® I.V.
ustekinumab for injection

Solution for Intravenous Infusion

130 mg/26 mL (5 mg/mL)

Selective Immunomodulating Agent

Janssen Inc.
19 Green Belt Drive
Toronto, Ontario
M3C 1L9

www.janssen.com/canada

Date of Initial Authorization:
December 12, 2008

Date of Revision:
January 5, 2023

Submission Control Number: 267288

RECENT MAJOR LABEL CHANGES

7 WARNINGS AND PRECAUTIONS, Immune, *Infant exposure* in utero	12/2022
7 WARNINGS AND PRECAUTIONS, 7.1.2 Breast-feeding	12/2022

TABLE OF CONTENTS

Sections or subsections that are not applicable at the time of authorization are not listed.

PART I: HEALTH PROFESSIONAL INFORMATION

Ustekinumab administered subcutaneously will be referred to throughout the Product Monograph as Stelara.
Ustekinumab administered through intravenous infusion will be referred to throughout the Product Monograph as Stelara I.V.

1 INDICATIONS

STELARA®/STELARA® I.V. (ustekinumab) should be used only by physicians who have sufficient knowledge of plaque psoriasis, psoriatic arthritis, Crohn's disease, and/or ulcerative colitis and who have fully familiarized themselves with the efficacy/safety profile of the drug.

Plaque Psoriasis

Stelara (ustekinumab) is indicated for:

- the treatment of chronic moderate to severe plaque psoriasis in adult patients who are candidates for phototherapy or systemic therapy
- the treatment of chronic moderate to severe plaque psoriasis in pediatric patients (6-17 years of age) who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies (see 1.1 Pediatrics).

Psoriatic Arthritis

Stelara (ustekinumab) is indicated for the treatment of adult patients with active psoriatic arthritis. Stelara can be used alone or in combination with methotrexate (MTX).

Crohn's Disease

Stelara/Stelara I.V. (ustekinumab) is indicated for the treatment of adult patients with moderately to severely active Crohn's disease, who have had an inadequate response, loss of response to, or were intolerant to either immunomodulators or one or more tumour necrosis factor-alpha (TNFα) antagonists, or have had an inadequate response, intolerance or demonstrated dependence on corticosteroids.

Ulcerative Colitis

Stelara/Stelara I.V. (ustekinumab) is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies.

1.1 Pediatrics

Pediatrics (6-17 years of age): Stelara (ustekinumab) is indicated for the treatment of chronic moderate to severe plaque psoriasis in pediatric patients (children and adolescents) from 6 to 17 years of age, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.

The safety and efficacy of Stelara has not been established in pediatric patients with plaque psoriasis <6 years of age. Pediatric studies of Stelara I.V. have not been conducted. The safety and efficacy of Stelara in pediatric patients with psoriatic arthritis, Crohn's disease, and ulcerative colitis have not been established (see 7.1.3 Pediatrics and 14.1 Clinical Trials by Indication, **Pediatric Plaque Psoriasis (6 to 17 years of age)**).

1.2 Geriatrics

Geriatrics (>65 years of age): No major age-related differences in clearance or volume of distribution were observed in clinical studies. Although no overall differences in safety and efficacy were observed between older and younger patients in clinical studies in approved indications, the number of patients aged 65 and over is not sufficient to determine whether they respond differently from younger patients (see 7.1.4 Geriatrics).

2 CONTRAINDICATIONS

- Stelara/Stelara I.V. is contraindicated in patients who are hypersensitive to ustekinumab or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container (see 7 WARNINGS AND PRECAUTIONS, **Sensitivity/Resistance, Hypersensitivity Reactions** and 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING).
- Stelara/Stelara I.V. is contraindicated in patients with severe infections such as sepsis, tuberculosis and opportunistic infections (see 7 WARNINGS AND PRECAUTIONS, **General, Infections**).

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

Stelara/Stelara I.V. (ustekinumab) is intended for use under the guidance and supervision of a physician.

The BioAdvance® Network has been established to facilitate the administration of Stelara/Stelara I.V. BioAdvance® clinics are staffed by qualified healthcare professionals specially trained in the administration of Stelara/Stelara I.V. and care of patients with Crohn's disease and ulcerative colitis. BioAdvance® clinics are available across Canada. Information about the BioAdvance® Network and location of the nearest BioAdvance® Network clinic can be obtained by calling Janssen Inc. Medical Information at: 1-800-567-3331.

4.2 Recommended Dose and Dosage Adjustment

Plaque Psoriasis

For the treatment of plaque psoriasis, Stelara is administered by subcutaneous injection.

Adults

The recommended dose of Stelara is 45 mg administered at Weeks 0 and 4, then every 12 weeks thereafter. Alternatively, 90 mg may be used in patients with a body weight greater than 100 kg. In patients weighing >100 kg, both 45 mg and 90 mg were shown to be efficacious. However, 90 mg was efficacious in a higher percentage of these patients than the 45 mg dose.

For patients who inadequately respond to dosing every 12 weeks, consideration may be given to treating as often as every 8 weeks.

Consideration should be given to discontinuing treatment in patients who have shown no response up to 12 weeks of treatment.

Re-treatment with a dosing regimen of Weeks 0 and 4 followed by 12-week dosing after interruption of therapy has been shown to be safe and effective (see 14.1 Clinical Trials by Indication, **Plaque Psoriasis – Adults, Efficacy of retreatment**).

Pediatrics (6 to 17 years of age)

The recommended dose of Stelara based on body weight is shown below (Table 1). Stelara should be administered at Weeks 0 and 4, then every 12 weeks thereafter.

Consideration should be given to discontinuing treatment in patients who have shown no response up to 12 weeks of treatment.

Table 1: Recommended dose of Stelara for pediatric psoriasis

Weight	Recommended Dose	Dosage Form
< 60 kg [a]	0.75 mg/kg*	vial
≥ 60 to ≤ 100 kg	45 mg	prefilled syringe, vial
> 100 kg [b]	90 mg	prefilled syringe

* To calculate the volume of injection (mL) for patients < 60 kg, use the following formula: *body weight* (kg) x *0.0083* (mL/kg). The calculated volume should be rounded to the nearest 0.01 mL and administered using a 1 mL graduated syringe. A 45 mg vial is available for pediatric patients who need to receive less than the full 45 mg dose.
[a] For patients with body weight < 60 kg, use the vial presentation only
[b] There were only 3 patients aged 12 to 17 years, with a body weight > 100 kg in the study

Table 2: Injection volumes of Stelara for pediatric psoriasis patients < 60 kg

Body weight at time of dosing (kg)	Dose (mg)	Volume of injection (mL)
15	11.3	0.12
16	12.0	0.13
17	12.8	0.14
18	13.5	0.15
19	14.3	0.16
20	15.0	0.17
21	15.8	0.17
22	16.5	0.18
23	17.3	0.19
24	18.0	0.20
25	18.8	0.21
26	19.5	0.22
27	20.3	0.22
28	21.0	0.23
29	21.8	0.24
30	22.5	0.25
31	23.3	0.26
32	24.0	0.27
33	24.8	0.27
34	25.5	0.28
35	26.3	0.29
36	27.0	0.30
37	27.8	0.31
38	28.5	0.32
39	29.3	0.32
40	30.0	0.33
41	30.8	0.34
42	31.5	0.35
43	32.3	0.36
44	33.0	0.37
45	33.8	0.37
46	34.5	0.38
47	35.3	0.39
48	36.0	0.40
49	36.8	0.41
50	37.5	0.42
51	38.3	0.42
52	39.0	0.43
53	39.8	0.44
54	40.5	0.45
55	41.3	0.46
56	42.0	0.46
57	42.8	0.47
58	43.5	0.48
59	44.3	0.49

Psoriatic Arthritis – Adults

For the treatment of psoriatic arthritis, Stelara is administered by subcutaneous injection. The recommended dose of Stelara is 45 mg administered at Weeks 0 and 4, then every 12 weeks thereafter. Alternatively, 90 mg may be used in patients with a body weight greater than 100 kg.

Crohn's Disease and Ulcerative Colitis – Adults

Intravenous induction dosing

In patients with Crohn's disease and ulcerative colitis, the recommended induction treatment regimen is a single intravenous (IV) tiered dose of Stelara I.V. based on body weight (Table 3) (see 4.4 Administration, **Intravenous Infusion (Crohn's Disease and Ulcerative Colitis)**).

Table 3: Initial dosing of Stelara I.V.

Body Weight of Patient at the time of dosing	Dose[a]	Number of 130 mg Stelara I.V. vials
≤ 55 kg	260 mg	2
> 55 kg to ≤ 85 kg	390 mg	3
> 85 kg	520 mg	4

[a] Recommended dose (approximately 6 mg/kg)

Subcutaneous maintenance dosing

The recommended maintenance dose of Stelara is 90 mg administered subcutaneously. The first subcutaneous dose should be given at week 8 following the intravenous induction dose. Subsequent doses should be given every 8 weeks thereafter.

In some patients, (e.g., those with low inflammatory burden) a single dose of Stelara I.V. followed by 90 mg subcutaneous dosing 8 weeks later, then every 12 weeks thereafter may be considered at the discretion of the treating physician. Patients should have their dose frequency adjusted to every 8 weeks if inadequate response occurs. Consideration should be given to discontinuing treatment in patients who show no evidence of therapeutic benefit 16 weeks after the IV induction dose (see 14 CLINICAL TRIALS).

Immunomodulators and/or corticosteroids may be continued during treatment with Stelara/Stelara I.V. In patients who have responded to treatment with Stelara/Stelara I.V. corticosteroids may be reduced or discontinued in accordance with standard of care.

If therapy is interrupted, resumption of treatment with subcutaneous dosing every 8 weeks is safe and effective.

Special Populations

Renal Insufficiency
Specific studies have not been conducted in patients with hepatic renal insufficiency.

Hepatic Insufficiency
Specific studies have not been conducted in patients with hepatic insufficiency.

4.4 Administration

Subcutaneous Administration

Stelara is supplied as 45 mg and 90 mg pre-filled syringes and 45 mg single-use vials. In pediatric patients, it is recommended that Stelara be administered by a health care provider. A patient may self-inject with Stelara if a physician determines that it is appropriate after proper training in subcutaneous injection technique and disposal (see PATIENT MEDICATION INFORMATION**, How to take Stelara**).

Prior to subcutaneous administration, visually inspect the solution for particulate matter and discoloration. The product is colourless to light yellow and may contain a few small translucent or white particles of protein. This appearance is not unusual for proteinaceous solutions. The product should not be used if solution is discolored or cloudy, or if other particulate matter is present. Stelara does not contain preservatives; therefore, any unused product remaining in the vial or syringe should not be used.

The needle cover on the pre-filled syringe contains dry natural rubber (a derivative of latex), which may cause allergic reactions in individuals sensitive to latex.

Patients should be instructed to inject the prescribed amount of Stelara according to the directions provided in the PATIENT MEDICATION INFORMATION Section.

Intravenous Infusion (Crohn's Disease and Ulcerative Colitis)

Stelara I.V. is supplied in a 130 mg vial. The solution is clear, colorless to light yellow with a pH of approximately 6.0. Intravenous infusion of Stelara I.V. should be administered by qualified health care professionals.

Instructions for dilution of Stelara I.V. (130 mg vial) Crohn's disease and ulcerative colitis
Stelara I.V. must be diluted and prepared for IV infusion by a healthcare professional using aseptic technique.

1. Calculate the dose and the number of Stelara I.V. vials needed based on patient's body weight (see Table 3). Each 26 ml vial of Stelara I.V. contains 130 mg of ustekinumab.
2. Withdraw, and then discard a volume of the 0.9% w/v sodium chloride solution from the 250 ml infusion bag equal to the volume of Stelara I.V. to be added. (26 mL for each vial of Stelara I.V. needed, for 2 vials - discard 52 mL, for 3 vials - discard 78 mL, for 4 vials - discard 104 mL). Alternatively, a 250 mL infusion bag containing 0.45% w/v sodium chloride solution may be used.
3. Withdraw 26 mL of Stelara I.V. from each vial needed and add it to the 250 ml infusion bag. The final volume in the infusion bag should be 250 ml. Gently mix.

4. Visually inspect the diluted solution before administration. Do not use if visibly opaque particles, discoloration or foreign particles are observed.
5. Infuse the diluted solution over a period of at least one hour. Once diluted, the infusion should be completed within eight hours of the dilution in the infusion bag.
6. Use only an infusion set with an in-line, sterile, non-pyrogenic, low protein-binding filter (pore size 0.2 micrometer).
7. Do not infuse Stelara I.V. concomitantly in the same intravenous line with other agents.
8. Stelara I.V. does not contain preservatives. Each vial is for single use only and any unused medicinal product should be disposed of in accordance with local requirements.

If necessary, the diluted infusion solution may be stored at room temperature. The infusion should be completed within 8 hours of the dilution in the infusion bag. Do not freeze. Discard any unused portion of the infusion solution.

4.5 Missed Dose

Patients who miss their scheduled dose of Stelara/Stelara I.V., should be advised to contact their healthcare provider for guidance.

5 OVERDOSAGE

Single doses up to 6 mg/kg intravenously have been administered in clinical studies without dose limiting toxicity. In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions or effects and appropriate symptomatic treatment be instituted immediately.

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

To help ensure the traceability of biologic products, including biosimilars, health professionals should recognise the importance of recording both the brand name and the non-proprietary (active ingredient) name as well as other product-specific identifiers such as the Drug Identification Number (DIN) and the batch/lot number of the product supplied.

Route of Administration	Dosage Form / Strength / Composition	Non-medicinal Ingredients
Subcutaneous Injection	Sterile solution in single-use pre-filled syringe: 45 mg / 0.5 mL, 90 mg / 1.0 mL or 45 mg / 0.5 mL vial	L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose, and water for injection.
Intravenous Infusion	Sterile solution in single-use vial 130 mg / 26 mL (5 mg/mL)	EDTA disodium salt dihydrate, L-histidine and L-histidine hydrochloride monohydrate, L-methionine, polysorbate 80, and sucrose.

Stelara/Stelara I.V. (ustekinumab) is approved in the following presentations:

Stelara

Pre-filled Syringe:
- 45 mg / 0.5 mL
- 90 mg / 1.0 mL

Single-use Vial:
- 45 mg / 0.5 mL

Stelara I.V.

Single-use Vial:
- 130 mg / 26 mL

Stelara: 45 mg Pre-filled Syringe/Vial or 90 mg Pre-filled Syringe

Stelara is supplied as a single-use, sterile solution for subcutaneous injection in a Type 1 glass syringe with a fixed 27G, half-inch needle and needle cover. The needle cover is manufactured using a dry natural rubber (a derivative of latex) (see 7 WARNINGS AND PRECAUTIONS, **Sensitivity/Resistance, Hypersensitivity Reactions**). The syringe is fitted with a passive safety guard. Stelara is also supplied as a sterile solution for subcutaneous injection in a single-use (Type 1) glass vial with a coated stopper. Only the needle cover on the pre-filled syringe contains latex. All other components of the vial and pre-filled syringe are latex free.

The solution is clear to slightly opalescent, colorless to light yellow with a pH of approximately 6.0. Each mL of Stelara contains 90 mg of ustekinumab. Stelara does not contain preservatives.

There are two strengths of Stelara available: 45 mg of ustekinumab in 0.5 mL and 90 mg of ustekinumab in 1.0 mL.

Stelara is available in single unit packaging presentations.

Stelara I.V.: 130 mg Vial

Stelara I.V., 130 mg vial, is supplied as a sterile solution for intravenous infusion in a single-use (Type 1) glass vial. The vial is stoppered with a latex-free coated stopper. The solution is clear, colorless to light yellow with a pH of approximately 6.0. Each mL of Stelara I.V. contains 5.0 mg of ustekinumab. Stelara I.V. does not contain preservatives. Stelara I.V. is available in one strength, 130 mg in 26 mL, and packaged as 1 single use vial.

7 WARNINGS AND PRECAUTIONS

General

Infections

Ustekinumab is a selective immunomodulator and may have the potential to increase the risk of infections and reactivate latent infections.

Stelara/Stelara I.V. should not be given to patients with any clinically important active infection. If a patient develops a serious infection they should be closely monitored and Stelara/Stelara I.V. should not be administered until the infection resolves or is adequately treated. Caution should be exercised when considering the use of Stelara/Stelara I.V. in patients with a chronic infection or a history of recurrent infection. Patients should be instructed to seek medical advice if signs or symptoms suggestive of an infection occur.

Prior to initiating treatment with Stelara/Stelara I.V., patients should be evaluated for tuberculosis infection. Stelara/Stelara I.V. should not be given to patients with active tuberculosis. Treatment of latent tuberculosis infection should be initiated prior to administering Stelara/Stelara I.V. Anti-tuberculosis therapy should also be considered prior to initiation of Stelara/Stelara I.V. in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed. In clinical studies, patients with latent tuberculosis who were concurrently treated with isoniazid did not develop tuberculosis. Patients receiving Stelara/Stelara I.V. should be monitored closely for signs and symptoms of active tuberculosis during and after treatment.

In clinical studies, serious bacterial, fungal, and viral infections were observed in subjects receiving Stelara/Stelara I.V. Serious infections requiring hospitalization occurred in the psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis development programs. In the psoriasis and psoriatic arthritis programs serious infections included diverticulitis, cellulitis, pneumonia, appendicitis, cholecystitis and sepsis. In the Crohn's disease program, serious infections included anal abscess, gastroenteritis, pneumonia and sepsis. Other clinically important infections included listeria meningitis and ophthalmic herpes which were reported in one patient each. In the ulcerative colitis program, serious infections included gastroenteritis and pneumonia (see 8 ADVERSE REACTIONS).

Carcinogenesis and Mutagenesis

Malignancies
Ustekinumab is a selective immunomodulator. Immunomodulating agents have the potential to increase the risk of malignancy. Some patients who received ustekinumab in clinical studies developed malignancies (see 8.2 Clinical Trial Adverse Reactions, **Malignancies**).

Stelara/Stelara I.V. has not been studied in patients with a history of malignancy. Caution should be exercised when considering the use of Stelara/Stelara I.V. in patients with a history of malignancy or when considering continuing treatment in patients who develop a malignancy.

All patients, in particular those greater than 60 years of age, those with a medical history of prolonged immunosuppressant therapy or those with a history of PUVA treatment, should be monitored for the appearance of skin cancer (see 8 ADVERSE REACTIONS).

Hepatic/Biliary/Pancreatic

Specific studies have not been conducted in patients with hepatic insufficiency.

Immune

Immunization
It is recommended that live viral or bacterial vaccines not be given concurrently with Stelara/Stelara I.V. (ustekinumab). No data are available on the secondary transmission of infection by live vaccines in patients receiving Stelara/Stelara I.V. Caution is advised when administering some live vaccines to household contacts of patients receiving Stelara/Stelara I.V. because of the potential risk for shedding from the household contact and transmission to the patient. Patients receiving Stelara/Stelara I.V. may receive concurrent inactivated or non-live vaccinations (see 9.4 Drug-Drug Interactions, **Live Vaccines**).

Prior to initiating therapy with Stelara/Stelara I.V., patients should receive all immunizations appropriate for age as recommended by current immunization guidelines. Long term treatment with Stelara does not appear to suppress the immune response to pneumococcal polysaccharide or tetanus vaccines polysaccharide or tetanus vaccines. During the long-term extension of a Phase 3 psoriasis study (PHOENIX 2), patients treated with Stelara for at least 3.5 years mounted similar antibody responses to both pneumococcal polysaccharide and tetanus vaccines as a non-systemically treated psoriasis control group. Similar proportions of patients developed protective levels of anti-pneumococcal and anti-tetanus antibodies and antibody titers were similar among Stelara-treated and control patients. However, non-live vaccinations received during a course of Stelara/Stelara I.V. may not elicit an immune response sufficient to prevent disease.

***Infant exposure* in utero**
For infants exposed *in utero* to ustekinumab, a six month waiting period following birth is recommended before the administration of live vaccines. Administration of a live vaccine prior to 6 months of age may be considered if ustekinumab serum levels are undetectable in the infant,

or the benefit of the vaccination clearly outweighs the risk of administration of live vaccines to the infant (see 7 WARNINGS AND PRECAUTIONS, **Immune, Immunization**).

Concomitant immunosuppressive therapy
In the Phase 3 psoriasis studies, the safety and efficacy of Stelara (ustekinumab) in combination with immunosuppressive agents or phototherapy have not been evaluated. In the Phase 3 psoriatic arthritis studies, concomitant methotrexate did not appear to influence the safety of Stelara. In Crohn's disease and ulcerative colitis studies, concomitant use of immunomodulators (6-mercaptopurine (6-MP), azathioprine (AZA), MTX) or corticosteroids did not appear to influence the overall safety of Stelara/Stelara I.V. Caution should be exercised when considering concomitant use of immunosuppressive agents and Stelara/Stelara I.V. or when transitioning from other biologic agents (see 9 DRUG INTERACTIONS, **Immunosuppressants**).

Immunotherapy
Stelara/Stelara I.V. (ustekinumab) has not been evaluated in patients who have undergone allergy immunotherapy. Stelara/Stelara I.V. may affect allergy immunotherapy. Caution should be exercised in patients receiving or who have received allergy immunotherapy particularly for anaphylaxis.

Neurologic

Reversible Posterior Leukoencephalopathy Syndrome
One case of reversible posterior leukoencephalopathy syndrome (RPLS) was observed during the clinical development programs which included 6709 ustekinumab-treated subjects. The subject, who had received 12 doses of Stelara over approximately two and a half years, presented with headache, seizures and confusion in the setting of alcohol abuse. No additional Stelara injections were administered and the subject fully recovered with appropriate treatment.

RPLS is a neurological disorder, which is not caused by demyelination or a known infectious agent. RPLS can present with headache, seizures, confusion and visual disturbances. Conditions with which it has been associated include preeclampsia, acute hypertension, cytotoxic agents, immunosuppressive therapy and alcohol abuse. Fatal outcomes have been reported.

If RPLS is suspected, administer appropriate treatment and discontinue Stelara/Stelara I.V.

Renal

Specific studies have not been conducted in patients with renal insufficiency.

Reproductive Health: Female and Male Potential

Women of Childbearing Potential: Women of childbearing potential initiating treatment with Stelara/Stelara I.V. should use effective methods of contraception and should receive preconception counselling before planning a pregnancy in accordance with disease specific clinical guidelines. Stelara/Stelara I.V. remains in the circulation for approximately 15 weeks

after treatment. In clinical trials, women of childbearing potential were required to use effective methods of contraception during treatment and for at least 15 weeks after treatment (see 7.1.1 Pregnant Women).

Sensitivity/Resistance

Hypersensitivity Reactions

Systemic
In post-marketing experience, serious allergic reactions, including anaphylaxis and angioedema, have been reported. If an anaphylactic or other serious allergic reaction occurs, institute appropriate therapy and discontinue administration of Stelara/Stelara I.V. (see 8 ADVERSE REACTIONS).

Respiratory
Cases of allergic alveolitis and eosinophilic pneumonia have been reported during post-approval use of ustekinumab. Clinical presentations included cough, dyspnoea, and interstitial infiltrates following one to three doses. Serious outcomes have included respiratory failure and prolonged hospitalisation. Improvement has been reported after discontinuation of ustekinumab and also, in some cases, administration of corticosteroids. If infection has been excluded and diagnosis is confirmed, discontinue ustekinumab and institute appropriate treatment.

Latex sensitivity
The needle cover on the pre-filled syringe contains dry natural rubber (a derivative of latex), which may cause allergic reactions in individuals sensitive to latex.

7.1 Special Populations

7.1.1 Pregnant Women

There is no evidence from animal studies of teratogenicity, birth defects or developmental delays at dose levels up to approximately 45-fold higher than the highest equivalent dose intended to be administered to patients with psoriasis and psoriatic arthritis (see 16 NON-CLINICAL TOXICOLOGY, **Reproductive and Developmental Toxicology**). However, animal reproductive and developmental studies are not always predictive of human response.

It is not known whether ustekinumab can cause fetal harm when administered to a pregnant woman or whether it can affect reproductive capacity. While it is known that human IgG antibodies, like ustekinumab, cross the placenta, no adequate and well-controlled studies have been conducted to evaluate if ustekinumab can cross the human placenta in pregnant women. In developmental toxicity studies in monkeys, ustekinumab was detected in fetal serum following repeated dosing of pregnant monkeys during the period of organogenesis. Although ustekinumab crossed the monkey placenta there was no evidence of teratogenicity in these studies. The decision to continue Stelara during pregnancy should be carefully evaluated taking into consideration clinical practice guidelines to ensure the safety of the pregnant woman and the fetus. Stelara/Stelara I.V. should be given to a pregnant woman only if the benefit clearly outweighs the risk.

7.1.2 Breast-feeding

Limited data from published literature suggests that ustekinumab is excreted in human breast milk in small amounts and it is not known if ustekinumab is absorbed systemically after ingestion. Because of the potential for adverse reactions in nursing infants from ustekinumab, a decision should be made whether to discontinue nursing or to discontinue the drug.

7.1.3 Pediatrics

Pediatrics (< 18 years of age): The efficacy of Stelara (ustekinumab) has been studied in 110 plaque psoriasis patients 12-17 years of age where the majority of patients (77/110) were 15-17 years of age. The efficacy of Stelara was studied in 44 plaque psoriasis patients 6-11 years of age where half of the patients (22/44) were 6-9 years of age. Studies of Stelara in pediatric plaque psoriasis patients below 6 years of age have not been conducted (see 14.1 Clinical Trials by Indication, **Pediatric Plaque Psoriasis (6 to 17 years of age)**).
Pediatric studies of Stelara I.V. have not been conducted. No studies have been conducted in pediatric patients with psoriatic arthritis, Crohn's disease or ulcerative colitis.

7.1.4 Geriatrics

Geriatrics (> 65 years of age): Of the 6709 patients exposed to Stelara/Stelara I.V. in clinical trials, a total of 353 were 65 years or older (183 patients with psoriasis, 69 patients with psoriatic arthritis, 58 patients with Crohn's disease and 43 patients with ulcerative colitis). No major age-related differences in clearance or volume of distribution were observed in clinical studies. Although no overall differences in safety and efficacy were observed between older and younger patients in clinical studies in approved indications, the number of patients aged 65 and over is not sufficient to determine whether they respond differently from younger patients. Patients over 60 years of age should be closely monitored for skin cancer (see 7 WARNINGS AND PRECAUTIONS, **Carcinogenesis and Mutagenesis**).

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

The most common adverse reactions (> 5%) in controlled periods of the clinical studies with Stelara/Stelara I.V. (ustekinumab) among all indications were nasopharyngitis, and headache. Most were considered to be mild and did not necessitate drug discontinuation. The overall safety profile of Stelara/Stelara I.V. was similar for patients among all indications. Serious infections and malignancies were also reported in clinical studies (see 8.2 Clinical Trial Adverse Reactions; **Infections** and **Malignancies**).

8.2 Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. The adverse reaction rates observed in the clinical trials; therefore, may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse reaction information from

clinical trials may be useful in identifying and approximating rates of adverse drug reactions in real-world use.

Adults

The safety data described below reflect exposure to Stelara/Stelara I.V. in 14 Phase 2 and Phase 3 studies in 6709 patients (4135 with psoriasis and/or psoriatic arthritis, 1749 with Crohn's disease, and 825 with ulcerative colitis), including 4577 exposed for at least 6 months, 3253 exposed for at least 1 year, 1482 exposed for at least 4 years and 838 for at least 5 years.

Psoriasis and Psoriatic Arthritis

The safety data described below reflect exposure to Stelara in 7 phase 2 and phase 3 studies in 4135 adult patients with psoriasis and/or psoriatic arthritis, including 3256 exposed for at least 6 months, 1482 exposed for at least 4 years and 838 for at least 5 years.

Table 4 summarizes the adverse reactions that occurred at a rate of at least 1% in the Stelara group during the placebo-controlled period of the Phase 3 studies (PHOENIX 1, PHOENIX 2, PSUMMIT 1 and PSUMMIT 2).

Table 4: Adverse reactions reported by > 1% of patients during the placebo controlled period of PHOENIX 1 and 2 and PSUMMIT 1 and 2*

	Placebo	Stelara (ustekinumab)	
		45 mg	90 mg
Patients treated	974	972	974
Infections and infestations			
Nasopharyngitis	64 (6.6%)	72 (7.4%)	70 (7.2%)
Upper respiratory tract infection	44 (4.5%)	46 (4.7%)	40 (4.1%)
Dental Infection	2 (0.2%)	9 (0.9%)	10 (1.0%)
Nervous system disorders			
Headache	29 (3.0%)	48 (4.9%)	41 (4.2%)
Dizziness	9 (0.9%)	11 (1.1%)	13 (1.3%)
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain	9 (0.9%)	16 (1.6%)	15 (1.5%)
Gastrointestinal disorders			
Diarrhea	15 (1.5%)	22 (2.3%)	18 (1.8%)
Nausea	10 (1.0%)	18 (1.9%)	15 (1.5%)
Skin and subcutaneous tissue disorders			
Pruritus	9 (0.9%)	14 (1.4%)	12 (1.2%)
Musculoskeletal and connective tissue disorders			
Arthralgia	23 (2.4%)	30 (3.1%)	26 (2.7%)
Back pain	9 (0.9%)	12 (1.2%)	19 (2.0%)
Myalgia	5 (0.5%)	8 (0.8%)	11 (1.1%)

	Placebo	Stelara (ustekinumab)	
		45 mg	90 mg
General disorders and administration site conditions			
Fatigue	16 (1.6%)	24 (2.5%)	24 (2.5%)
Injection site erythema	6 (0.6%)	8 (0.8%)	16 (1.6%)

*Placebo controlled periods are through Week 12 in PHOENIX 1 AND 2 and through Week 16 in PSUMMIT 1 and 2.

Table 5 present the rates at which the Stelara ADRs occurred in treatment groups in the ACCEPT trial.

Table 5: Adverse drug reactions reported by ≥ 1% of patients through Week 12 in ACCEPT

	ENBREL® (etanercept)	Stelara (ustekinumab)	
		45 mg	90 mg
Patients treated	347	209	347
Infections and infestations			
Nasopharyngitis	29 (8.4%)	21 (10.0%)	34 (9.8%)
Upper respiratory tract infection	20 (5.8%)	13 (6.2%)	22 (6.3%)
Nervous system disorders			
Headache	38 (11.0%)	31 (14.8%)	41 (11.8%)
Dizziness	8 (2.3%)	3 (1.4%)	6 (1.7%)
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain	14 (4.0%)	5 (2.4%)	14 (4.0%)
Gastrointestinal disorders			
Diarrhea	9 (2.6%)	8 (3.8%)	9 (2.6%)
Nausea	8 (2.3%)	8 (3.8%)	10 (2.9%)
Skin and subcutaneous tissue disorders			
Pruritus	14 (4.0%)	12 (5.7%)	16 (4.6%)
Musculoskeletal and connective tissue disorders			
Arthralgia	9 (2.6%)	11 (5.3%)	10 (2.9%)
Back pain	7 (2.0%)	14 (6.7%)	15 (4.3%)
Myalgia	7 (2.0%)	3 (1.4%)	7 (2.0%)
General disorders and administration site conditions			
Fatigue	13 (3.7%)	8 (3.8%)	19 (5.5%)
Injection site erythema	51 (14.7%)	2 (1.0%)	2 (0.6%)

Crohn's Disease

In the three Phase 3 studies and two Phase 2 studies, 1749 subjects with Crohn's disease were exposed to Stelara/Stelara I.V. with 849 exposed for 6 months and 464 exposed for at least 1 year with a total 1106 subject-years of follow-up.

The safety of Stelara/Stelara I.V. was assessed in three Phase 3 randomized, double-blind, placebo-controlled studies. Two 8-week IV induction studies (UNITI-1 and UNITI-2) were followed by a 44-week subcutaneous randomized withdrawal maintenance study (IM-UNITI) representing 52 weeks of therapy. The overall safety profile of Stelara/Stelara I.V. was consistent with the safety profile seen in the psoriasis and psoriatic arthritis clinical studies with the exception of new adverse drug reactions of acne, asthenia, vomiting and vulvovaginal mycotic infections.

The safety profile remained generally consistent throughout the Week 272 safety analysis.

Table 6: Adverse drug reactions reported by ≥ 1%[#] of Stelara I.V. (ustekinumab) treated patients UNITI-1 and UNITI-2 Induction Studies through Week 8

Patients Treated	Placebo (n=466)	Stelara I.V. ~6mg/kg[¥] (n=470)
Treatment Emergent Adverse Events (SOC/preferred term)		
Gastrointestinal disorders		
Nausea	22 (4.7%)	25 (5.3%)
Vomiting	12 (2.6%)	20 (4.3%)
Infections and infestations		
Nasopharyngitis	23 (4.9%)	25 (5.3%)
Musculoskeletal and connective tissue disorders		
Arthralgia	22 (4.7%)	24 (5.1%)
Back Pain	9 (1.9%)	10 (2.1%)
General disorders and administration site conditions		
Asthenia	2 (0.4%)	7 (1.5%)
Skin and subcutaneous tissue disorders		
Pruritus	2 (0.4%)	7 (1.5%)
Acne	2 (0.4%)	5 (1.1%)

[#] ≥ 1% and more frequently with ustekinumab than placebo
[¥] tiered weight-based dose approximating 6 mg/kg (see 4 DOSAGE AND ADMINISTRATION, Table 3)

Table 7: Adverse drug reactions reported by ≥ 1%¥ of patients in any Stelara (ustekinumab)-treated groups IM-UNITI study through Week 0 to Week 44 of maintenance

Patients Treated	Placebo (n=133)	Stelara 90 mg	
		Q12w (n=132)	Q8w (n=131)
Treatment Emergent Adverse Events (SOC/preferred term)			
Infections and Infestations			
Nasopharyngitis	10 (7.5%)	17 (12.9%)	14 (10.7%)
Vulvovaginal mycotic infection (including candidiasis)	1 (0.8%)	1 (0.8%)	6 (4.6%)
Gastrointestinal system disorders			
Diarrhea	7 (5.3%)	11 (8.3%)	5 (3.8%)
Nausea	9 (6.8%)	10 (7.6%)	4 (3.1%)
Musculoskeletal and connective tissue disorder			
Arthralgia	19 (14.3%)	22 (16.7%)	18 (13.7%)
Back pain	6 (4.5%)	5 (3.8%)	6 (4.6%)
Myalgia	1 (0.8%)	5 (3.8%)	1 (0.8%)
General disorders and administration site conditions			
Fatigue	6 (4.5%)	8 (6.1%)	6 (4.6%)
Injection site erythema	0	1 (0.8%)	7 (5.3%)
Injection site pain	1 (0.8%)	2 (1.5%)	0
Skin and subcutaneous tissue disorder			
Pruritus	3 (2.3%)	2 (1.5%)	5 (3.8%)
Acne	1 (0.8%)	1 (0.8%)	2 (1.5%)
Nervous system disorder			
Headache	15 (11.3%)	15 (11.4%)	16 (12.2%)
Psychiatric disorders			
Depression	2 (1.5%)	3 (2.3%)	2 (1.5%)

¥ ≥ 1% and more frequently with either Stelara 90 mg q12w or Stelara 90 mg q8w than placebo

Ulcerative Colitis

The safety of Stelara/Stelara I.V. was evaluated in two randomized, double-blind, placebo-controlled studies (UNIFI-I and UNIFI-M) in 960 adult patients with moderately to severely active ulcerative colitis. The overall safety profile was similar for patients with psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis.

The safety profile remained generally consistent throughout the Week 96 safety analysis.

Table 8: Adverse drug reactions reported by ≥ 1%[#] of Stelara I.V. (ustekinumab) treated patients in the ulcerative colitis induction study (UNIFI-I) through Week 8

Patients Treated	Placebo (n=319)	Stelara I.V. ~6mg/kg[¥] (n=320)
Treatment Emergent Adverse Events (SOC/preferred term)		
Gastrointestinal disorders		
Vomiting	1 (0.3%)	4 (1.3%)
Infections and infestations		
Nasopharyngitis	9 (2.8%)	18 (5.6%)
Musculoskeletal and connective tissue disorders		
Arthralgia	3 (0.9%)	6 (1.9%)
General disorders and administration site conditions		
Fatigue	5 (1.6%)	8 (2.5%)
Nervous system		
Dizziness	1 (0.3%)	4 (1.3%)
Respiratory, thoracic and mediastinal disorders		
Oropharyngeal pain	1 (0.3%)	8 (2.5%)

[#] ≥ 1% and more frequently with ustekinumab than placebo

[¥] tiered weight-based dose approximating 6 mg/kg (see 4 DOSAGE AND ADMINISTRATION, Table 3)

Table 9: Adverse drug reactions reported by ≥ 1%[¥] of patients in any Stelara (ustekinumab)-treated patients in the ulcerative colitis maintenance study (UNIFI-M) through Week 0 to Week 44 of maintenance

Patients Treated	Placebo (n=175)	Stelara 90 mg	
		Q12w (n=172)	Q8w (n=176)
Treatment Emergent Adverse Events (SOC/preferred term)			
Infections and Infestations			
Nasopharyngitis	28 (16.0%)	31 (18.0%)	26 (14.8%)
Upper respiratory tract infection	8 (4.6%)	5 (2.9%)	16 (9.1%)
Sinusitis	2 (1.1%)	2 (1.2%)	7 (4.0%)
Gastrointestinal system disorders			
Diarrhea	2 (1.1%)	5 (2.9%)	7 (4.0%)
Nausea	4 (2.3%)	4 (2.3%)	6 (3.4%)
Musculoskeletal and connective tissue disorder			
Arthralgia	15 (8.6%)	15 (8.7%)	8 (4.5%)
General disorders and administration site conditions			
Fatigue	4 (2.3%)	4 (2.3%)	7 (4.0%)
Injection site erythema	1 (0.6%)	1 (0.6%)	3 (1.7%)
Skin and subcutaneous tissue disorder			
Acne	0 (0%)	2 (1.2%)	3 (1.7%)
Nervous system disorder			
Dizziness	0 (0%)	0 (0%)	3 (1.7%)
Headache	7 (4.0%)	11 (6.4%)	18 (10.2%)
Respiratory, thoracic and mediastinal disorders			
Nasal congestion	0 (0%)	0 (0%)	3 (1.7%)
Oropharyngeal pain	5 (2.9%)	4 (2.3%)	7 (4.0%)
Psychiatric disorders			
Depression	1 (0.6%)	2 (1.2%)	1 (0.6%)

[¥] ≥ 1% and more frequently with either Stelara 90 mg q12w or Stelara 90 mg q8w than placebo

Infections:

In placebo-controlled studies of patients with psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis, the rates of infection or serious infection were similar between Stelara/Stelara I.V.-treated patients and those treated with placebo. In the placebo-controlled period of these clinical studies, the rate of infection was 1.36 per patient-year of follow-up in Stelara/Stelara I.V.-treated patients, and 1.34 per patient-year of follow-up in placebo-treated patients. Serious infections occurred at a rate of 0.03 per patient-year of follow-up in Stelara/Stelara I.V.-treated patients (30 serious infections in 930 patient-years of follow-up) and 0.03 per patient-year of follow-up in placebo-treated patients (15 serious infections in 434 patient-years of follow-up) (see 7 WARNINGS AND PRECAUTIONS).

In the controlled and non-controlled portions of placebo-controlled psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis clinical studies representing 11,581 patient-years of exposure in 6,709 patients, the median follow-up was 1.0 years; 1.1 years for psoriatic disease studies, 0.6 year for Crohn's disease studies and 1.0 years for ulcerative colitis studies. The rate of infection was 0.91 per patient-year of follow-up in Stelara/Stelara I.V.-treated patients. The rate of serious infections was 0.02 per patient-year of follow-up in Stelara/Stelara I.V.-treated patients (199 serious infections in 11581 patient-years of follow-up) and included pneumonia, anal abscess, sepsis, cellulitis, diverticulitis, gastroenteritis and viral infections.

Malignancies:

In the placebo-controlled period of the psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis clinical studies, the incidence of non-melanoma skin cancer was 0.43 per 100 patient-years of follow-up for Stelara/Stelara I.V.-treated patients (4 patients in 929 patient-years of follow-up) compared with 0.46 per 100 patient-years of follow-up for placebo-treated patients (2 patient in 433 patient-years of follow-up) during the placebo-controlled periods. In a Phase 3 clinical trial (ACCEPT) comparing ustekinumab and etanercept for the treatment of moderate to severe plaque psoriasis, 209 patients received ustekinumab 45 mg, 347 patients received ustekinumab 90 mg, and 347 patients received etanercept. Through Week 12, three (0.5%) subjects in the ustekinumab groups had a non-melanoma skin cancer detected in areas of psoriasis that had cleared with treatment. No skin cancers were observed in the etanercept group but due to the short treatment period, the possible pre-existing malignancies and the differences in efficacy (see 14 CLINICAL TRIALS), the clinical relevance has not been established.

The incidence of malignancies excluding non-melanoma skin cancer was 0.11 per 100 patient-years of follow-up for Stelara/Stelara I.V.-treated patients (1 patient in 929 patient-years of follow-up) compared with 0.23 per 100 patient-years of follow-up for placebo-treated patients (1 patient in 434 patient-years of follow-up) during the placebo-controlled periods. In the ACCEPT trial, through Week 12, one subject (0.2%) with a familial history of breast cancer was diagnosed with breast cancer versus no malignancies in the etanercept group.

In the controlled and non-controlled periods of psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis clinical studies representing 11,561 patient-years of exposure in 6709 patients, the median follow-up was 1.0 years; 1.1 years for psoriatic disease studies, 0.6 year for Crohn's

disease studies and 1.0 years for ulcerative colitis studies. Malignancies excluding non-melanoma skin cancers were reported in 62 patients in 11561 patient-years of follow-up. This represents an incidence of 0.54 per 100 patients-years of follow-up for Stelara/Stelara I.V.-treated patients. This rate of malignancies reported in Stelara/Stelara I.V.-treated patients was comparable to the rate expected in the general population (standardized incidence ratio = 0.93 [95% confidence interval: 0.71,1.20]). The most frequently observed malignancies, other than non-melanoma skin cancer, were prostate (16), colorectal (7), melanoma (6), and breast (5). The incidence of non-melanoma skin cancer was 0.49 per 100 patient-years of follow-up for Stelara/Stelara I.V.-treated patients (56 patients in 11545 patient-years of follow-up). The ratio of patients with basal versus squamous cell skin cancers (3:1) is comparable with the ratio expected in the general population.

Among 1569 patients exposed to Stelara for at least 3 years, 0.9% (n= 14) of patients reported NMSC and 1.4% (n=22) of patients reported malignancies excluding NMSC. This represents an incidence of 0.18 and 0.29 per 100 patient-years of follow-up for NMSC and malignancies excluding NMSC, respectively.

Hypersensitivity and Infusion Reactions:

Subcutaneous Administration
During the controlled periods of the psoriasis and psoriatic arthritis clinical studies of ustekinumab, rash and urticaria have each been observed in < 1% of patients.

In the maintenance Crohn's disease study, 1.7% of patients reported a placebo injection-site reaction and 3.0% reported a Stelara injection-site reaction.

Intravenous Administration
In Crohn's disease and ulcerative colitis induction studies, no events of anaphylaxis or other serious infusion reactions were reported. In these studies, 2.2% of 785 placebo treated patients and 1.9% of 790 patients treated with the recommended dose of Stelara I.V. reported adverse events occurring during or within an hour of the infusion.

Immunogenicity:

In psoriasis and psoriatic arthritis clinical studies, up to 12.4% of patients treated with ustekinumab developed antibodies to ustekinumab. In Crohn's disease and ulcerative colitis clinical studies, 2.9% and 4.6% of patients, respectively, developed antibodies to ustekinumab when treated with ustekinumab for approximately 1 year. No apparent association between the development of antibodies to ustekinumab and the development of injection site reactions was observed. 123 of 168 (73%) of psoriasis and psoriatic arthritis patients who were positive for antibodies to ustekinumab had neutralizing antibodies. Patients positive for antibodies to ustekinumab exhibited mean or median serum levels of ustekinumab that were consistently lower than those in patients negative or undetectable for antibodies to ustekinumab and tended to have lower efficacy; however, antibody positivity did not preclude a clinical response.

Immunogenicity tests are generally product-specific. Comparison of antibody rates to those from other products, or comparison of the incidence of antibodies between different tests without cross-validation is not appropriate.

8.2.1 Clinical Trial Adverse Reactions - Pediatrics

Pediatric Patients with Psoriasis

The safety of Stelara has been studied in two phase 3 studies of pediatric patients with moderate to severe plaque psoriasis. The first study was in 110 patients from 12 to 17 years of age treated for up to 60 weeks (CADMUS). The second study was in 44 patients from 6 to 11 years of age treated for up to 56 weeks (CADMUS Jr.). In general, the adverse events reported in these two studies were similar to those seen in previous studies in adults with plaque psoriasis.

Pediatrics (12 to 17 years of age)

Table 10: Adverse reactions reported by > 5% of patients during the placebo-controlled period of CADMUS

	Placebo	Stelara (ustekinumab)	
		Half Standard Dosage	Standard Dosage
Patients treated	37	37	36
Infections and infestations			
Upper respiratory tract infection	2 (5.4%)	1 (2.7%)	3 (8.3%)
Nervous system disorders			
Headache	2 (5.4%)	4 (10.8%)	3 (8.3%)
Gastrointestinal disorders			
Diarrhea	0	0	2 (5.6%)

Pediatrics (6 to 11 years of age)

No new safety issues were identified in pediatric patients 6 to 11 years of age and the observed safety profile in these pediatric patients was similar to the safety profile observed in Stelara-treated adolescent patients 12 to 17 years of age.

8.3 Less Common Clinical Trial Adverse Reactions

The following adverse reactions occurred at rates less than 1% during the controlled period of Stelara/Stelara I.V. clinical trials:

General disorders and administration site conditions: injection site reactions (including swelling, pruritus, induration, hemorrhage, hematoma), asthenia

Infections and infestations: cellulitis, herpes zoster, viral upper respiratory tract infections, vulvovaginal mycotic infections, dental infections

Psychiatric disorders: depression

Respiratory, thoracic and mediastinal disorders: nasal congestion

Skin and Subcutaneous tissue disorders: acne

8.4 Abnormal Laboratory Findings: Hematologic, Clinical Chemistry and Other Quantitative Data

During the placebo-controlled period of the Phase 2 and Phase 3 psoriasis studies (through week 12), an increase in non-fasting blood glucose levels was observed, as shown in Table 11. The clinical significance of these changes in glucose is unknown. No such increase in fasting blood glucose levels was observed in the same subjects.

Table 11: Proportion of patients with elevated non-fasting blood glucose levels in clinical trials

Increase in non-fasting blood glucose levels	Placebo n(%)	Combined ustekinumab group n(%)
Number of Patients	730	1580
Subjects with any abnormal value	49 (6.7%)	83 (5.3%)
Subjects with > 1 abnormal value	9 (1.2%)	35 (2.2 %)

8.5 Post-Market Adverse Reactions

Additional adverse events reported from worldwide post-marketing experience with ustekinumab are included in Table 12. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to ustekinumab exposure.

Table 12: Post-marketing Reports

Immune system disorders	Hypersensitivity reactions (including rash, urticaria) Serious allergic reactions (including anaphylaxis and angioedema)
Infections and infestations	Lower respiratory tract infection
Respiratory, thoracic and mediastinal disorders	Allergic alveolitis, eosinophilic pneumonia
Skin and subcutaneous tissue disorders	Pustular psoriasis Exfoliative dermatitis, erythrodermic psoriasis, hypersensitivity vasculitis

9 DRUG INTERACTIONS

9.2 Drug Interactions Overview

Specific drug interaction studies have not been conducted with Stelara/Stelara I.V. (ustekinumab).

In population pharmacokinetic analysis, the effect of the most frequently used concomitant medications in patients with psoriasis (including paracetamol/acetaminophen, ibuprofen, acetylsalicylic acid, metformin, atorvastatin, naproxen, levothyroxine, hydrochlorothiazide, and influenza vaccine) on pharmacokinetics of ustekinumab was explored and none of the concomitant medications exerted significant impact. In psoriatic arthritis studies, concomitant

MTX use did not appear to influence the pharmacokinetics of ustekinumab. In Crohn's disease and ulcerative colitis induction studies, immunomodulators (6-MP, AZA, MTX) were used concomitantly in approximately 30% of patients and corticosteroids were used concomitantly in approximately 40% and 50% of Crohn's disease and ulcerative colitis patients, respectively. Use of these concomitant therapies did not appear to influence the pharmacokinetics of ustekinumab.

9.3 Drug-Behavioural Interactions

The pharmacokinetics of ustekinumab were not impacted by the use of tobacco or alcohol.

9.4 Drug-Drug Interactions

Live Vaccines
Live vaccines should not be given concurrently with Stelara/Stelara I.V. (ustekinumab) (see 7 WARNINGS AND PRECAUTIONS, **Immune, Immunization**). Information regarding the administration of live vaccines in infants exposed to ustekinumab *in utero* is provided earlier in this product monograph (see 7 WARNINGS AND PRECAUTIONS, **Immune, *Infant exposure* in utero**).

Immunosuppressants
The safety and efficacy of Stelara/Stelara I.V. (ustekinumab) in combination with immunosuppressive agents or phototherapy have not been evaluated (see 7 WARNINGS AND PRECAUTIONS, **Immune**, **Concomitant immunosuppressive therapy**).

CYP450 Substrates
The effects of IL-12 or IL-23 on the regulation of CYP450 enzymes were evaluated in an *in vitro* study using human hepatocytes, which showed that IL-12 and/or IL-23 at levels of 10 ng/mL did not alter human CYP450 enzyme activities (CYP1A2, 2B6, 2C9, 2C19, 2D6, or 3A4). The clinical significance of this is not known, although these results do not suggest the need for dose adjustments in patients who are receiving concomitant CYP450 substrates.

9.5 Drug-Food Interactions

Interactions with food have not been established.

9.6 Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7 Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

Ustekinumab is a fully human IgG1κ monoclonal antibody, a first-in-class agent that binds with specificity to the shared p40 protein subunit of human cytokines interleukin IL-12 and IL-23. Ustekinumab inhibits the bioactivity of human IL-12 and IL-23 by preventing p40 from binding to the IL-12Rβ1 receptor protein expressed on the surface of immune cells. Ustekinumab cannot bind to IL-12 or IL-23 that is already bound to IL-12Rβ1 cell surface receptors. Thus, ustekinumab is not likely to contribute to complement or antibody- mediated cytotoxicity of cells expressing IL-12 and/or IL-23 receptors.

IL-12 and IL-23 are heterodimeric cytokines secreted by activated antigen-presenting cells, such as macrophages and dendritic cells. IL-12 stimulates natural killer (NK) cells and drives the differentiation of CD4+ T cells toward the T helper 1(Th1) phenotype and stimulates interferon gamma (IFNγ) production. IL-23 induces the T helper 17 (Th17) pathway and promotes secretion of IL-17A, IL-21, and IL-22. Levels of IL-12 and IL-23 are elevated in the skin and blood of patients with psoriasis, and serum IL12/23p40 distinguishes patients with psoriatic arthritis from healthy individuals, implicating IL-12 and IL-23 in the pathophysiology of psoriatic inflammatory diseases. Genetic polymorphisms in IL23A, IL23R, and IL-12B genes confer susceptibility to these disorders. Additionally, IL-12 and IL-23 are highly expressed in lesional psoriatic skin, and IL-12-mediated induction of IFNγ correlates with psoriasis disease activity. IL-23 responsive T-cells have been found in the entheses in a mouse model of inflammatory arthritis, where IL-23 drives entheseal inflammation. In addition, there is pre-clinical evidence implicating IL-23 and downstream pathways in bone erosion and destruction through up-regulation of receptor activator of nuclear factor-κB ligand (RANKL), which activates osteoclasts.

In patients with Crohn's disease, IL-12 and IL-23 are elevated in the intestines and lymph nodes.

By binding the shared p40 subunit of IL-12 and IL-23, ustekinumab may exert its clinical effects in psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis through interruption of the Th1 and Th17 cytokine pathways, which have been implicated as contributors in the pathology of these diseases.

10.2 Pharmacodynamics

Treatment with ustekinumab resulted in significant improvement in histological measures of psoriasis including epidermal hyperplasia and cell proliferation. These results are consistent with the clinical efficacy observed. In patients with psoriasis and/or psoriatic arthritis Stelara (ustekinumab) had no apparent effect on the percentages of circulating immune cell populations including memory and naive T-cell subsets or circulating cytokine levels. Systemic markers of inflammation were measurable in the serum at baseline and 4 markers (MDC, VEGF, MCSF-1 and YKL-40) showed modest differences in concentration post-treatment in Stelara-treated patients as compared to placebo.

Treatment with ustekinumab resulted in a decrease in the gene expression of its molecular targets IL-12 and IL-23 as shown by analyses of mRNA obtained from lesional skin biopsies of psoriatic patients at baseline and up to two weeks post-treatment. In addition, ustekinumab down-regulated the gene expression of inflammatory cytokines and chemokines such as MCP-1, TNF-alpha, IP-10 and IL-8 in lesional skin biopsies. These results are consistent with the significant clinical benefit observed with ustekinumab treatment.

In psoriasis and psoriatic arthritis studies, clinical response (improvement in PASI or ACR measurements, respectively) appeared to be related to serum ustekinumab levels. Patients with psoriasis with higher PASI response had higher median serum concentrations of ustekinumab than those with lower clinical responses. In psoriasis studies, the proportion of patients with psoriasis who achieved PASI 75 response increased with increasing serum levels of ustekinumab. The proportion of patients who achieved PASI 75 response at Week 28 increased with increasing serum ustekinumab trough levels at Week 28. In psoriatic arthritis studies, patients achieving an ACR 20 response had higher median serum concentrations of ustekinumab than ACR 20 non-responders. The proportion of patients who achieved ACR 20 and ACR 50 response increased with increasing serum levels of ustekinumab.

In patients with Crohn's disease and ulcerative colitis, treatment with Stelara/Stelara I.V. resulted in a significant decrease in inflammatory markers including C-Reactive Protein (CRP) and fecal calprotectin. In patients with Crohn's disease, decrease in gene expression for IL-12Rβ1and IL-23 was observed in inflamed colon tissue in responders to Stelara I.V. treatment while no significant changes were observed in placebo treated patients at Week 6.

10.3 Pharmacokinetics

The median pharmacokinetic parameters of ustekinumab following a single SC administration in adult patients with psoriasis are shown in Table 11. The pharmacokinetic parameters of ustekinumab (CL/F, V_z/F, and $t_{1/2}$) were generally comparable between 45 mg and 90 mg subcutaneous doses.

Table 11: Summary of Pharmacokinetic Parameters of Ustekinumab Following a Single 45 or 90 mg Subcutaneous Administration in Adult Patients with Psoriasis

Dose	45 mg			90 mg		
PK parameter	N	Median (Range)	Mean (± SD)	N	Median (Range)	Mean (± SD)
C_{max} (mcg/mL)	22	2.4 (1.0, 5.4)	2.7 (± 1.2)	24	5.3 (1.2, 12.3)	6.1 (± 3.6)
t_{max} (day)	22	13.5 (1.9, 58.2)	15.3 (± 13.5)	24	7.0 (2.9, 27.1)	9.9 (± 7.4)
AUC (mcg·day/mL)	18	84.9 (31.2, 1261.9)	196.7 (± 298.2)	21	226.9 (57.1, 755.5)	274.9 (± 206.5)
$t_{1/2}$ (day)	18	19.8 (5.0, 353.6)	45.6 (± 80.2)	21	21.2 (13.6, 85.8)	26.7 (± 19.3)
CL/F (mL/day/kg)	18	5.3	5.8	21	4.5	5.7

		(0.2, 12.9)	(± 3.5)		(1.5, 14.9)	(± 3.6)
V_z/F (mL/kg)	18	154.2 (32.6, 280.5)	160.5 (± 64.5)	21	160.5 (37.3, 354.1)	178.7 (± 85.2)

Source data: C0379T04 CSR

Dose Linearity: The systemic exposure of ustekinumab (C_{max} and AUC) increased in a linear manner following a single subcutaneous administration at doses ranging from approximately 24 mg to 240 mg in patients with psoriasis.

Single Dose vs. Multiple Doses: Serum concentration-time profiles of ustekinumab were generally predictable after single or multiple subcutaneous dose administrations on the basis of a one-compartment model. In patients with psoriasis, steady-state serum concentrations of ustekinumab were achieved by Week 28 after initial subcutaneous doses at Weeks 0 and 4 followed by doses every 12 weeks. The median steady-state trough concentration ranged from 0.21 mcg/mL to 0.26 mcg/mL (45 mg; n = 242 to 390) and from 0.47 mcg/mL to 0.49 mcg/mL (90 mg; n = 236 to 386) in patients with psoriasis. There was no apparent accumulation in serum ustekinumab concentration over time when given subcutaneously every 12 weeks.

Population Pharmacokinetic Analysis
Of the demographic factors (e.g., gender, race, age, body size), baseline patient physical or biochemical characteristics, medical or medication history, or concomitant medications evaluated in a population pharmacokinetic analysis, only body weight, diabetes comorbidity, and positive immune response to ustekinumab were found to be important covariates affecting the systemic exposure to ustekinumab in patients with moderate to severe psoriasis. Body weight and positive immune response to ustekinumab were also found to be important covariates affecting the systemic exposure to ustekinumab in subjects with psoriatic arthritis. Clinical relevance of the effects of these important covariates, however, needs to be evaluated concurrently with clinical efficacy and safety data.

Absorption:
The median time to reach the maximum serum concentration (t_{max}) was 8.5 days after a single 90 mg subcutaneous administration in healthy subjects (n = 30). The median t_{max} values of ustekinumab following a single subcutaneous administration of either 45 mg or 90 mg in patients with psoriasis were comparable to that observed in healthy subjects.

The absolute bioavailability (F) of ustekinumab following a single subcutaneous administration was estimated to be 57.2% in patients with psoriasis (n = 17).

Following the recommended IV induction dose, median peak serum ustekinumab concentration was 126.1 mcg/mL (IQ range 106.1 – 146.2 mcg/mL) in patients with Crohn's disease and 127.0 mcg/mL (IQ range 109.2 – 145.9 mcg/mL) in patient with ulcerative colitis. Starting at Week 8, subcutaneous maintenance dosing of 90 mg ustekinumab was administered every 8 or 12 weeks. Steady state ustekinumab concentration was achieved by the start of the second maintenance dose.

Following subcutaneous maintenance dosing of 90 mg ustekinumab every 8 weeks, median steady-state trough concentrations ranged from 1.97 mcg/mL to 2.24 mcg/mL in patients with

Crohn's disease and 2.69 mcg/mL to 3.09 mcg/mL in patients with ulcerative colitis. Following subcutaneous maintenance dosing of 90 mg ustekinumab every 12 weeks, median steady state trough concentrations ranged from 0.61 mcg/mL to 0.76 mcg/mL in patients with Crohn's disease and 0.92 mcg/mL to 1.19 mcg/mL in patients with ulcerative colitis. The steady-state trough ustekinumab levels resulting from 90 mg ustekinumab every 8 weeks were associated with higher clinical remission rates as compared to the steady-state trough levels following 90 mg every 12 weeks.

Distribution:
The median apparent volume of distribution during the terminal phase (V_z/F) following a single subcutaneous administration to patients with psoriasis ranged from 76 to 161 mL/kg (n = 4 to 21).

In a population pharmacokinetic analysis of ustekinumab in patients with Crohn's disease, the total volume of distribution at steady-state was 4.62 L and 4.44 L in patients with ulcerative colitis.

Metabolism:
The exact metabolic pathway for ustekinumab is unknown.

Elimination:
The median apparent clearance (CL/F) following a single subcutaneous administration to patients with psoriasis ranged from 2.7 to 5.3 mL/day/kg. The median half-life ($t_{1/2}$) of ustekinumab was approximately 3 weeks in patients with psoriasis and/or psoriatic arthritis, Crohn's disease and ulcerative colitis ranging from 15 to 32 days across all psoriasis and psoriatic arthritis studies (n = 4 to 55).

In a population pharmacokinetic analysis , the clearance of ustekinumab was 0.19 L/day (95% CI: 0.185, 0.197) in patients with Crohn's disease and 0.19 L/day (95% CI: 0.179, 0.192) in patients with ulcerative colitis with an estimated median terminal half-life of approximately 19 days in patients with Crohn's disease and ulcerative colitis.

Special Populations and Conditions

- **Pediatrics**
  Pediatrics (< 18 years of age): Studies of Stelara in pediatric patients with plaque psoriasis below 6 years of age have not been conducted. No pharmacokinetic data are available in pediatric patients with Crohn's disease or ulcerative colitis. Pediatric studies of Stelara I.V. have not been conducted.

  Serum ustekinumab concentrations in plaque psoriasis patients 6 to 17 years of age, treated with the recommended weight-based dose were generally comparable to those in the adult psoriasis population treated with the adult dose.

- **Geriatrics**
  Geriatrics (> 65 years of age): No specific studies have been conducted in elderly patients. A population pharmacokinetic analysis indicated there were no apparent changes in CL/F

and V/F estimates in patients ≥ 65 years.

- **Sex, Ethnic Origin and Genetic Polymorphism:** The apparent clearance of ustekinumab was not impacted by sex, age, or race.

- **Hepatic Insufficiency:** No pharmacokinetic data are available in patients with impaired hepatic function.

- **Renal Insufficiency:** No pharmacokinetic data are available in patients with renal insufficiency.

- **Obesity:**
  Impact of Weight on Pharmacokinetics:
  Serum ustekinumab concentrations were affected by weight in patients with psoriasis and/or psoriatic arthritis. When given the same dose, patients of higher weight (> 100 kg) had lower median serum ustekinumab concentrations compared with those in patients of lower weight (≤ 100 kg). However, across doses, the median trough serum concentrations of ustekinumab in patients with higher weight (> 100 kg) in the 90 mg group were comparable to those in patients with lower weight (≤ 100 kg) in the 45 mg group.

11 STORAGE, STABILITY AND DISPOSAL

Stelara/Stelara I.V. must be refrigerated at 2 to 8ºC and protected from light. Keep the product in the original carton to protect from light until the time of use. Do not freeze. Do not shake.

If needed, individual Stelara pre-filled syringes may be stored at room temperature up to 30°C for a maximum single period of up to 30 days in the original carton with protection from light. Record the date when the pre-filled syringe is first removed from the refrigerator and the new expiry date on the carton in the spaces provided. The new expiry date must not exceed the original expiry date printed on the carton. Once a syringe has been stored at room temperature, it should not be returned to the refrigerator. Discard the syringe if not used within 30 days at room temperature storage.

If necessary, the diluted Stelara I.V. infusion solution may be stored for up to eight hours at room temperature. Do not freeze. Discard any unused portion of the infusion solution.

12 SPECIAL HANDLING INSTRUCTIONS

Following administration of Stelara/Stelara I.V., discard any unused portion. The syringe should be disposed of in a puncture-resistant container for syringes and needles. Patients or caregivers should be instructed in the technique as well as proper syringe and needle disposal, and not to reuse these items.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: ustekinumab

Chemical name: ustekinumab

Molecular formula and molecular mass: Ustekinumab is a fully human IgG1κ mAb, with an approximate molecular weight of 148,600 daltons.

Physicochemical properties: STELARA® (ustekinumab) is clear to slightly opalescent, colourless to light yellow with a pH of approximately 6.0. Stelara I.V. is clear, colorless to light yellow with a pH of approximately 6.0.

Product Characteristics:

Stelara

Stelara (ustekinumab) is supplied as a single-use, sterile solution for subcutaneous injection in a Type 1 glass syringe with a fixed 27G, half-inch needle and needle cover. The needle cover is manufactured using a dry natural rubber (a derivative of latex) (see 7 WARNINGS AND PRECAUTIONS, **Sensitivity/Resistance, Hypersensitivity Reactions**). The syringe is fitted with a passive safety guard. Stelara is also supplied as a sterile solution for subcutaneous injection in a single-use (Type 1) glass vial for SC administration‡.

Stelara is supplied as 2 dosage presentations at 45 mg in 0.5 mL volume as a pre-filled syringe or a single-use vial or at 90 mg in a 1 mL volume as a pre-filled syringe. Each 1 mL of Stelara solution contains 90 mg ustekinumab. No preservatives are present.

Stelara I.V.

Stelara I.V., 130 mg vial, is supplied as a sterile solution for intravenous infusion in a single-use (Type 1) glass vial. The vial is stoppered with a coated stopper.

Viral Inactivation

Ustekinumab is produced by a recombinant cell line cultured by continuous perfusion and is purified by a series of steps that includes measures to inactivate and remove viruses.

14 CLINICAL TRIALS

14.1 Clinical Trials by Indication

Plaque Psoriasis - Adults

The safety and efficacy of Stelara were assessed in two multicentre, randomized, double-blind, placebo-controlled studies (PHOENIX 1 and PHOENIX 2) in patients 18 years of age and older with chronic (> 6 months) plaque psoriasis who had a minimum body surface area (BSA) involvement of 10%, and Psoriasis Area and Severity Index (PASI) score ≥ 12 and who were candidates for phototherapy or systemic therapy. Patients with guttate, erythrodermic, or pustular psoriasis were excluded from the studies. No concomitant anti-psoriatic therapies were allowed during the study with the exception of low-potency topical corticosteroids on the face and groin after Week 12. A total of 1996 patients were enrolled in the two studies. The safety and efficacy of Stelara beyond 5 years have not been established.

In addition, a multicenter, randomized, active-controlled study (ACCEPT) compared the safety and efficacy of Stelara and etanercept in patients 18 years of age and older with chronic (> 6 months) plaque psoriasis who had a minimum BSA involvement of 10%, PASI score ≥ 12, Physician Global Assessment (PGA) score ≥ 3, who were candidates for phototherapy or systemic therapy, and who had had an inadequate response to, intolerance to, or contraindication to cyclosporine, methotrexate, or PUVA therapy. A total of 903 patients were enrolled in the study.

Baseline disease characteristics across PHOENIX 1 and 2 were similar (Table 12 and Table 13). In both studies, patients in all treatment groups had a median baseline PASI score ranging from 17 to 18. Approximately two-thirds of all patients had received prior phototherapy, 69% had received either prior conventional systemic or biologic therapy for the treatment of psoriasis, with 56% receiving prior conventional systemic therapy and 43% receiving prior biologic therapy. A total of 28% of study patients had a history of psoriatic arthritis. Similar disease characteristics were also seen in the ACCEPT trial (Table 12 and Table 13).

Table 12: Summary of patient demographics for PHOENIX 1, PHOENIX 2 and ACCEPT

Study #	Study design	Dosage, route of administration and duration	Study subjects (n)	Mean age (Range)	Sex
C0743T08 (PHOENIX 1)	Double-Blind Placebo-Controlled	Fixed doses: Placebo (N = 255) Placebo → 45 mg SC regimen[a] (N = 123) Placebo → 90 mg SC regimen[a] (N = 120) 45 mg SC Weeks 0, 4 then q12w (N = 255) 90 mg SC Weeks 0, 4 then q12w (N = 256)	N=766	45.3 (19,76)	M=531 F=235
C0743T09 (PHOENIX 2)	Double-Blind Placebo-Controlled	Fixed doses: Placebo (N = 410)-Placebo → 45 mg SC regimen[a] (N = 197) Placebo → 90 mg SC regimen[a] (N = 195) 45 mg SC Weeks 0, 4 then q12w (N = 409) 90 mg SC Weeks 0, 4 then q12w (N = 411)	N=1230	46.2 (18, 86)	M=840 F=390
C0743T12 (ACCEPT)	Assessor-Blind Active-Comparator Controlled	Fixed doses: Etanercept 50 mg (N=347) twice weekly through Week 12 Stelara 45 mg (N=209) at Week 0 and 4 Stelara 90 mg (N=347) at Week 0 and 4	N= 903	45.0 (18, 81)	M=613 F=290

[a] The placebo groups crossed over to receive Stelara (45 mg or 90 mg) at Weeks 12 and 16 then q12w

Table 13: Baseline Disease Characteristics in PHOENIX 1, PHOENIX 2 and ACCEPT

	PHOENIX 1		PHOENIX 2		ACCEPT	
	Placebo	Stelara	Placebo	Stelara	Etanercept	Stelara
Patients randomized at Week 0	N=255	N=511	N=410	N=820	N=347	N=556
Median BSA	22.0	21.0	20.0	21.0	19.0	20.0
BSA ≥ 20%	145 (57%)	276 (54%)	217 (53%)	445 (54%)	169 (49%)	289 (52%)
Median PASI	17.80	17.4	16.90	17.60	16.8	17.1
PASI ≥ 20	91 (36%)	169 (33%)	133 (32%)	300 (37%)	102 (29%)	205 (37%)
PGA of marked or severe	112 (44%)	223 (44%)	160 (39%)	328 (40%)	148 (43%)	242 (44%)
History of psoriatic arthritis	90 (35%)	168 (33%)	105 (26%)	200 (24%)	95 (27%)	157 (28%)
Prior phototherapy	150 (59%)	342 (67%)	276 (67%)	553 (67%)	224 (65%)	368 (66%)
Prior conventional systemic therapy excluding biologics[a]	142 (56%)	282 (55%)	241 (59%)	447 (55%)	199(57%)	311 (56%)
Prior conventional systemic or biologic therapy[a]	189 (74%)	364 (71%)	287 (70%)	536 (65%)	218(63%)	337 (61%)
Failed to respond to, had contraindication for, or intolerant to ≥ 1 conventional therapy[a]	139 (55%)	270 (53%)	254 (62%)	490 (60%)	347 (100%)	555 (100%)
Failed to respond to, had contraindication for, or intolerant to ≥ 3 conventional therapies[a]	30 (12%)	54 (11%)	66 (16%)	134 (16%)	52 (15%)	78 (14%)

[a] In PHOENIX 1 and 2, conventional systemic agents include acitretin, PUVA, methotrexate, and cyclosporine. In ACCEPT, conventional systemic agents included PUVA, methotrexate, and cyclosporine. All patients were required to be etanercept naïve at baseline in ACCEPT, but in PHOENIX 1 and 2 patients may have previously received etanercept.

PHOENIX 1 evaluated the safety and efficacy of Stelara versus placebo in 766 patients with plaque psoriasis. Patients were randomized in equal proportion to placebo, 45 mg or 90 mg of Stelara. Patients randomized to Stelara received 45 mg or 90 mg doses at Weeks 0 and 4 followed by the same dose every 12 weeks. Patients randomized to receive placebo at Weeks 0 and 4 crossed over to receive Stelara (either 45 mg or 90 mg) at Weeks 12 and 16 followed by the same dose every 12 weeks. To evaluate the efficacy of every 12-week dosing, patients who were PASI 75 responders at both Weeks 28 and 40 were re-randomized to either continue dosing of Stelara every 12 weeks or to placebo (i.e., withdrawal of therapy). Patients withdrawn from Stelara at Week 40 reinitiated Stelara at their original dosing regimen when they experienced at least a 50% loss of their PASI improvement obtained at Week 40. Patients were followed for at least 76 weeks.

PHOENIX 2 evaluated the safety and efficacy of Stelara versus placebo in 1230 patients with plaque psoriasis. This study design was identical to PHOENIX 1 through Week 28.

Dose Adjustment (every 8 weeks)
At Week 28, PHOENIX 1 patients who were nonresponders (< PASI 50 response) discontinued treatment and patients who were partial responders (≥ PASI 50 response and < PASI 75 response) were adjusted to every-8-week dosing. PASI 75 responders at Week 28 who became partial responders or nonresponders at Week 40 were adjusted to every-8-week dosing.

In PHOENIX 2, patients who were partial responders at Week 28 were re-randomized to either continue every 12 weeks dosing of Stelara or to switch to every 8 weeks dosing.

All patients were followed for up to 76 weeks in PHOENIX 1 and up to 52 weeks in PHOENIX 2 following first administration of study treatment.

In both studies, the primary endpoint was the proportion of patients who achieved a reduction in score of at least 75% from baseline at Week 12 by the PASI (PASI 75). Patients achieving ≥ 90% improvement in PASI from baseline (PASI 90) were considered PASI 90 responders and patients with ≥ 50% improvement in PASI from baseline (PASI 50) were considered PASI 50 responders. Another key efficacy assessment was the Physician's Global Assessment (PGA), a 6-category scale ranging from 0 (cleared) to 5 (severe) that indicates the physician's overall assessment of psoriasis focusing on plaque thickness/induration, erythema, and scaling.

The Dermatology Life Quality Index (DLQI), a dermatology-specific quality of life instrument designed to assess the impact of the disease on a patient's quality of life, was assessed in both PHOENIX 1 and PHOENIX 2. Other efficacy assessments included the Nail Psoriasis Severity Index (NAPSI), a physician-assessed score that measures the severity of nail involvement (PHOENIX 1); the Itch Visual Analog Scale (VAS), used to assess the severity of itch at the time of the assessment (PHOENIX 1); the Hospital Anxiety and Depression Scale (HADS), a self-rating tool developed to evaluate psychological measures in patients with physical ailments (PHOENIX 2); and the Work Limitations Questionnaire (WLQ), a 25-item, self-administered questionnaire that was used to measure the impact of chronic health conditions on job performance and work productivity among employed populations (PHOENIX 2).

The ACCEPT trial compared the efficacy of Stelara to etanercept and evaluated the safety of Stelara and etanercept in moderate to severe psoriasis patients. The active-controlled portion of the study was from Week 0 to Week 12, during which the efficacy and safety of etanercept and 2 dose levels of Stelara were evaluated. This trial was powered to test the superiority of each dose level to etanercept and the primary endpoint was the proportion of patients who achieved a PASI 75 at week 12.

Study results

The results of PHOENIX 1 and PHOENIX 2 for key psoriasis clinical outcomes are presented in Table 14.

Efficacy at the Primary Endpoint, PHOENIX 1 and PHOENIX 2

The onset of action with Stelara was rapid and improvement was seen within 2 weeks of the first dose. In both the PHOENIX 1 and PHOENIX 2 studies, a significantly greater proportion of patients randomized to treatment with Stelara were PASI 75 responders compared with placebo at Week 12 (Table 14). In the PHOENIX 1 study, 67% and 66% of patients receiving Stelara 45 mg and 90 mg, respectively, achieved a PASI 75 response at Week 12 compared with 3% of patients receiving placebo. In the PHOENIX 2 study, 67% and 76% of patients receiving Stelara 45 mg and 90 mg, respectively, achieved a PASI 75 response at Week 12 compared with 4% of patients receiving placebo.

All 3 components of the PASI (plaque thickness/induration, erythema, and scaling) contributed comparably to the improvement in PASI.

The efficacy of Stelara was significantly superior ($p<0.001$) to placebo across all subgroups defined by baseline demographics, clinical disease characteristics (including patients with a history of psoriatic arthritis) and prior medication usage. While pharmacokinetic modelling suggested a trend towards higher CL/F in patients with diabetes, a consistent effect on efficacy was not observed.

Table 14: Clinical Outcomes - PHOENIX 1 and PHOENIX 2

	PHOENIX 1			**PHOENIX 2**		
		Stelara			**Stelara**	
	Placebo	**45 mg**	**90 mg**	**Placebo**	**45 mg**	**90 mg**
Week 12						
Patients randomized	255	255	256	410	409	411
PASI response						
PASI 50 response[a]	26 (10%)	213 (84%)	220 (86%)	41 (10%)	342 (84%)	367 (89%)
PASI 75 response[a]	8 (3%)	171 (67%)	170 (66%)	15 (4%)	273 (67%)	311 (76%)
PASI 90 response[a]	5 (2%)	106 (42%)	94 (37%)	3 (1%)	173 (42%)	209 (51%)
PASI 100 response[a]	0 (0%)	33 (13%)	28 (11%)	0 (0%)	74 (18%)	75 (18%)
PGA of Cleared or Minimal[a]	10 (4%)	151 (59%)	156 (61%)	18 (4%)	277 (68%)	300 (73%)
Week 28						
Patients evaluated	--	250	243	--	397	400
PASI response						
PASI 50 response	--	228 (91%)	234 (96%)	--	369 (93%)	380 (95%)
PASI 75 response	--	178 (71%)	191 (79%)	--	276 (70%)	314 (79%)
PASI 90 response	--	123 (49%)	135 (56%)	--	178 (45%)	217 (54%)
PASI 100 response	--	52 (21%)	71(29 %)	--	74(19%)	118 (30%)
PGA of Cleared or Minimal	--	146 (58%)	160 (66%)	--	241(61%)	279 (70%)

[a] $p < 0.001$ for 45 mg or 90 mg comparison with placebo.

Other efficacy measures at Week 12

In both PHOENIX 1 and PHOENIX 2, compared with placebo, significantly greater proportions of patients randomized to 45 mg or 90 mg Stelara achieved a cleared or minimal PGA score, and significantly greater proportions of patients randomized to 45 mg or 90 mg Stelara were PASI 50, PASI 90 and PASI 100 responders at Week 12 (Table 14). In the PHOENIX 1 study, 60% and 62% of the patients treated with 45 mg and 90 mg Stelara, respectively, achieved PGA scores of cleared or minimal compared with 4% of placebo-treated patients. In PHOENIX 2, 68% and 73% of patients receiving 45 mg or 90 mg Stelara, respectively, had cleared or minimal PGA scores compared with 5% of the placebo patients. In PHOENIX 1, PASI 90 was achieved by 42% and 37% of the patients treated with 45 mg and 90 mg Stelara, respectively, compared with 2% of placebo-treated patients. In addition, a significantly higher proportion of subjects treated with either 45 mg (13%) or 90 mg (11%) achieved a PASI of 0 (i.e., PASI 100 response) compared with the placebo group (0.0%; $p<0.001$). In PHOENIX 2, the percentage of patients achieving PASI 100 and PASI 90 was 18% and 42%, respectively, in the 45 mg Stelara group, and 18% and 51%, respectively, in the 90 mg Stelara group versus 1% in the placebo group. The percentage of patients achieving PASI 50 in PHOENIX 1 was 84% and 86% in the 45 mg and 90 mg Stelara groups, respectively, compared with 10% in the placebo group. Similarly, 84% of patients treated with 45 mg Stelara, 89% of patients treated with 90 mg Stelara and 10% of patients treated with placebo reached PASI 50 in PHOENIX 2 (Table 14).

Response over time

In PHOENIX 1, significantly greater proportions of Stelara-treated patients had PASI 50 responses (9% and 10% for the 45 mg and 90 mg groups, respectively) compared with placebo (2%) by Week 2 ($p<0.001$). Significantly greater proportions of patients treated with Stelara achieved PASI 75 responses (9% and 12% for the 45 mg and 90 mg Stelara groups, respectively) compared with placebo (0.4%) by Week 4 ($p<0.001$). Maximum response was generally achieved by Week 24 in the 45 mg and 90 mg Stelara treatment groups, and response rates were generally sustained through Week 36 (Figure 1). In PHOENIX 1, PASI 75 rates at Week 24 were 76% for the 45 mg group, and 85% for the 90 mg group. Higher response rates were observed in patients receiving Stelara 90 mg than in those receiving Stelara 45 mg by Week 16 and these higher response rates were sustained through Week 36 (Figure 1). Similar results were observed in the PHOENIX 2 study through Week 28.

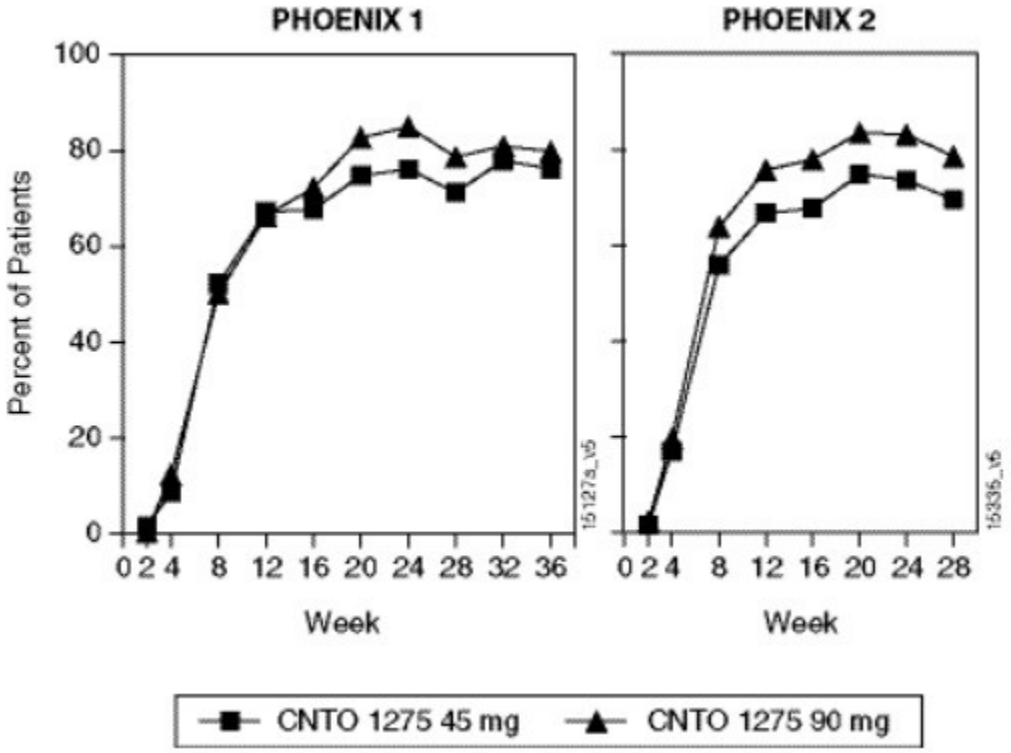


Figure 1: PASI 75 response over time in PHOENIX 1 and 2

In prespecified analyses of efficacy by body weight in PHOENIX 1 and PHOENIX 2, no consistent pattern of dose response was seen in patients ≤ 100 kg. In patients who weighed > 100 kg, higher PASI 75 response rates were seen with 90 mg dosing compared with 45 mg dosing, and a higher proportion of patients receiving 90 mg dosing had PGA scores of cleared or minimal compared with patients receiving 45 mg dosing (Table 15).

Table 15: Clinical Outcomes by Weight – PHOENIX 1 and PHOENIX 2

Week 12						
	PHOENIX 1			**PHOENIX 2**		
		Stelara			**Stelara**	
	Placebo	**45 mg**	**90 mg**	**Placebo**	**45 mg**	**90 mg**
Patients randomized at Week 0	255	255	256	410	409	411
PASI 75 response by weight						
≤ 100 kg						
N	166	168	164	290	297	289
PASI 75 response	6 (4%)	124 (74%)	107 (65%)	12 (4%)	218 (73%)	225 (78%)
>100 kg						
N	89	87	92	120	112	121
PASI 75 response	2 (2%)	47 (54%)	63 (68%)	3 (3%)	55 (49%)	86 (71%)
PGA of Cleared or Minimal by weight						
≤ 100 kg						
N	166	168	164	290	297	289
PGA response	7 (4%)	110 (65%)	104 (63%)	16 (6%)	219 (74%)	217 (75%)
> 100 kg						
N	89	87	92	120	112	121
PGA response	3 (3%)	44 (51%)	54 (59%)	4 (3%)	59 (53%)	85 (70%)

Week 28				
	PHOENIX 1		**PHOENIX 2**	
	Stelara		**Stelara**	
	45 mg	**90 mg**	**45 mg**	**90 mg**
N	250	243	397	400
PASI 75 response by weight				
≤ 100 kg				
N	164	153	287	280
PASI 75 response	130 (79%)	124 (81%)	217 (76%)	226 (81%)
> 100 kg				
N	86	90	110	119
PASI 75 response	48 (56%)	67 (74%)	59 (54%)	88 (74%)
PGA of Cleared or Minimal by weight				
≤ 100 kg				
N	164	153	287	280
PGA response	107 (65%)	107 (70%)	194 (68%)	208 (74%)
> 100 kg				
N	86	90	110	119
PGA response	40 (47%)	54 (60%)	49 (45%)	71 (60%)

Therapeutic benefit of long-term continuous use

At Week 40 in PHOENIX 1, among patients who were PASI 75 responders at both weeks 28 and 40, 162 patients were re-randomized to receive Stelara at 45 mg and 90 mg given every 12 weeks (maintenance treatment) and 160 were re-randomized to receive placebo (treatment withdrawal). Maintenance of PASI 75 was significantly superior with continuous maintenance treatment compared with treatment withdrawal (p<0.001) through at least 1.5 years of follow-up. Similar results were seen with each dose of Stelara.

At 1 year (Week 52), 89% of patients re-randomized to maintenance treatment were PASI 75 responders compared with 63% of patients re-randomized to placebo (treatment withdrawal) (p<0.001) (Table 16). At Week 76, 84% of patients re-randomized to maintenance treatment were PASI 75 responders compared with 19% of patients re-randomized to placebo (treatment withdrawal) (p<0.001). Through 18 months (Week 76), the proportion of subjects in the combined maintenance treatment group who were PASI 50 responders remained consistently at greater than 95%. By contrast, the proportion of PASI 50 responders in the combined withdrawal group progressively decreased over time such that by Weeks 52 and 76, only 50% and 31% remained as PASI 50 responders respectively. Among patients withdrawn from treatment, the rates of loss of the various PASI responses (PASI 50, 75, 90) were generally comparable in all groups regardless of dose. No rebound of psoriasis occurred in patients who were randomized to treatment withdrawal. Among the patients who reached PASI 75 response at weeks 28 and 40 and were re-randomized to maintenance treatment, 82% were PASI 75 responders at 3 years (Week 148). At 5 years (Week 244), 80% of patients (112/140) re-randomized to maintenance treatment were PASI 75 responders.

Table 16: Summary of PASI response from Week 40 through Week 76 in subjects randomized at Week 40 in PHOENIX 1

	Stelara		**Stelara**		**Stelara**	
	45 mg		**90 mg**		**Combined**	
	Placebo	**q12 wks**	**Placebo**	**q12 wks**	**Placebo**	**q12 wks**
Patients randomized at Week 40	73	77	87	85	160	162
Week 52 N	73	77	86	85	159	162
≥ 90% improvement	27 (37.0%)	45 (58.4%)	33 (38.4%)	60 (70.6%)	60 (37.7%)	105 (64.8%)
≥ 75% improvement	47 (64%)	67 (87.0%)	53 (61.6%)	77 (90.6%)	100 (62.9%)	144 (88.9%)
≥ 50% improvement	63 (86%)	75 (97.4%)	71 (82.6%)	83 (97.6%)	134 (84.3%)	158 (97.5%)
Week 76 N	71	77	85	82	156	159
≥ 90% improvement	5 (7.0%)	38 (49.4%)	4 (4.7%)	52 (63.4%)	9 (5.8%)	90 (56.6%)
≥ 75% improvement	14 (19.7%)	63 (81.8%)	15 (17.6%)	71 (86.6%)	29 (18.6%)	134 (84.3%)
≥ 50% improvement	22 (31.0%)	74 (96.1%)	27 (31.8%)	79 (96.3%)	49 (31.4%)	153 (96.2%)

Efficacy of retreatment

In PHOENIX 1, after randomized withdrawal from therapy at week 40, patients reinitiated their original Stelara treatment regimen after a loss of ≥ 50% of PASI improvement. Retreatment with Stelara resulted in 71% of evaluated patients regaining PASI 75 response within 8 weeks after

reinitiating therapy and 85% of evaluated patients regaining PASI 75 response within 12 weeks after reinitiating therapy.

Dosing interval adjustment

In PHOENIX 1, Week 28 and Week 40 partial responders and Week 40 nonresponders were adjusted from every-12-week to every-8-week dosing. Approximately 40%-50% of Week 28 partial responders to every-12-week dosing achieved PASI 75 response after adjustment to every-8-week dosing and this proportion of PASI 75 responders was maintained through Week 52. A similar proportion of patients who were PASI 75 responders at Week 28 and subsequently became partial responders or nonresponders at Week 40 achieved PASI 75 response following a dosing interval adjustment to every 8 weeks.

In PHOENIX 2, among patients initially randomized to 90 mg dosing who were partial responders at Week 28, dosing adjustment to every 8 weeks resulted in consistently superior efficacy as compared with continued every 12 weeks dosing: Partial responders randomized to 90 mg every 8 weeks achieved PASI 75 response at more visits between Weeks 40 and 52 than partial responders randomized to continue 90 mg every 12 weeks ($p = 0.014$), and a higher proportion of subjects achieved a PASI 75 response at Week 52 (68.8% with every 8 weeks dosing versus 33.3% with every 12 weeks dosing; $p = 0.004$). Among patients initially randomized to 45 mg dosing who were partial responders at Week 28, response rates were not higher among patients in whom dosing was adjusted to every 8 weeks compared with patients who continued every 12 weeks dosing.

Quality of life

In PHOENIX 1 and 2, the mean baseline DLQI scores ranged from 11 to 12. In PHOENIX 1, the mean baseline SF-36 Physical Component ranged from 47-49 and the mean baseline SF-36 Mental Component was approximately 50. Quality of life improved significantly in patients randomized to 45 mg or 90 mg Stelara compared with patients randomized to placebo as evaluated by DLQI in PHOENIX 1 and 2 and SF-36 in PHOENIX 1. Quality of life improvements were significant as early as 2 weeks in patients treated with Stelara ($p<0.001$) and these improvements were maintained over time with continued dosing.

In PHOENIX 1, 65% and 71% of patients treated with 45 mg and 90 mg of Stelara, respectively, showed a clinically meaningful reduction (5 or more points) in DLQI from baseline at week 12 compared to 18% in placebo group ($p<0.001$ for both groups compared with placebo). Furthermore, 33% and 34% of patients treated with 45 mg and 90 mg of Stelara, respectively, showed a DLQI score of 0 compared to 1% in the placebo group ($p<0.001$ for both groups compared with placebo), indicating no impairment in QOL from disease or treatment in these patients. In PHOENIX 2, 72% and 77% of patients treated with 45 mg and 90 mg of Stelara, respectively, showed a clinically meaningful reduction (5 or more points) in DLQI from baseline at Week 12 compared to 21% in placebo group ($p<0.001$ for both groups compared with placebo). In addition, 37% and 39% of patients treated with 45 mg and 90 mg of Stelara, respectively, showed a DLQI score of 0 compared to 1% in the placebo group ($p<0.001$ for both groups compared with placebo).

In PHOENIX 1, the median baseline NAPSI score for nail psoriasis was 4.0 and the median number of fingernails involved with psoriasis was 8.0. Nail psoriasis improved significantly in

patients randomized to 45 mg or 90 mg Stelara compared with patients randomized to placebo when measured by the NAPSI score (p≤0.001). Improvements in physical and mental component summary scores of the SF-36 and in the Itch Visual Analogue Scale (VAS) were also significant in each Stelara treatment group compared with placebo (p<0.001). In PHOENIX 2, the Hospital Anxiety and Depression Scale (HADS) and Work Limitations Questionnaire (WLQ) were also significantly improved in each Stelara treatment group compared with placebo (p<0.001).

ACCEPT

Significantly greater proportions of subjects treated with Stelara 45 mg (67%; p = 0.012) or 90 mg (74%; p < 0.001) were PASI 75 responders at Week 12 compared with the etanercept group (56.8%). PASI 90 response was observed in 36% and 45 % of patients in the Stelara 45 mg and 90 mg groups, respectively, compared with 23% of patients receiving etanercept (p<0.001 for each comparison versus etanercept). PASI 100 response was observed in 12% and 21% of patients in the Stelara 45 mg and 90 mg groups, respectively, compared to 6% of patients receiving etanercept (Table 17). In addition, a greater proportion of patients in the Stelara 45 mg and 90 mg treatment groups achieved a PGA score of “cleared” or “minimal” (65 % and 71 %, respectively) compared with patients in the etanercept treatment group (49 %) (p<0.001 for each comparison versus etanercept).

Table 17: Clinical outcomes at Week 12: ACCEPT

	ACCEPT		
	Etanercept (50mg twice a week)	Stelara (at week 0 and week 4)	
		45 mg	90 mg
Patients randomized	347	209	347
PASI response			
PASI 50 response	286 (82%)	181 (87%)	320 (92%)[a]
PASI 75 response	197 (57%)	141 (67%)[b]	256 (74%)[a]
PASI 90 response	80 (23%)	76 (36%)[a]	155 (45%)[a]
PASI 100 response	22 (6%)	25 (12%)[c]	74 (21%)[a]
PGA of Cleared or Minimal[a]	170 (49%)	136 (65%)[a]	245 (71%)[a]
PASI 75 RESPONSE BY WEIGHT			
≤ 100 kg			
N	251	151	244
PASI 75 response	154 (61%)	109 (72%)	189 (77%)
> 100 kg			
N	96	58	103
PASI 75 response	43 (45%)	32 (55%)	67 (65%)
PGA of Cleared or Minimal by weight			
≤ 100 kg			
N	251	151	244
PGA response	131 (52%)	110 (73%)	185 (76%)
> 100 kg			

	ACCEPT		
	Etanercept (50mg twice a week)	Stelara (at week 0 and week 4)	
		45 mg	90 mg
N	96	58	103
PGA response	39 (41%)	26 (45%)	60 (58%)

[a] p <0.001 for Stelara 45 mg or 90 mg comparison with etanercept.
[b] p =0.012 for Stelara 45 mg comparison with etanercept.
[c] p =0.020 for Stelara 45 mg comparison with etanercept.

Greater proportions of subjects in the Stelara 45 mg and 90 mg groups achieved PASI 75 responses when compared with subjects in the etanercept group regardless of a subject's previous psoriasis medication history.

Pediatric Plaque Psoriasis (6 to 17 years of age)

The safety and efficacy of Stelara in pediatric patients with plaque psoriasis was assessed in two multicenter phase 3 studies, CADMUS and CADMUS Jr.

Plaque Psoriasis – Pediatrics (12 to 17 years of age): CADMUS

The efficacy of Stelara was studied in 110 pediatric patients 12 to 17 years of age, in a multicenter, Phase 3, randomized, double blind, placebo-controlled study (CADMUS). Two distinct, subcutaneous weight based dosages of Stelara were studied. Randomization was stratified by investigational site and baseline weight (≤ 60 kg or > 60 kg).

Patients were randomized to one of four treatment groups (Groups 1, 2, 3a and 3b) at week 0 as follows:
Group 1: Stelara half-standard dosage at Weeks 0 and 4 followed by doses every 12 weeks, with the last dose at Week 40.
Group 2: Stelara standard dosage at Weeks 0 and 4 followed doses every 12 weeks, with the last dose at Week 40.
Group 3: Placebo at Weeks 0 and 4. At Weeks 12 and 16, subjects crossed over to receive either Stelara half-standard dosage (Group 3a) or standard dosage (Group 3b) followed by doses every 12 weeks, with the last dose at Week 40. The dosage assignment (Group 3a or 3b) following crossover was randomly assigned at week 0, ensuring that the assignment remained double blinded throughout the duration of the study.
All subjects were followed for efficacy through Week 52 and for safety through Week 60.

Adolescent patients with a diagnosis of plaque-type psoriasis for at least 6 months prior to first study agent administration, who had moderate to severe disease, and with PASI ≥ 12, PGA ≥ 3 and BSA involvement of at least 10%, and who were candidates for systemic or phototherapy, were eligible for the study. 43% and 11% of subjects had prior exposure to conventional systemic or biologic therapies respectively.

The primary endpoint was the proportion of patients who achieve a PGA score of cleared (0) or minimal (1) at Week 12. Secondary endpoints included PASI 75 at Week12. Subjects who discontinued study treatment due to lack of efficacy, an adverse event (AE) of psoriasis, or who

started a protocol-prohibited medication/therapy prior to Week 12 were considered as non-responders. Subject with missing PGA or PASI scores at Week 12 were considered non-responders. For the Week 12 analysis, any subject receiving moderate to high potency topical steroid preparations were considered as non-responders.

The study population were predominantly Caucasian (89%) and 51% were female. Median body weight was 61.6 kg, 56% had a body weight of between 50 and 70 kg and the median body mass index was 22.15 kg/m^2. Median psoriasis duration was 5.29 years with median age at onset of 10 years. The majority of subjects (70.0%) were 15 to 17 years of age, with a median age of 15.5 years. 57% of subjects had ≥ 20% body surface area affected with psoriasis and median PASI score was 18.8 (range 12-51), and 62% and 38% of subjects had PGA scores of moderate and marked/severe respectively.

Table 18: Summary of patient demographics for CADMUS

Study #	Study design	Dosage, route of administration and duration	Study subjects (n)	Mean age (Range)	Sex
CNTO1275 PSO3006 (CADMUS)	Double-Blind Placebo-Controlled	Fixed doses (weight based): Placebo (N=37) Placebo → Half-standard dosage (N=19) Placebo → Standard dosage (N=18) Half-standard dosage Weeks 0, 4 then q12w (N=37) Standard dosage Weeks 0, 4 then q12w (N=36)	N=110	15,2 (12,17)	M=54 (49%) F=56 (51%)

Study Results

At Week 12, subjects treated with Stelara showed significantly greater improvement in their psoriasis compared with placebo (Table 19).

Table 19: Summary of Primary and Secondary End-points at Week 12

	Placebo	Stelara Half Standard Dose	Stelara Standard Dose
	n (%)	n (%)	n (%)
Patients randomized at Week 0	37	37	36
Number of patients who achieved a PGA score of cleared (0) or minimal (1)	2 (5.4%)	25 (67.6%)[a]	25 (69.4%)[a]
PASI 75 responders	4 (10.8%)	29 (78.4%)[a]	29 (80.6%)[a]

[a] p<0.001

P-values are based on the Cochran-Mantel-Haenszel chi-square test stratified by baseline weight (≤ 60kg, > 60kg).

Multiplicity was controlled by sequential testing of endpoints.

All patients were followed for efficacy for up to 52 weeks following first administration of study agent. The PGA scores of cleared (0) or minimal (1) and PASI 75 responders at Week 52 are summarized in Table 20.

Table 20: Summary of Secondary Endpoints at Week 52

	Stelara Half- Standard Dose	Stelara Standard Dose
Number of evaluable subjects at Week 52	n=34	n=35
Number of patients who achieved a PGA score of cleared (0) or minimal (1)	20 (58.8%)	20 (57.1%)
PASI 75 responders	23 (67.6%)	28 (80%)

Plaque Psoriasis – Pediatrics (6 to 11 years of age): CADMUS Jr

The efficacy of Stelara was studied in 44 pediatric patients 6 to 11 years of age with moderate to severe plaque psoriasis in an open label, single-arm, multicenter, Phase 3 study. Patients were treated with the recommended dose of Stelara (n=44) based on body weight measured at each visit (see 4.2 Recommended Dose and Dosage Adjustment) by subcutaneous injection at Weeks 0 and 4 followed by every 12 week (q12w) dosing.

The primary endpoint was the proportion of patients who achieved a PGA score of cleared (0) or minimal (1) at Week 12. Secondary endpoints included PASI 75 at Week 12.

Patients with moderate to severe plaque-type psoriasis with or without psoriatic arthritis (PsA) for at least 6 months prior to first administration of study drug, with widespread lesions defined by PASI ≥ 12, PGA ≥ 3, and involved BSA ≥ 10% and who were candidates for phototherapy or systemic treatment or had psoriasis poorly controlled with topical therapy after an adequate dose and duration of therapy were eligible for the study. Approximately 18% and 5% of patients had prior exposure to conventional systemic or biologic therapies respectively. The study population was predominantly Caucasian (91%) and 61% were female. The median body weight was 33.3 kg, with 91% of patients having a body weight less than 60 kg. The median body mass index was 18.0 kg/m^2. The median psoriasis duration was 2.9 years and the median age of onset of disease was 6.0 years. The median percent of BSA affected with psoriasis was 18.0%. The median PASI score was 16.1. The median age was 9.5 years, with 50.0% of subjects < 10 years of age. All ages across the age range (≥ 6 to < 12 year of age) were represented in the study population. The majority of subjects (65.9%) had PGA scores of moderate and 34.1% had a PGA score of marked or severe. The median PASI score was 16.1 and the median Children's Dermatology Life Quality Index (CDLQI) score was 7.0 (representing a moderate impact of psoriasis on quality of life).

Table 21: Summary of patient demographics for CADMUS Jr

Study #	Study design	Dosage, route of administration and duration	Study subjects (n)	Mean age (Range)	Sex
CNTO1275 PSO3013 (CADMUS Jr)	Open-label single arm, multicentre	Fixed doses (weight based): Standard dosage (0.75 mg/kg for patients < 60 kg, 45 mg for patients ≥ 60 kg to ≤ 100 kg and 90 mg for patients > 100 kg) Weeks 0, 4 then q12w (N=36)	N=44	8.9 (6,11)	M=17 (39%) F=27 (61%)

Study Results

At Week 12, patients treated with Stelara showed clinically meaningful improvements in their psoriasis. All patients were followed for efficacy for up to 52 weeks following first administration Stelara. The PGA scores and PASI 75 responders at Week 12 and 52 are summarized in Table 22. Efficacy measured by PGA score of 0 or 1 was observed as early as the first post-baseline visit at Week 4 and increased through Week 16 and then remained relatively stable through Week 52. Improvements in PGA and PASI were maintained through Week 52.

Table 22: Summary of Primary and Secondary End-points at Week 12 and 52: CADMUS Jr. (Age 6-11)

	Stelara Week 12	**Stelara Week 52**
	N (%)	N (%)
Patients enrolled at Week 0	44	41
Number of patients who achieved a PGA score of cleared (0) or minimal (1)	34 (77.3%)	31 (75.6%)
PGA of cleared (0)	17 (38.6%)	23 (56.1%)
PASI 75 responders	37 (84.1%)	36 (87.8%)

Psoriatic Arthritis

The safety and efficacy of Stelara was assessed in two multicenter, randomized, double-blind, placebo-controlled, phase 3 studies, PSUMMIT I and PSUMMIT II, in patients with active psoriatic arthritis. Patients were randomized to receive treatment with either Stelara 45 mg, 90 mg, or placebo subcutaneous injections at Weeks 0 and 4 followed by every 12 week (q12w) dosing. The primary endpoint in these studies was the reduction in the signs and symptoms of psoriatic arthritis (PsA) as measured by the percentage of ACR 20 responders at Week 24. Secondary endpoints included change from baseline in Disability Index of the Health Assessment Questionnaire (HAQ-DI), PASI 75, ACR 50, ACR 70 and change from baseline in total radiographic scores of the hands and feet at Week 24. Efficacy data were collected and analyzed through Week 52.

These studies included 927 adult patients (≥18 years) who had active psoriatic arthritis (≥5 swollen joints and ≥5 tender joints, despite disease modifying antirheumatic (DMARD) and/or nonsteroidal anti-inflammatory (NSAID) therapy. Methotrexate (MTX) use was allowed during the studies but was not mandatory. Approximately 50% of patients continued on stable doses of MTX (≤25 mg/week). In PSUMMIT I and PSUMMIT II, 80% and 86% of the patients, respectively, had been previously treated with DMARDs.

In PSUMMIT I patients, who had been previously treated with anti-TNFα therapy, prior to the first study dose, were excluded. In PSUMMIT II, the majority of patients (58%, n=180) had been previously treated with one or more an anti-TNFα agent(s) for at least 8 weeks (14 weeks with infliximab) or had discontinued anti-TNFα for intolerance at any time. Among the patients who had been previously treated with an anti-TNFα agent, over 70% had discontinued their anti-TNFα treatment for lack of efficacy or intolerance.

Patients with each subtype of psoriatic arthritis were enrolled, including polyarticular arthritis with no evidence of rheumatoid nodules (39%, N=362), spondylitis with peripheral arthritis (28%, N=255), asymmetric peripheral arthritis (21%, N=193), distal interphalangeal (DIP) arthritis (12%, N=112) and arthritis mutilans (0.5%, N=5). Over 70% and 40% of the patients in both studies had enthesitis and dactylitis at baseline, respectively.

Table 23: Summary of patient demographics in PSUMMIT I and PSUMMIT II

Study #	Study design	Dosage, route of administration and duration	Study subjects (n)	Mean age (Range)	Sex
CNTO1275 PSA3001 (PSUMMIT I)	Double-Blind Placebo-Controlled	Placebo SC (n=206): Placebo SC at Weeks 0, 4,16, and 20 Placebo→45 mg SC at Weeks 24 and 28 followed by q12w dosing through Week 88 45 mg SC (n=205): 45 mg SC at Weeks 0 and 4 followed by q12w dosing through Week 88 90 mg SC (n=204): 90 mg SC at Weeks 0 and 4 followed by q12w dosing through Week 88	615	47.1 (18, 81)	M=330 F=285
CNTO1275 PSA3002 (PSUMMIT II)	Double-Blind Placebo-Controlled	Placebo SC (n=104): Placebo SC at Weeks 0, 4, 16, and 20 45 mg SC at Weeks 24 and 28 followed by q12w dosing through Week 40 45 mg SC (n=103): 45 mg SC at Weeks 0 and 4 followed by q12w dosing through Week 40 90 mg SC (n=105): 90 mg SC at Weeks 0 and 4 followed by q12w dosing through Week 40	312	48.0 (19, 75)	M=148 F=164

Study Results

Reduction in Signs and Symptoms

In both studies, a significantly greater proportion of patients achieved ACR 20 and ACR 50 responses at Week 24 in the Stelara 45 mg and 90 mg groups compared to placebo (Table 24). In PSUMMIT I, a significantly greater proportion of patients and in PSUMMIT II, a numerically

greater proportion of patients (p=NS) achieved ACR 70 responses in the Stelara 45 mg and 90 mg groups compared to placebo (Table 24).

Table 24: Number of patients who achieved ACR 20, ACR 50 and ACR 70 at Week 24

	PSUMMIT I			PSUMMIT II		
		Stelara			Stelara	
	Placebo (N=206)	45 mg (N= 205)	90 mg (N= 204)	Placebo (N= 104)	45 mg (N= 103)	90 mg (N= 105)
ACR 20	47 (23%)	87 (42%) [a]	101 (50%) [a]	21 (20%)	45 (44%)[a]	46 (44%) [a]
ACR 50	18 (9%)	51 (25%) [a]	57 (28%) [a]	7 (7%)	18 (17%) [b]	24 (23%) [a]
ACR 70	5 (2%)	25 (12%) [a]	29 (14%) [a]	3 (3%)	7 (7%) [c]	9 (9%) [c]

[a] $p<0.001$, [b] $p<0.05$, [c] p= NS

An ACR 20 response (Felson et al, 1995) was defined as:

1. ≥ 20% improvement in swollen joint count (66 joints) and tender joint count (68 joints); and
2. ≥ 20 % improvement in ≥3 of the following 5 assessments:

- Patient's assessment of pain [Visual Analog Scale (VAS)]
- Patient's global assessment of disease activity (VAS)
- Physician's global assessment of disease activity (VAS)
- Patient's assessment of physical function as measured by the HAQ-DI
- CRP

ACR 50 or ACR 70 are similarly defined.

The time course for ACR 20 response rates during the first 24 weeks in both studies for patients receiving Stelara or placebo are summarized in Figure 2. During the controlled phase of the studies, ACR 20 responses showed improvement at the first assessment (Week 4) and maximum responses were achieved at Week 20 or 24. ACR 20, 50 and 70 responses continued to improve or were maintained through Week 52.

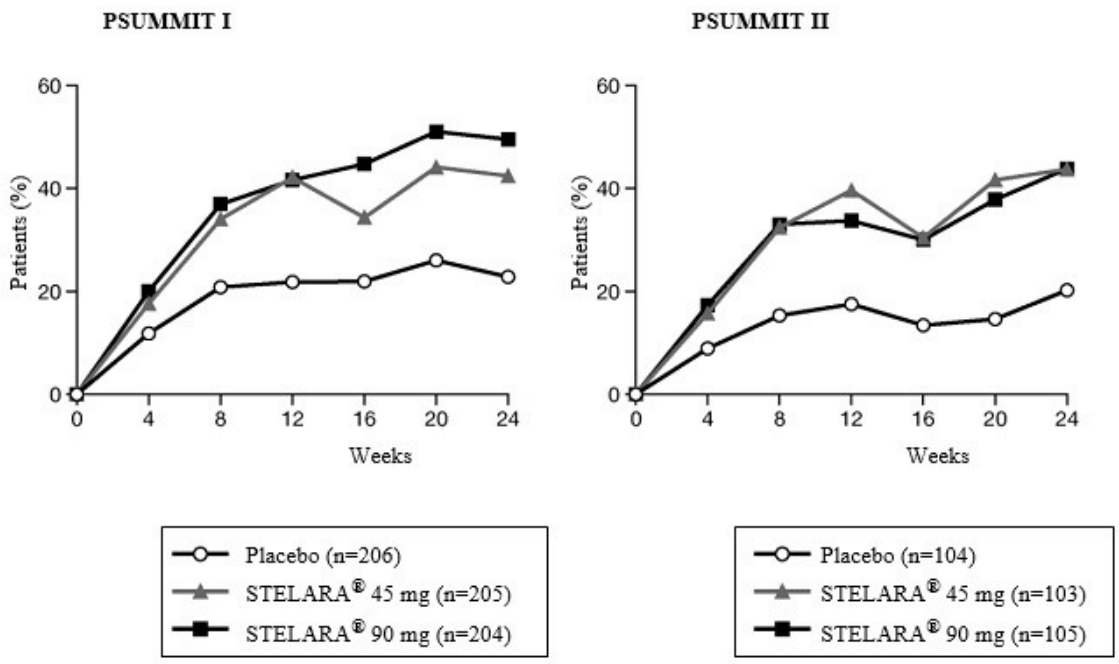


Figure 2: Percent of patients achieving ACR 20 response through Week 24

In PSUMMIT I, of 205 subjects randomized to Stelara 45 mg, 153 continued the same dose and were available for evaluation at Week 52. Among those, ACR 20, 50 and 70 responses were achieved by 99 (64.7%), 57 (37.3%) and 34 (22.2%) subjects respectively. Of 204 subjects randomized to Stelara 90 mg, 185 were available for evaluation at Week 52. Among those, ACR 20, 50 and 70 responses were achieved by 120 (64.9%), 74 (40%) and 41 (22.2%) subjects respectively.

In PSUMMIT II, of 103 subjects randomized to Stelara 45 mg, 68 continued the same dose and were available for evaluation at Week 52. Among those, ACR 20, 50, and 70 responses were achieved by 41 (60.3%), 23 (33.8%) and 11 (16.2%) subjects respectively. Of 105 subjects randomized to Stelara 90 mg, 83 were available for evaluation at Week 52. Among those, ACR 20, 50 and 70 responses were achieved by 49 (59%), 26 (31.3%) and 17 (20.5%) subjects respectively.

Additionally, within each weight group (≤100 kg and >100 kg), ACR 20, ACR 50 and ACR 70 responses were consistently higher in the Stelara 45 mg and 90 mg groups than in the placebo group (Table 25).

Table 25: Number of patients who achieved ACR 20, ACR 50 and ACR 70 responses by weight at Week 24

	PSUMMIT I			PSUMMIT II		
		Stelara			Stelara	
	Placebo (N=206)	45 mg (N=205)	90 mg (N=204)	Placebo (N=104)	45 mg (N=103)	90 mg (N=105)

Patients randomized with weight ≤100 kg at baseline	154	153	154	74	74	73
ACR 20	39 (25%)	67 (44%)	78 (51%)	17 (23%)	32 (43%)	34 (47%)
ACR 50	14 (9%)	38 (25%)	48 (31%)	6 (8%)	15 (20%)	21 (29%)
ACR 70	5 (3%)	20 (13%)	26 (17%)	3 (4%)	6 (8%)	8 (11%)
Patients randomized with weight >100 kg at baseline	52	52	50	30	29	31
ACR 20	8 (15%)	20 (38%)	23 (46%)	4 (13%)	13 (45%)	12 (39%)
ACR 50	4 (8%)	13 (25%)	9 (18%)	1 (3%)	3 (10%)	3 (10%)
ACR 70	0	5 (10%)	3 (6%)	0	1 (3%)	1 (3%)

Stelara treatment resulted in significantly greater improvement compared with placebo for each ACR component at week 24 (Table 26).

Table 26: Median percent improvement from baseline in ACR components at Week 24

	PSUMMIT I			**PSUMMIT II**		
		Stelara			**Stelara**	
	Placebo (N=206)	**45 mg (N=205)**	**90 mg (N=204)**	**Placebo (N=104)**	**45 mg (N=103)**	**90 mg (N=105)**
Number of swollen joints [d]	21.54	58.82 [a]	60.00 [a]	0.00	52.94 [b]	50.00 [c]
Number of tender joints [e]	13.61	45.45 [a]	51.51 [a]	0.00	33.33 [a]	35.00 [c]
Patient's assessment of pain [f]	0.00	31.33 [a]	42.58 [a]	0.00	24.19 [a]	24.29 [a]
Patient global assessment [f]	4.11	32.84 [a]	42.44 [a]	0.00	21.25 [a]	22.54 [a]
Physician global assessment [f]	17.64	48.39 [a]	55.91 [a]	0.83	36.67 [a]	36.11 [a]
Disability index (HAQ-DI)[g]	0.00	22.22 [a]	32.46 [a]	0.00	12.50 [a]	14.29 [a]
CRP (mg/dL) [h]	0.00	38.56 [a]	48.30 [a]	0.00	25.61 [c]	33.69 [a]

[a] p<0.001
[b] p<0.05
[c] p<0.01
[d] Number of swollen joints counted (0-66)
[e] Number of tender joints counted (0-68)
[f] Visual analogue scale; 0=best, 10=worst.
[g] Disability Index of the Health Assessment Questionnaire; 0=best, 3=worst, measures the patient's ability to perform the following: dress/groom, arise, eat, walk, reach, grip, maintain hygiene, and maintain daily activity.
[h] CRP: (Normal Range 0.0-1.0 mg/dL)

In PSUMMIT I and PSUMMIT II, the proportion of subjects with good or moderate Disease Activity Index Score 28 using C-reactive protein (DAS28-CRP) responses and the proportion of subjects in DAS28 remission were greater in both Stelara-treated groups compared to placebo at Week 24. DAS28-CRP responses were maintained through Week 52.

Methotrexate Use

The proportion of patients achieving ACR responses were consistently greater in patients treated with Stelara than those treated with placebo regardless of concomitant MTX use. Responses observed in the Stelara groups were similar in patients receiving or not receiving concomitant MTX. ACR responses were maintained through Week 52 (Table 27).

Table 27: Summary of patients achieving ACR 20, ACR 50 and ACR 70 responses through Week 24 by methotrexate usage

PSUMMIT I						
	Receiving MTX at baseline			*Not receiving MTX at baseline*		
		Stelara			**Stelara**	
	Placebo (N=206)	**45 mg (N=205)**	**90 mg (N=204)**	**Placebo (N=206)**	**45 mg (N=205)**	**90 mg (N=204)**
Patients randomized	96	99	101	110	106	103
ACR 20	25 (26%)	43 (43%)	46 (46%)	22 (20%)	44 (42%)	55 (53%)
ACR 50	8 (8%)	23 (23%)	27 (27%)	10 (9%)	28 (26%)	30 (29%)
ACR 70	2 (2%)	11 (11%)	13 (13%)	3 (3%)	14 (13%)	16 (16%)
PSUMMIT II						
	Receiving MTX at baseline			*Not receiving MTX at baseline*		
		Stelara			**Stelara**	
	Placebo (N=104)	**45 mg (N=103)**	**90 mg (N=105)**	**Placebo (N=104)**	**45 mg (N=103)**	**90 mg (N=105)**
Patients randomized	49	54	52	55	49	53
ACR 20	14 (29%)	27 (50%)	21 (40%)	7 (13%)	18 (37%)	25 (47%)
ACR 50	4 (8%)	10 (19%)	12 (23%)	3 (5%)	8 (16%)	12 (23%)
ACR 70	2 (4%)	4 (7%)	3 (6%)	1 (2%)	3 (6%)	6 (11%)

Prior Anti-TNFα therapy

PSUMMIT II evaluated 180 patients who were previously treated with one or more anti-TNFα agents for at least 8 weeks (14 weeks with infliximab), or had documented intolerance of anti-TNFα therapy at any time in the past.

Among patients previously treated with anti-TNFα agents, a greater proportion of Stelara-treated patients in both the 45 mg and 90 mg groups achieved an ACR 20 response at Week 24 compared to placebo (37% and 34% vs 15%). ACR 20 response was generally maintained through Week 52.

Enthesitis and Dactylitis

For patients with enthesitis and/or dactylitis at baseline, in PSUMMIT I, greater improvement in enthesitis and dactylitis score was observed in the Stelara 45 mg and 90 mg groups compared to placebo. For enthesitis, the median improvement was 43% and 50% for each dose group respectively, compared to 0% for placebo. For dactylitis, the median improvement was 75% and

71% for each dose group respectively, compared to 0% for placebo. In PSUMMIT II, a greater improvement was observed in enthesitis score in both doses and in dactylitis score in the 90 mg group compared with the placebo group. In both studies, improvement in enthesitis score and dactylitis score were maintained at Week 52.

Psoriasis Skin Response

In PSUMMIT I and PSUMMIT II, the proportion of patients with psoriasis involvement of ≥3% BSA at baseline who achieved a ≥75% improvement in the PASI assessment at Week 24 was significantly greater in the Stelara 45 mg and 90 mg groups compared with the placebo group (Table 28). In both studies the proportion of patients achieving the PASI 75 response was maintained through Week 52.

Table 28: Number of patients who achieved PASI 75, PASI 90 and PASI 100 responses at Week 24

	PSUMMIT I			PSUMMIT II		
		Stelara [a]			Stelara [a]	
	Placebo (N=206)	45 mg (N=205)	90 mg (N=204)	Placebo (N= 104)	45 mg (N=103)	90 mg (N=105)
Patients with ≥ 3% BSA psoriasis skin involvement at baseline	146	145	149	80	80	81
PASI 75	16 (11%)	83 (57%)	93 (62%)	4 (5%)	41 (51%)	45 (56%)
PASI 90	4 (3%)	60 (41%)	65 (44%)	3 (4%)	24 (30%)	36 (44%)
PASI 100	2 (1%)	29 (20%)	41 (28%)	1 (1%)	13 (16%)	17 (21%)

[a] p<0.001 for 45 mg or 90 mg comparison with placebo.

Additionally, within each weight group (≤ 100 kg and > 100 kg), PASI 75, 90 and 100 responses were consistently higher in the Stelara 45 mg and 90 mg groups than in the placebo group. In both studies, the proportion of patients who achieved a PASI 75 response at Week 24 was consistently higher in Stelara 45 mg and 90 mg groups compared with placebo regardless of concomitant MTX use. PASI 75 responses were maintained through Week 52.

Radiographic Response

Structural damage in both hands and feet was assessed by readers unaware of treatment group and order of visits, and expressed as change in total van der Heijde-Sharp score (vdH-S score), modified for PsA by addition of hand distal interphalangeal (DIP) joints, compared to baseline. A pre-specified major secondary endpoint based on the integrated analysis combining data from 927 subjects in both PSUMMIT I and PSUMMIT II was performed. At Week 24, based on this integrated analysis, patients treated with either Stelara 45 mg (n=308, mean change in total vdH-S score=0.40) or 90 mg (n=309, mean change=0.39) demonstrated significantly less progression of structural damage compared to placebo (n=310, mean change=0.97), p<0.05 and p<0.001 for the 45 mg and 90 mg groups, respectively. This effect was demonstrated irrespective of concomitant MTX use, and was maintained through Week 52.

Similar results were seen in PSUMMIT I for patients treated with either Stelara 45 mg (n=205, mean change=0.28) or 90 mg (n=204, mean change=0.17) compared to placebo (n=206, mean

change=1.20). In PSUMMIT II, the mean change was 0.66 for 45 mg (n=103), 0.81 for 90 mg (n=105) and 0.51 for placebo (n=104).

Physical Function and Health-Related Quality of Life

In PSUMMIT I and PSUMMIT II, physical function and health-related quality of life were assessed using the Disability Index of the Health Assessment Questionnaire (HAQ-DI) and the SF-36 health survey.

Patients treated with Stelara 45 mg and 90 mg showed significant improvement in physical function as assessed by the HAQ-DI at Week 24 as compared to placebo in both PSUMMIT I and PSUMMIT II. The proportion of patients achieving a clinically meaningful ≥ 0.3 improvement in HAQ-DI score from baseline at Week 24 was also significantly greater in the Stelara groups when compared with placebo. Improvement was observed at the first assessment (Week 4), reached maximum at Week 12 and was maintained through Week 24. In both studies the improvement in HAQ-DI at Week 24 was consistently greater in the Stelara 45 mg and 90 mg groups compared with placebo regardless of concomitant MTX use. Improvement in HAQ-DI score from baseline was maintained at Week 52 (Table 29).

Table 29: Improvement in physical function as measured by HAQ-DI at Week 24

	PSUMMIT I			**PSUMMIT II**		
		Stelara			**Stelara**	
	Placebo (N=206)	**45 mg (N=205)**	**90 mg (N=204)**	**Placebo (N=104)**	**45 mg (N=103)**	**90 mg (N=105)**
HAQ-DI Baseline Score						
N	204	205	204	104	103	104
Mean (SD)	1.24 (0.647)	1.22 (0.610)	1.22 (0.634)	1.25 (0.723)	1.34 (0.704)	1.29 (0.666)
Median	1.25	1.25	1.25	1.25	1.38	1.25
Improvement in HAQ-DI						
N[c]	206	205	204	104	103	105
Mean (SD)	0.10 (0.390)	0.31 (0.521)	0.40 (0.514)	0.03 (0.380)	0.21 (0.461)	0.22 (0.436)
Median	0.00	0.25[a]	0.25[a]	0.00	0.13[b]	0.25[a]
HAQ-DI Responders*	58 (28%)	98 (48%)[a]	97 (48%)[a]	17 (16%)	35 (34%)[b]	40 (38%)[a]

[a] p<0.001

[b] p<0.01

[c] Includes all randomized subjects

* achieving a ≥ 0.3 improvement from baseline

In PSUMMIT I, of 205 subjects randomized to Stelara 45 mg, 153 continued the same dose and were available for evaluation at Week 52. Among those, the HAQ-DI response was achieved by 83 (54.2%) subjects. Of 204 subjects randomized to Stelara 90 mg, 185 were available for evaluation at Week 52. Among those, HAQ-DI response was achieved by 102 (55.1%) subjects.

In PSUMMIT II, of 103 subjects randomized to Stelara 45 mg, 68 continued the same dose and were available for evaluation at Week 52. Among those, the HAQ-DI response was achieved by

29 (42.6%) subjects. Of 105 subjects randomized to Stelara 90 mg, 83 were available for evaluation at Week 52. Among those, HAQ-DI response was achieved by 44 (53%) subjects.

In both PSUMMIT I and PSUMMIT II, at Week 24, the change from baseline in the SF-36 physical component summary (PCS) scores was significantly greater in the Stelara 45 mg and 90 mg groups compared with the placebo group. In both studies, the change from baseline in the SF-36 mental component summary (MCS) scores at Week 24 was greater in both Stelara groups compared with the placebo group. In both studies, the change from baseline in the SF-36 PCS and MCS scores was maintained at Week 52.

The DLQI was assessed by comparing the change in DLQI scores from baseline for those patients with ≥3% BSA at baseline. In both studies at Week 24, there was a greater improvement from baseline in DLQI scores in both the Stelara 45 mg and 90 mg groups as compared with placebo and the improvement was maintained at Week 52.

In PSUMMIT II, the improvement from baseline in Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) scores at Week 24 was greater in the Stelara 45 mg and 90 mg groups compared with the placebo group. Similarly, the percentage of patients with clinically meaningful improvement in fatigue from baseline (4 points in FACIT-F) was greater in both dose groups compared with the placebo group. The change from baseline in the FACIT-F scores was maintained at Week 52.

Crohn's Disease

The safety and efficacy of Stelara/Stelara I.V. were evaluated in three randomized, double-blind, placebo-controlled clinical trials in adult patients with moderately to severely active Crohn's disease (Crohn's Disease Activity Index [CDAI] score of 220 to 450). The clinical development program consisted of two 8-week IV induction studies (UNITI-1 and UNITI-2) followed by a 44-week subcutaneous randomized withdrawal maintenance study (IM-UNITI) representing 52 weeks of therapy (Table 30).

Table 30: Summary of controlled clinical trials supporting safety and efficacy in patients with CD

Study #	Study Design	Dosage: Route of Administration and Duration	Study Subjects (n)	Median Age (Range)	Sex
UNITI-1 (Induction)	Multicentre, double-blinded, randomized, placebo-controlled	IV administration at Week 0	741	36 (18, 71)	M: 317, 43 F: 424, 57
		Placebo	247		
		Stelara I.V. 130 mg	245		
		Stelara I.V. ~6 mg/kg[a]	249		
UNITI-2 (Induction)	Multicentre, double-blinded, randomized, placebo-controlled	IV administration at Week 0	628	37.0 (18, 77)	M:293, 47 F:335, 53
		Placebo	210		
		Stelara I.V. 130 mg	209		
		Stelara I.V. ~6 mg/kg[a]	209		
IM-UNITI (Maintenance)	Multicentre, double-blinded, placebo-controlled randomized-withdrawal,	SC administration at Week 0 [b], and then q8w or q12w for 44 weeks	397	36.0 (18, 75)	M:173, 44 F: 224, 56
		placebo	133		
		Stelara 90 mg q8w	132		
		Stelara 90 mg q12 w	132		

[a] tiered weight-based dose approximating 6 mg/kg (see 4 DOSAGE AND ADMINISTRATION)
[b] 8 weeks following the intravenous dose of Stelara I.V.

Induction Studies: UNITI-1 and UNITI-2

UNITI-1 and UNITI-2 studies included 1409 (UNITI-1, n=769; UNITI-2 n=640) patients. Of these subjects, 1368 (UNITI-1, n=741; UNITI-2, n=627) patients are included in the final efficacy analysis. In both studies, patients were permitted to concomitantly receive oral 5-ASA compounds, immunomodulators, corticosteroids, and/or antibiotics. Patients were randomized to receive a single IV administration of either 130 mg Stelara I.V., or approximately 6 mg/kg Stelara I.V. designed as a tiered dose based on patient body weight (Table 3) or placebo at Week 0.

The primary endpoint for UNITI-1 and UNITI-2 was clinical response defined as a reduction in CDAI score of ≥ 100 points or CDAI score < 150 (for subjects with a baseline CDAI score of ≥ 220 to ≤ 248) at Week 6. Secondary endpoints included clinical remission (CDAI score of < 150 points) at Week 8, clinical response at Week 8, 70-point response at Week 3, and 70-point response at Week 6. Efficacy data were collected and analyzed through Week 8 for both studies.

In UNITI-1, patients had failed or were intolerant to prior anti-TNFα therapy. At baseline, patients had a median (min, max) baseline CDAI score of 317 (198, 515), and approximately 46% (n=340) patients were receiving corticosteroids (including budesonide) and 31.4% of patients were receiving immunomodulators. Approximately 48% had failed 1 prior anti-TNFα therapy and 52% had failed 2 or 3 prior anti-TNFα therapies (40.8% and 10.4%, respectively). In this study, 29.1% patients had an inadequate initial response (primary non-responders), 69.4%

responded but subsequently lost response (secondary non-responders), and 36.4% were intolerant to anti-TNFα therapies.

Patients in UNITI-2 had failed at least one conventional therapy (corticosteroids or immunomodulators) and were either anti-TNFα naïve (68.6%) or had previously received but not failed anti-TNFα therapy (31.4%). At baseline, patients had a median (min, max) baseline CDAI score of 292.5 (198, 608), and approximately 40% patients were receiving corticosteroids (including budesonide) and 35% patients were receiving immunomodulators.

Maintenance: IM-UNITI

The maintenance study (IM-UNITI) evaluated 388 patients who achieved clinical response (≥ 100 point reduction in CDAI score or CDAI score < 150 [patients with a baseline CDAI score of ≥ 220 to ≤ 248]) at Week 8 of induction with Stelara I.V. in UNITI-1 or UNITI-2 out of 397 patients who were randomized into the study. Of those, approximately 60% of the patients entered the maintenance study in remission. Patients were randomized to receive a subcutaneous maintenance regimen of either 90 mg Stelara every 8 weeks, 90 mg Stelara every 12 weeks or placebo for an additional 44 weeks. Patients who completed the maintenance study through Week 44 were eligible to continue treatment through Week 272. An efficacy analysis was performed at Week 92 of the extension study.

Concomitant doses of oral 5-ASA compounds, immunomodulators, corticosteroids and antibiotics were permitted. At baseline, 45.6% of patients were receiving corticosteroids and 35% of patients were receiving immunomodulators. Corticosteroids were tapered at the start of the maintenance trial and during the trial in patients in clinical response. The primary endpoint was clinical remission (CDAI < 150) at Week 44 of maintenance. Secondary endpoints assessed at Week 44 of maintenance included clinical response, clinical remission among Stelara treated patients in clinical remission after induction, corticosteroid-free remission, and clinical remission in the subset of patients who were refractory or intolerant to anti-TNFα treatment. Other endpoints and planned analyses included evaluations for inflammatory markers, such as C-reactive protein and fecal calprotectin, fistula response, and patient reported outcomes.

Study Results

Induction of Response and Remission

In these induction studies, efficacy was higher and better sustained in the tiered dose group compared to the 130 mg dose group, and tiered dosing is therefore the recommended IV induction dose. In both UNITI-1 and UNITI-2, a significantly greater proportion of patients were in clinical response at Week 6 and remission at Week 8 in the group treated with Stelara I.V. compared to placebo (Table 31, Figure 3). Clinical response and remission were observed as early as Week 3 in Stelara I.V. treated patients and continued to improve through Week 8 (Figure 3)

Table 31: Induction of Clinical Response and Remission in UNITI-1* and UNITI 2**

	UNITI-1			UNITI-2		
	Placebo N=247	**Stelara I.V. N=249**	**Treatment difference, 95% CI and p-value**	**Placebo N=209**	**Stelara I.V. N=209**	**Treatment difference, 95% CI and p-value**
Clinical Response Week 6[c]	53 (21.5%)	84 (33.7%)	12% (4%, 20%) p = 0.003[ab]	60 (28.7%)	116 (55.5%)	27% (18%, 36%) p < 0.001[ab]
Clinical Remission, Week 8[c]	18 (7.3%)	52 (20.9%)	14% (8%, 20%) p < 0.001[ab]	41 (19.6%)	84 (40.2%)	21% (12%, 29%) p < 0.001[ab]
Clinical Response Week 8[c]	50 (20.2%)	94 (37.8%)	18% (10%, 25%) p < 0.001[ab]	67 (32.1%)	121 (57.9%)	26% (17%, 35%) p < 0.001[ab]
70 Point Response, Week 6[c]	75 (30.4%)	109 (43.8%)	13% (5%, 22%) p = 0.002[ab]	81 (38.8%)	135 (64.6%)	19% (10%, 28%) p < 0.001[ab]
70 Point Response, Week 3[c]	67 (27.1%)	101 (40.6%)	13% (5%, 22%) p < 0.001[ab]	66 (31.6%)	106 (50.7%)	26% (17%, 35%) p < 0.001[ab]

Clinical remission is defined as CDAI score < 150; Clinical response is defined as reduction in CDAI score by at least 100 points or being in clinical remission (for subjects with a baseline CDAI score of ≥ 220 to ≤ 248).

70 point response is defined as reduction in CDAI score by at least 70 points

* Patients who failed or were intolerant to anti-TNF α agents

** Patients who failed or were intolerant to corticosteroids or immunomodulators. Patients may have previously received but not failed an anti- TNF α agent or were never treated with an anti-TNF α agent

[a] Based on a Cochran-Mantel-Haenszel chi-square test, stratified by study region (Asia, Eastern Europe, or Rest of World), CDAI score (≤ 300 or > 300), and initial response to TNF antagonist therapy (yes or no; CRD3001 only)

[b] To control the overall Type I error rate at the 0.05 significance level, the endpoints were tested in the hierarchical order presented in this table

[c] Subjects who had a prohibited Crohn's disease-related surgery, had prohibited concomitant medication changes, or had insufficient data to determine response and remission status were considered to not be in response or remission.

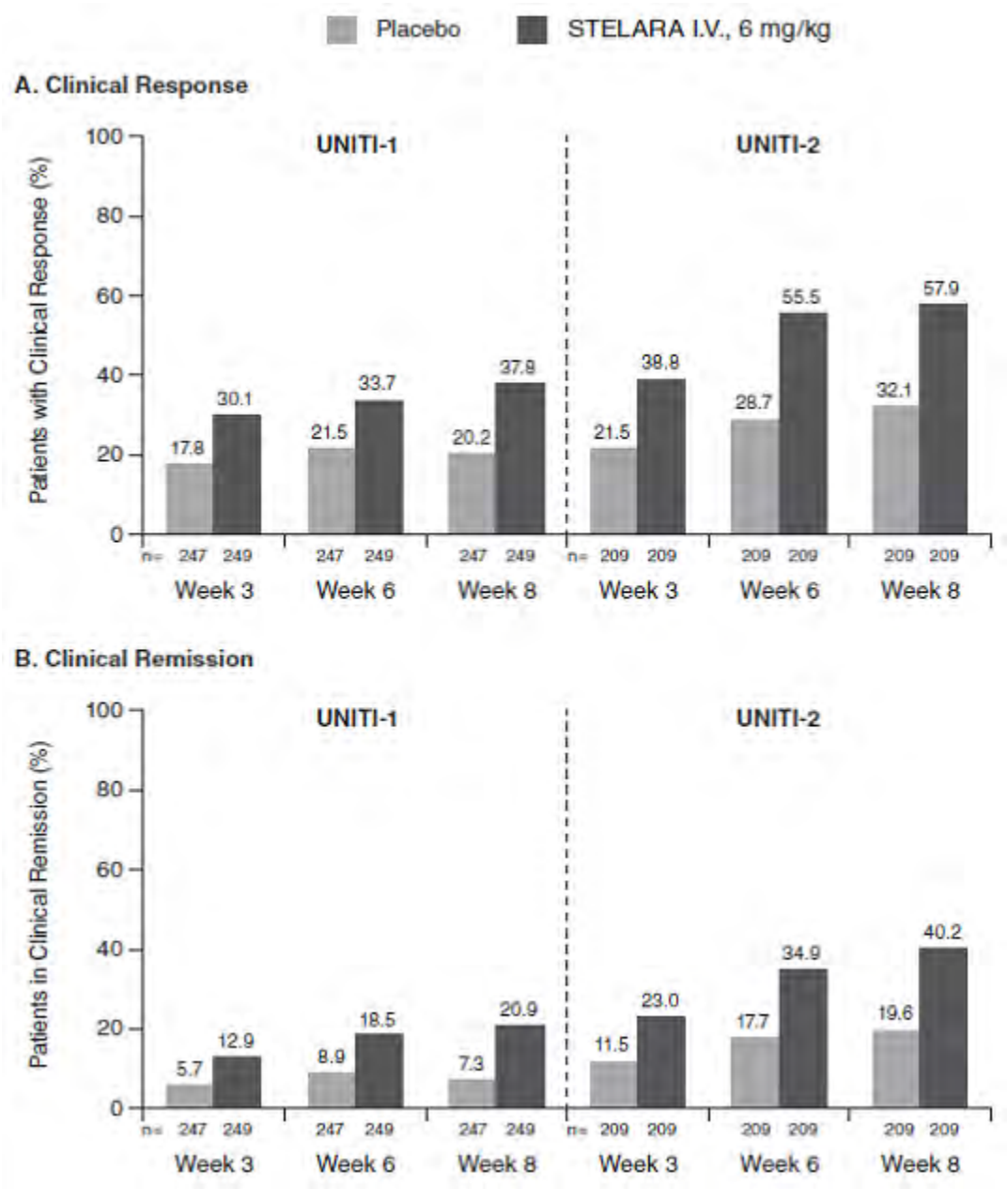


Figure 3: Proportion of Stelara I.V. treated patients in clinical response (A) and remission (B) through Week 8 in UNITI-1 and UNITI-2 studies

Anti-TNFα Naïve group

UNITI-2 evaluated 246 patients (69% of the UNITI-2 population) who have had an inadequate response, loss of response or were intolerant to conventional therapy but have never been exposed to anti-TNF α agents. Among this subgroup of patients, 56.3% of Stelara I.V.-treated patients and 32.6% of patients treated with placebo achieved a clinical response at Week 6.

Maintenance of Response and Remission

In IM-UNITI, significantly higher proportions of patients maintained clinical remission and response in the Stelara treated groups as compared to placebo at Week 44 of maintenance (Table 32).

Table 32: Maintenance of Clinical Response and Remission in IM-UNITI (Week 44; 52 weeks from initiation of the induction dose)

	Placebo* N=131†	90 mg Stelara every 12 weeks N=129†	Treatment difference, 95% CI and p-value	90 mg Stelara every 8 weeks N=128†	Treatment difference, 95% CI and p-value
Clinical Remission [c] n (%)	47 (35.9%)	63 (48.8%)	13% (1%, 25%) p = 0.040 [ab]	68 (53.1%)	17% (5%, 29%) p = 0.005 [ab]
Clinical Response [c] n (%)	58 (44.4%)	75 (58.1%)	14% (2%, 26%) p = 0.033 [ab]	76 (59.4%)	15% (3%, 27%) p = 0.018 [ab]
Clinical Remission in patients in remission at the start of maintenance therapy [c] n/N (%)	36/79 (45.6%)	44/7[illegible] (56.4[illegible]	10.8% (-5%, 26%) p = 0.189 [abd]	52/78 (66.7%)	21% (6%, 36%) p = 0.007 [ab]

Clinical remission is defined as CDAI score < 150; Clinical response is defined as reduction in CDAI of at least 100 points or being in clinical remission (for subjects with a baseline CDAI score of ≥ 220 to ≤ 248)

* The placebo group consisted of patients who were in response to Stelara and were randomized to receive placebo at the start of maintenance therapy.

† Patients who achieved a clinical response to Stelara I.V. at start of maintenance therapy

[a] Based on a Cochran-Mantel-Haenszel chi-square test, stratified by clinical remission status at Week 0 (yes or no), Stelara I.V. induction dose (130 mg or tiered doses approximating ustekinumab 6 mg/kg), and induction study (UNITI-1 or UNITI-2)

[b] To control the overall Type I error rate at the 0.05 significance level, the endpoints were tested in the hierarchical order presented in this table for the q8w dosing regimen and then in the same hierarchical order for the q12w regimen.

[c] Subjects who had a prohibited Crohn's disease-related surgery, had a loss of response, had prohibited concomitant medication changes, discontinued study agent due to lack of efficacy or due to an adverse event indicated to be of worsening Crohn's disease, or had insufficient data to determine the response and remission status were considered to not be in response or remission.

[d] p-value is not significant at the 0.05 level of significance.

Patients who were not in clinical response 8 weeks after Stelara I.V. induction were not included in the primary efficacy analysis for IM-UNITI; however, these patients were eligible to receive a 90 mg subcutaneous injection of Stelara upon entry in IM-UNITI. Of these patients, 236/467 (50.5%) achieved clinical response eight weeks later and were followed for the duration of the study.

In IM-UNITI, patients who did not maintain response to Stelara when treated every 12 weeks were allowed to increase the frequency of dosing and receive Stelara every 8 weeks. In these patients (n=29), 55% and 41% achieved clinical response and clinical remission respectively 16 weeks after dosing frequency adjustment.

Of the randomized patients in clinical remission at Week 44 who entered the long-term extension, 57/69 (83%) and 52/65 (80%) of patients who received Stelara q8w and q12w respectively were in clinical remission at Week 92. Of the randomized patients in clinical response at Week 44 who entered the long-term extension, 64/78 (82%) and 69/82 (84%) of patients who received Stelara q8w and q12w respectively were in clinical response at Week 92.

Corticosteroid Use in Maintenance

At Week 44, 47% and 43% of patients who received Stelara q8w and q12w respectively were corticosteroid-free and in clinical remission compared to 30% of patients in the placebo group. In the subgroup of patients who were on corticosteroids at baseline, 30% of subjects in the Stelara treated groups were corticosteroid free and in clinical remission at Week 44, compared to 15% in the placebo group.

Endoscopic Assessment of Bowel Mucosa

Mucosal disease of the bowel (ileum and colon) was evaluated in 252 patients with baseline endoscopic disease activity in a substudy. At Week 8, after a single IV induction dose, the reduction in Simplified Endoscopic Activity Score for Crohn's Disease (SES-CD) was -3.0 in patients treated with Stelara I.V. (n=83), compared -0.7 in patients treated with placebo (n=97).

Other Health Related Outcomes

Health-related quality of life was assessed by the disease specific instrument, Inflammatory Bowel Disease Questionnaire (IBDQ). In UNITI-1, the median change from baseline in the IBDQ score at Week 8 was 20 in the group treated with Stelara I.V. compared with 7 in the placebo group. The corresponding changes in UNITI-2 are 29 in the group treated with Stelara I.V. compared with 9 in the placebo group. At Week 44, the median change in IBDQ scores from Week 0 of the maintenance study was -2.5 in the Stelara q12w dose group and -2.0 in the Stelara q8w dose group, compared with -14.5 in the placebo group.

Ulcerative Colitis

The safety and efficacy of Stelara/Stelara I.V. was assessed in two randomized, double-blind, placebo-controlled, clinical trials in adult patients with moderately to severely active ulcerative colitis who had an inadequate response to or failed to tolerate a biologic (i.e., anti-TNFα agent and/or vedolizumab) or conventional therapy. An 8-week IV induction study (UNIFI-I) was followed by a 44-week subcutaneous randomized withdrawal maintenance study (UNIFI-M) representing a total 52 weeks of therapy (Table 33).

Disease assessment was based on the Mayo score, which ranged from 0 to 12 and has four subscores that were each scored from 0 (normal) to 3 (most severe): stool frequency, rectal bleeding, findings of endoscopy, and physician global assessment. Moderately to severely active ulcerative colitis was defined at baseline (Week 0) as Mayo score of 6 to 12, including a Mayo endoscopy subscore ≥ 2. The endoscopy subscore was assessed by the investigator (ie,

local endoscopist) during the endoscopy procedure and by a central reader who reviewed a video of the endoscopy. Patients were permitted to receive concomitant aminosalicylates, immunomodulators, and/or corticosteroids and 90% of patients continued to receive at least one of these medications.

Table 33: Summary of controlled clinical trials supporting safety and efficacy in patients with UC

Study #	Study Design	Dosage: Route of Administration and Duration	Study Subjects (n)	Median Age (Range)	Sex
UNIFI-I (Induction)	Multicentre, double-blinded, randomized, placebo-controlled	IV administration at Week 0	961	41 (18-84)	M: 582, 61 F: 379, 39
		Placebo	319		
		Stelara I.V. 130 mg	320		
		Stelara I.V. ~6 mg/kg [a]	322		
UNIFI-M (Maintenance)	Multicentre, double-blinded, placebo-controlled randomized-withdrawal	SC administration at Week 0 [b], and then q8w or q12w for 44 weeks	523	40 (18-84)	M: 297, 57 F: 226, 43
		Placebo	175		
		Stelara 90 mg q8w	176		
		Stelara 90 mg q12w	172		

[a] tiered weight-based dose approximating 6 mg/kg (see 4 DOSAGE AND ADMINISTRATION)
[b] 8 weeks following the intravenous dose of Stelara I.V.

Induction Study: UNIFI-I

In the induction study (UNIFI-I), 961 patients were randomized to receive a single intravenous administration of 130 mg Stelara I.V., or approximately 6 mg/kg Stelara I.V. designed as a tiered dose based on patient body weight (Table 3) or placebo at Week 0. Randomization was stratified by biologic failure status (yes/no) and region (Eastern Europe, Asia, or rest of world).

The primary endpoint was clinical remission (defined as a Mayo score ≤ 2 points, with no individual sub-score > 1) at Week 8. The secondary endpoints included: clinical response (≥ 3 points and 30% decrease in Mayo score with either a decrease from baseline in the rectal bleeding subscore ≥ 1 or a rectal bleeding subscore of 0 or 1), improvement of endoscopic appearance of the mucosa (Mayo endoscopy subscore of 0 or 1), and histo-endoscopic mucosal healing (defined as combined improvement of endoscopic appearance of the mucosa and histologic healing of the colon tissue [neutrophil infiltration in < 5% of crypts, no crypt destruction, and no erosions, ulcerations, or granulation tissue]).

Patients enrolled in UNIFI-I had to have failed conventional therapy (corticosteroids or immunomodulators) or at least one biologic (an anti-TNFα agent and/or integrin antagonist). Of the total population, 49% of patients had failed conventional therapy but not a biologic (of which 94% were biologic-naïve) and 51% of patients had failed or were intolerant to a biologic. Approximately 50% of patients had failed at least 1 prior anti-TNFα agent (of which 48% were primary non-responders) and 17% had failed both an anti-TNFα agent and an integrin antagonist. At induction baseline and throughout the study, approximately 52% of patients were

receiving oral corticosteroid, 28% of patients were receiving immunomodulators (AZA, 6-MP, or MTX) and 69% of patients were receiving aminosalicylates.

In UNIFI-I, a significantly greater proportion of patients were in clinical remission and response and achieved improvement of endoscopic appearance of the mucosa and histo-endoscopic mucosal healing in the Stelara I.V. treated group (at the recommended dose of approximately 6 mg/kg) compared to placebo at Week 8 (Table 34).

Table 34: Results for Efficacy Endpoints at Week 8 in UNIFI-I*

	Placebo N = 319	**Stelara I.V. ~6 mg/kg N = 322**	**Treatment difference, 97.5% CI**
Clinical Remission**	17 (5.3%)	50 (15.5%)	10.2 (5.0, 15.5)[a]
Biologic-naïve[/]	15/151 (9.9%)	27/147 (18.4%)	
With prior biologic failure	2/161 (1.2%)	21/166 (12.7%)	
Improvement of endoscopic appearance of the mucosa[‡]	44 (13.8%)	87 (27.0%)	13.3 (6.4, 20.1)[a]
Biologic-naïve[/]	32/151 (21.2%)	49/147 (33.3%)	
With prior biologic failure	11/161 (6.8%)	35/166 (21.1%)	
Clinical Response[§]	100 (31.3%)	199 (61.8%)	30.5 (22.2, 38.8)[a]
Biologic-naïve[/]	54/151 (35.8%)	98/147 (66.7%)	
With prior biologic failure	44/161 (27.3%)	95/166 (57.2%)	
Histo-Endoscopic Mucosal Healing[†]	28 (8.8%)	58 (18.0%)	9.3 (3.4, 15.2)[a]
Biologic-naïve[/]	21/151 (13.9%)	33/147 (22.4%)	
With prior biologic failure	6/161 (3.7%)	22/166 (13.3%)	

* Subjects who had insufficient data or had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to the Week 8 visit were considered not to have achieved the respective endpoints

[/] An additional 7 patients on placebo and 9 patients on Stelara (~6 mg/kg) had been exposed to, but had not failed, biologics.

** Clinical remission is defined as Mayo score ≤2 points, with no individual subscore > 1

[‡] Improvement of endoscopic appearance of the mucosa is defined as a Mayo endoscopic sub-score of 0 or 1 determined by central review of the endoscopy

[§] Clinical response was defined as a decrease from baseline in the Mayo score by ≥ 30% and ≥ 3 points, with either a decrease from baseline in the rectal bleeding subscore ≥ 1 or a rectal bleeding subscore of 0 or 1

[†] Histo-endoscopic mucosal healing is defined as combined improvement of endoscopic appearance of the mucosa (Mayo endoscopy sub-score of 0 or 1) and histologic healing of the colon tissue (neutrophil infiltration in < 5% of crypts, no crypt destruction, and no erosions, ulcerations, or granulation tissue)

[a] $p < 0.001$; p-value is based on a Cochran-Mantel-Haenszel (CMH) chi-square test stratified by biologic failure status and region. Type I error rate is controlled at the 0.025 significance level based on a pre-defined hierarchical testing procedure

Maintenance Study: UNIFI-M

The maintenance study (UNIFI-M), evaluated 523 patients who achieved clinical response at Week 8 following the administration of Stelara I.V. in UNIFI-I. These patients were randomized

to receive a subcutaneous maintenance regimen of either 90 mg Stelara every 8 weeks, 90 mg Stelara every 12 weeks or placebo for 44 weeks. Randomization was stratified by clinical remission status at maintenance baseline (yes/no), oral corticosteroid use at maintenance baseline (yes/no), and induction treatment.

The primary endpoint was the proportion of patients in clinical remission at Week 44. Secondary endpoints included the proportion of patients maintaining clinical response through Week 44, the proportion of patients with improvement of endoscopic appearance of the mucosa at Week 44, the proportion of patients with corticosteroid-free clinical remission at Week 44, and the proportion of patients maintaining clinical remission through Week 44 in patients who achieved clinical remission 8 weeks after induction. Patients who completed the maintenance study through Week 44 were eligible to continue treatment through Week 96.

Results of the primary and secondary endpoints at Week 44 in patients treated with Stelara at the recommended dosage (90 mg every 8 weeks) compared to the placebo are shown in Table 35.

Table 35: Results for Efficacy Endpoints at Week 44 in UNIFI-M (52 weeks from initiation of the induction dose)*

	Placebo[¥] N = 175	Stelara 90 mg every 8 Weeks N = 176	Treatment difference, 95% CI
Clinical Remission**	42 (24.0%)	77 (43.8%)	19.7 (10.3, 29.0)[ab]
Biologic-naïve[+]	27/84 (32.1%)	40/79 (50.6%)	
With prior biologic failure	15/88 (17.0%)	36/91 (39.6%)	
Maintenance of Clinical Response through Week 44[§]	78 (44.6%)	125 (71.0%)	26.4 (16.6, 36.1)[ab]
Biologic-naïve[+]	44/84 (52.4%)	61/79 (77.2%)	
With prior biologic failure	34/88 (38.6%)	59/91 (64.8%)	
Improvement of Endoscopic Appearance of the Mucosa[†]	50 (28.6%)	90 (51.1%)	22.5 (12.8, 32.2)[ab]
Biologic-naïve[+]	30/84 (35.7%)	46/79 (58.2%)	
With prior biologic failure	20/88 (22.7%)	41/91 (45.1%)	
Corticosteroid free clinical remission	41 (23.4%)	74 (42.0%)	18.5 (9.3, 27.8)[ab]
Biologic-naïve[+]	27/84 (32.1%)	39/79 (49.4%)	
With prior biologic failure	14/88 (15.9%)	34/91 (37.4%)	
Maintenance of clinical remission through Week 44 in patients who achieved clinical remission 8 weeks after induction	17/45 (37.8%)	22/38 (57.9%)	
Biologic-naïve[+]	9/25 (36.0%)	12/16 (75.0%)	
With prior biologic failure	8/20 (40.0%)	10/20 (50.0%)	

* Subjects who had insufficient data or had a prohibited change in UC medication, an ostomy or colectomy, or used a rescue medication after clinical flare, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC prior to the Week 44 visit were considered not to have achieved the respective endpoints

[¥] The placebo group consisted of patients who were in response to Stelara I.V. and were randomized to receive placebo at the start of maintenance therapy

[+] An additional 3 patients on placebo and 6 patients on q8w Stelara had been exposed to, but had not failed, biologics

** Clinical remission is defined as Mayo score ≤2 points, with no individual subscore > 1

[§] Clinical response was defined as a decrease from baseline in the Mayo score by ≥ 30% and ≥ 3 points, with either a decrease from baseline in the rectal bleeding subscore ≥ 1 or a rectal bleeding subscore of 0 or 1

[†] Improvement of endoscopic appearance of the mucosa is defined as a Mayo endoscopic sub-score of ≤ 1 point

[a] $p < 0.001$

[b] p value is based on a Cochran-Mantel-Haenszel (CMH) chi-square test stratified by clinical remission status at maintenance baseline (not applicable to the last endpoint) and induction treatment. Type I error rate is controlled based on a pre-defined hierarchical testing procedure

Week 16 Responders to Stelara I.V Induction

Patients who were not in clinical response 8 weeks after Stelara I.V. induction were not included in the primary efficacy analysis for UNIFI-M; however, these patients were eligible to receive a 90 mg subcutaneous injection of Stelara at Week 8. Of the 101 patients who received the

recommended induction dose of 6 mg/kg who were not in clinical response at Week 8, 59/101 (58.4%) achieved clinical response at Week 16 of UNIFI-I and received Stelara every 8 weeks during UNIFI-M. Patients who did not achieve clinical response at Week 16 were discontinued from the study.

Histo-Endoscopic Mucosal Healing
The proportion of patients achieving histo-endoscopic mucosal healing at Week 44 was 79/176 (44.9%) in patients receiving Stelara every 8 weeks compared to 41/175 (23.4%) in patients treated with placebo. The relationship of histo-endoscopic mucosal healing at Week 44 to progression of disease or long-term outcomes was not evaluated.

15 MICROBIOLOGY

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

The toxicity of ustekinumab was specifically evaluated in a number of nonclinical studies. An overview of these toxicity studies is provided in Table 36.

General Toxicology: In repeated-dose toxicity studies in cynomolgus monkeys, ustekinumab was well tolerated following IV doses up to 45 mg/kg/week for up to 1 month and following twice-weekly SC doses up to 45 mg/kg for 6 months. There were no ustekinumab-related findings in the immunotoxicity and cardiovascular safety pharmacology evaluations. In histopathology evaluations there were no preneoplastic changes observed. No evidence of ustekinumab-related local intolerance was observed in examinations of subcutaneous injection sites in a local tolerance study and in the chronic subcutaneous toxicity study.

The 45 mg/kg dose is approximately 45-fold higher than the highest equivalent dose intended to be administered to patients with psoriasis (based on administration of a 90 mg SC dose to a 90 kg patient) and the average C_{max} value observed following the last SC 45 mg/kg dose in the 6-month chronic toxicity study in cynomolgus monkeys was approximately 118-fold higher than the median C_{max} value of ustekinumab observed following 4 weekly 90 mg SC doses in psoriasis patients.

Carcinogenicity
The carcinogenic potential has not been evaluated.

Genotoxicity
The genotoxic potential has not been evaluated.

Reproductive and Developmental Toxicology: Three developmental toxicity studies were conducted in cynomolgus monkeys. No ustekinumab-related maternal toxicity, abortions, still-births, embryotoxicity, developmental delays, malformations or birth defects were observed at doses up to 45 mg/kg following weekly or twice weekly administration of ustekinumab via the IV

or SC routes, respectively. In neonates born from pregnant monkeys treated with ustekinumab, no adverse effects on growth or functional development were observed and no deficits were observed in immunotoxicity evaluations. In a male fertility study in cynomolgus monkeys, no ustekinumab-related effects on mating behaviour, sperm parameters, or serum concentrations of male hormones were observed following twice weekly subcutaneous administration of ustekinumab at doses up to 45 mg/kg.

A female fertility toxicity study was conducted in mice using an analogous antibody that binds to and inhibits IL-12 and IL-23 activity in mice. Twice weekly subcutaneous administration of the anti-mouse IL-12/23 antibody was well tolerated at doses up to 50 mg/kg and no adverse effects on female fertility parameters were observed.

Table 36: Non-Clinical Toxicology Studies with ustekinumab

Study	Species/ Strain	Route	Duration of Dosing	Doses (mg/kg)	Results
Repeat-Dose Toxicity					
Subchronic toxicity	Monkey/ Cynomolgus	IV	1 month	9, 45 weekly	No treatment-related signs of toxicity.
Subchronic toxicity	Monkey/ Cynomolgus	IV	1 month	9, 45 weekly	No treatment-related signs of toxicity.
Chronic toxicity	Monkey/ Cynomolgus	SC	6 months	22.5, 45 twice weekly	No treatment-related signs of toxicity. No preneoplastic changes observed on histopathology.
Reproductive and Developmental Toxicity					
Embryofetal Development	Monkey/ Cynomolgus	IV	Pregnant females: gestation day 20 to gestation day 50	9, 45 weekly	No maternal or fetal abnormalities were observed.
Embryofetal Development	Monkey/ Cynomolgus	SC	Pregnant females: gestation day 20 – gestation day 51	22.5, 45 twice weekly	A statistically significant increase in maternal 17ß-estradiol levels relative to the control group was observed on days 80 and 100 of gestation in the 22.5 and 45 mg/kg groups. However, foetal 17ß-estradiol levels were not affected, and there were no other treatment-related maternal or foetal

Study	Species/ Strain	Route	Duration of Dosing	Doses (mg/kg)	Results
					abnormalities observed at either dose level.
Male fertility	Monkey/ Cynomolgus	SC	Males: 13 weeks	22.5, 45 twice weekly	No changes in fertility parameters observed.
Female fertility	Mouse/Crl CD-1	SC	Beginning 15 days before cohabitation and continuing through day 7 of presumed gestation	25, 50 twice weekly	No maternal or fetal abnormalities were observed.
Embryofetal and pre- and postnatal development	Monkey/ Cynomolgus	SC	Pregnant females: gestation day 20 – postpartum day 30	22.5, 45 twice weekly	No effects on pregnancy or delivery; or morphological, functional and immunological developmental parameters of offspring. Ustekinumab was detected in the milk of lactating monkeys.
Local Tolerance					
Pharmacokinetics and injection site irritation	Monkey/ Cynomolgus	SC	18 days	45 twice weekly	Minimal signs of local irritation at injection sites were observed, with no associated histopathologic findings.
Other Toxicity Studies					
Tissue cross-reactivity	Human Tissues	In vitro		1.13,11.3, 113, 225 mg/mL	No binding to nontarget normal human tissues.
Tissue cross-reactivity	Human Tissues	In vitro		1.13,11.3, 113, 225 mg/mL	No binding to nontarget normal human tissues
Asthma model	Monkey/ Cynomolgus	IV	Single dose	9, 45	No exacerbation of pulmonary function or cellular responses.

Study	Species/ Strain	Route	Duration of Dosing	Doses (mg/kg)	Results
Asthma model	Monkey/ Cynomolgus	IV	1 week	45	No exacerbation of pulmonary function or cellular responses.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **STELARA**®
'stel ar' a'
ustekinumab injection
Solution for Subcutaneous Injection

Read this carefully before you start taking **Stelara** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Stelara**.

What is Stelara used for?

- **Adults with Plaque Psoriasis**

Stelara is a prescription medicine that is approved for adults with moderate to severe plaque psoriasis that is chronic (doesn't go away).

- **Children 6 to 17 years of age with Plaque Psoriasis**

Stelara is a prescription medicine that is approved for children and adolescent patients 6 to 17 years of age with moderate to severe plaque psoriasis that is chronic (doesn't go away) and who have had an inadequate response to other treatments.

- **Adults with Psoriatic Arthritis**

Stelara is a prescription medicine that is approved for adults with active psoriatic arthritis.

Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis. If you have active psoriatic arthritis, you will be given Stelara by injection under the skin, alone or in combination with methotrexate, to reduce signs and symptoms of your arthritis, help improve your ability to perform daily activities (such as dressing, walking and climbing stairs) and improve your psoriasis.

- **Adults with Crohn's disease or ulcerative colitis**

Stelara/Stelara I.V. is a prescription medicine that is approved for adults with moderately to severely active Crohn's disease and for adults with moderately to severely active ulcerative colitis. For patients with Crohn's disease or ulcerative colitis, the first dose, Stelara I.V., is given by an intravenous infusion, through a needle placed in a vein. Subsequent doses of Stelara are given by injection under the skin.

Crohn's disease (CD) is a chronic inflammatory bowel disorder. Ulcerative colitis is an inflammatory disease of the colon. If you have moderately to severely active Crohn's disease or ulcerative colitis that has not responded to other medications and you are an adult, you may be given Stelara/Stelara I.V. to help relieve your symptoms and keep the disease under control. Stelara/Stelara I.V. may help reduce or stop the use of your corticosteroid medication.

How does Stelara work?

Stelara blocks the action of two proteins in your body called interleukin 12 (IL-12) and interleukin 23 (IL-23). In people with psoriasis, psoriatic arthritis, Crohn's disease or ulcerative colitis, their immune system may attack parts of their body and that attack uses IL-12 and IL-23. Ustekinumab can block the IL-12 and IL-23 from causing the immune system to attack the skin, nails, joints or the digestive tract.

What are the ingredients in Stelara?

Medicinal ingredients: ustekinumab

Non-medicinal ingredients: L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose and water for injection. No preservatives are present.

Stelara comes in the following dosage forms:

Pre-filled Syringe:
- 45 mg / 0.5 mL
- 90 mg / 1.0 mL

Single-use Vial:
- 45 mg / 0.5 mL

Do not use Stelara if:

- you have a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- you have had an allergic reaction to Stelara, Stelara I.V., or any of the other ingredients in Stelara. See below for a complete list of ingredients in Stelara.
- after the expiration date on the label.
- the seal is broken.
- the liquid is discoloured, cloudy or you can see other particulate matter floating in it.
- you know or think that it may have been exposed to extreme temperatures (such as accidentally frozen or heated).

You should not receive a live vaccine while taking Stelara.

If you used Stelara while pregnant, tell your baby's healthcare professional about your Stelara use before the baby receives any vaccine, including live vaccines, such as the BCG vaccine (used to prevent tuberculosis), rotavirus vaccine, or any other live vaccines.

Always keep medicine out of the reach of children.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Stelara. Talk about any health conditions or problems you may have, including if you:

- ever had an allergic reaction to Stelara or Stelara I.V. Ask your healthcare professional if you are not sure.
- have any kind of infection even if it is very minor.
- have an infection that won't go away or a history of infection that keeps coming back.
- have burning when you urinate.
- have diarrhea or abdominal pain.
- have had TB (tuberculosis), notice blood in your phlegm or if you have recently been near anyone who might have TB.
- have or have had any type of cancer.
- have any new or changing skin lesions.
- have recently received or are scheduled to receive a vaccine. Tell your healthcare professional if anyone in your house needs a vaccine. The viruses in some vaccines can spread to people with a weakened immune system and can cause serious problems.
- are receiving or have received “allergy shots”, especially for serious allergic reactions.
- are pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding. Stelara may pass into your breast milk in small amounts.

Contact your healthcare professional immediately:

- if you develop signs of a serious allergic reaction such as skin rash, swollen face, lips, mouth, throat, wheezing, dizziness, trouble swallowing or breathing.
- if you develop headache, vision problems, seizures or change in mental status (for example, confusion).

The needle cover on the pre-filled syringe contains dry natural rubber (a form of latex). This may cause allergic reactions in people who are sensitive to latex. Tell your healthcare professional if you have ever had an allergic reaction to latex and developed any allergic reaction to Stelara injection.

There is limited experience with Stelara in pregnant and breastfeeding women. If you are a woman of childbearing potential, you should use effective contraception when starting Stelara and talk to your healthcare professional before planning to conceive a child. If you are pregnant or breastfeeding, your healthcare professional will help you decide whether or not to use Stelara.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Know the medicines you take. Keep a list of your medicines and show them to your healthcare professionals when you get a new medicine.

The following may interact with Stelara:

- Stelara may change the way the body responds to live vaccines.
- Stelara may interact with other medications that decrease the activity of the immune system.

Your healthcare professional will assess your health before each treatment.

If you have questions, ask your health care provider.

How to take Stelara:

Instructions for injecting Stelara under the skin yourself:

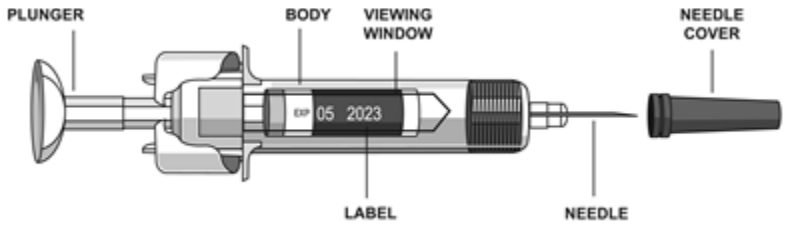
Stelara may be injected by your healthcare provider. In children 6 to 17 years of age, it is recommended that all doses of Stelara be administered by a health care provider. However, your healthcare professional may decide that it is right for you or your caregiver to learn how to inject Stelara under the skin (subcutaneously) yourself. Before you self-inject Stelara, you must be trained by a healthcare professional. If you or your caregiver have not been trained, please contact your healthcare provider to schedule a training session. Call your healthcare provider if you have any questions about giving yourself an injection. Stelara is not to be mixed with other liquids for injection.

INSTRUCTIONS FOR INJECTING STELARA USING A PRE-FILLED SYRINGE

To reduce the risk of accidental needle sticks to users, each pre-filled syringe is equipped with a needle guard that is automatically activated to cover the needle after complete delivery of the syringe content.

Do not shake Stelara at any time. Prolonged vigorous shaking may damage the product. If the product has been shaken vigorously, don't use it.

1: PREPARING FOR PRE-FILLED SYRINGE USE



Take the Syringe out of the Refrigerator
If your dose amount is 90 mg and you receive two 45 mg packages, you need to give a second injection right after the first. Choose a different site for the second injection. Children who weigh 60 kg or more may use the prefilled syringe.

Check Expiration Date
Open the box and remove the pre-filled syringe. Check the expiration date on the pre-filled syringe and the label of the box. If the expiration date has passed, or if the pre-filled syringe has been kept at room temperature up to 30°C for longer than 30 days or if the pre-filled syringe has been stored above 30°C, DO NOT use the pre-filled syringe.

Assemble Additional Supplies
Assemble the additional supplies you will need for your injection. These include an antiseptic wipe, a cotton ball or gauze, and a sharps container for syringe disposal.

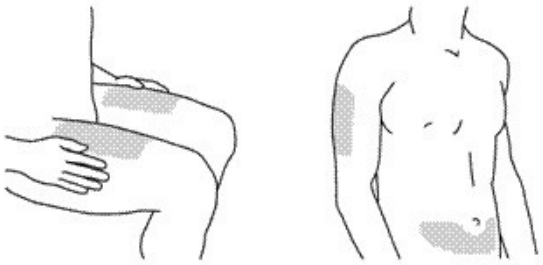
Check Solution in Syringe
Hold the pre-filled syringe with the covered needle pointing upward. Make sure the syringe is not damaged. Look at the solution or liquid in the syringe to make sure that it is clear to slightly opalescent and colorless to slightly yellow. DO NOT use if it is frozen, discolored, cloudy or contains particles and contact your healthcare provider for assistance.

DO NOT remove the needle cover from the pre-filled syringe.

DO NOT pull back on the plunger head at any time.

2: CHOOSING AND PREPARING THE INJECTION SITE

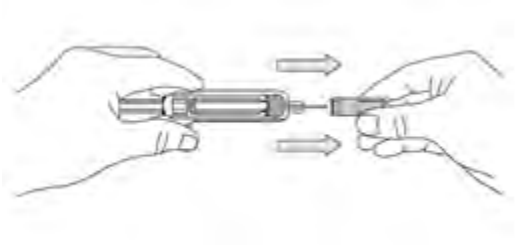
Choose the Injection Site*
Good sites are the top of the thigh and around the tummy (abdomen) but about 2 inches away from the belly button (navel). Avoid, if possible, skin involved with psoriasis. If your caregiver is giving you the injection, they may use the upper arms or buttocks as well.



*Areas in gray are recommended injection sites.

Prepare the Injection Site
Thoroughly wash your hands with soap and warm water. Wipe the injection site with an antiseptic wipe. DO NOT touch this area again before giving the injection.

3: INJECTING THE MEDICATION



Remove the Needle Cover
When you are ready to inject, pick up the pre-filled syringe, hold the body of the syringe with one hand and pull the needle cover straight off. Throw the needle cover into the trash. You may notice a small air bubble in the pre-filled syringe. You do not need to remove the air bubble. You may also see a drop of liquid at the end of the needle – this is normal. Do not touch the needle or allow it to touch any surface.

Note: The needle cover should NOT be removed until you are ready to inject the dose. Do not use syringe if it is dropped without the needle cover in place. If you drop the syringe without the needle cover in place, please contact your healthcare provider for assistance.

Inject the Medication
Gently pinch the cleaned skin between your thumb and index finger. Don't squeeze it.

Push the syringe needle into the pinched skin.

Push the plunger with your thumb as far as it will go to inject all of the liquid.

Push it slowly and evenly, keeping the skin pinched.

When the plunger meets the end of the syringe barrel, and all of the medication has been injected, release the pinched skin and gently remove the needle. Following complete injection, the needle guard will automatically extend over the needle and lock as you take your hand off the plunger.

4: AFTER THE INJECTION

Dispose of the Empty Syringe
Immediately dispose of the empty syringe into the sharps container. For your safety and health and for the safety of others, needles and syringes **must NEVER** be re-used. Dispose of sharps container according to your local regulations.

Use a Cotton Ball or Gauze
There may be a small amount of blood or liquid at the injection site, which is normal. You can press a cotton ball or gauze over the injection site and hold for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

INSTRUCTIONS FOR INJECTING STELARA FROM A 45 mg/0.5 mL VIAL

Do not shake Stelara Solution for Subcutaneous Injection at any time. Prolonged vigorous shaking may damage the product. If the product has been shaken vigorously, don't use it. Stelara is not to be mixed with other liquids for injection.

1: CHECK VIAL(S) AND ASSEMBLE MATERIALS

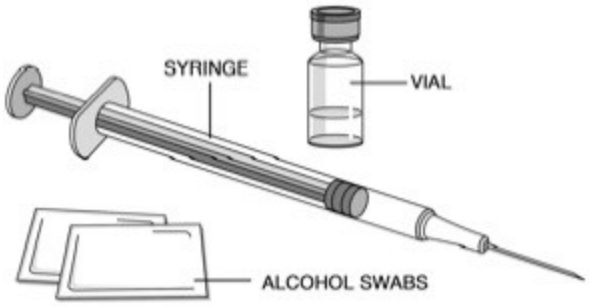
Take the Vial(s) out of the Refrigerator
If your dose is 45 mg you will receive one 45 mg vial. If your dose is 90 mg, you will receive two 45 mg vials. If you receive two 45 mg vials for a 90 mg dose, you will need to give yourself two injections one right after the other. Use a new needle and syringe. Choose a different site for the second injection.

Children weighing less than 60 kg require a dose lower than 45 mg. Make sure you know the proper amount (volume) and type of syringe needed for dosing. If you don't know the amount or type of syringe needed, contact your healthcare provider for further instructions.

Check Expiration Date
Open the box and remove the vial. Check the expiration date on the vial and the label of the box. If the expiration date has passed, don't use it.

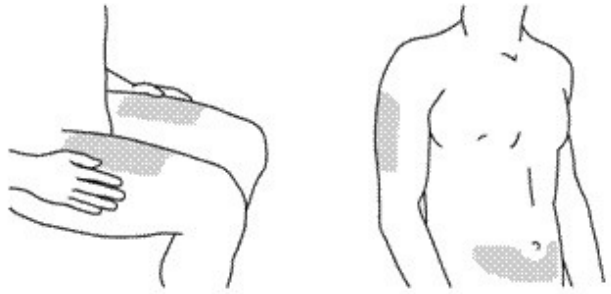
Check Solution in Vial
Make sure the vial is not damaged. Look at the solution or liquid in the vial to make sure that it is clear to slightly opalescent and colorless to slightly yellow. **DO NOT** use if it is frozen, discolored, cloudy or contains particles and contact your healthcare provider for assistance.

Assemble Additional Supplies
Assemble the additional supplies you will need for your injection. These include an antiseptic wipe, a cotton ball or gauze, and a sharps container for syringe disposal.



2: CHOOSING AND PREPARING THE INJECTION SITE

Choose the Injection Site*
Good sites are the top of the thigh and around the tummy (abdomen) but about 2 inches away from the belly button (navel). Avoid, if possible, skin involved with psoriasis. If your caregiver is giving you the injection, they may use the upper arms or buttocks as well.



*Areas in gray are recommended injection sites.

Prepare the Injection site
Thoroughly wash your hands with soap and warm water. Wipe the injection site with an antiseptic wipe. DO NOT touch this area again before giving the injection.

3: PREPARING THE DOSE

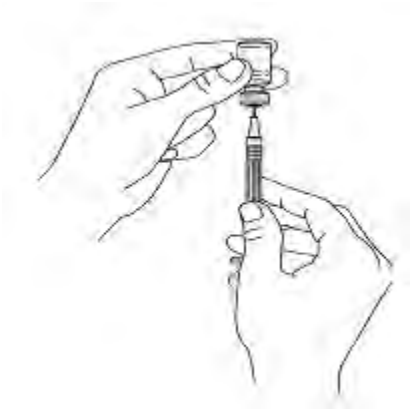
Remove the cap from the top of the vial but do not remove the stopper. Clean the stopper with an antiseptic wipe.

Remove the needle cover from the syringe. Do not touch the needle or allow the needle to touch anything.

Put the vial on a flat surface and push the syringe needle through the rubber stopper.

Turn the vial and the syringe upside down.
For adults and children 6 to 17 years of age, who weigh 60 kg or more, pull on the syringe plunger to fill the syringe with the entire amount (volume) of liquid prescribed by your healthcare provider. It is important that the needle is always in the liquid in order to prevent air bubbles from forming in the syringe.

For children 6 years of age or older who weigh less than 60 kg, the amount of liquid prescribed by your health care provider may be less than 0.5 mL. Your health care provider will recommend how much liquid is needed.



Remove the needle from the vial
Hold the syringe with the needle pointing up to see if it has any air bubbles inside. If there are air bubbles tap the side gently until the air bubbles go to the top of the syringe and press the plunger until all of the air (but none of the liquid) has been removed. Do not lay the syringe down or allow the needle to touch anything.

4: INJECTING THE MEDICATION

Gently pinch the cleaned skin between your thumb and index finger. Don't squeeze it.

Push the syringe needle into the pinched skin.

Push the plunger with your thumb as far as it will go to inject all of the liquid. Push it slowly and evenly, keeping the skin gently pinched.

When the plunger is pushed as far as it will go, take out the needle and let go of the skin.

Press an antiseptic wipe over the injection site for a few seconds after the injection.

Dispose the Empty Syringe and Vial(s)
Discard any unused portion of Stelara in accordance with local requirements. Immediately dispose of the empty syringe into the sharps container. For your safety and health and for the safety of others, vials, needles and syringes must NEVER be re-used. Dispose of sharps container according to your local regulations. Empty vials, antiseptic wipes, and other supplies can be placed in your regular trash.

Use a Cotton Ball or Gauze
There may be a small amount of blood or liquid at the injection site, which is normal. You can press a cotton ball or gauze over the injection site and hold for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

Usual dose:

Psoriasis
For treatment of psoriasis, Stelara is given by injection under the skin.

Adults:
The recommended dose of Stelara is 45 mg at Weeks 0 and 4 then every 12 weeks thereafter. Your healthcare professional may consider treating you as often as every 8 weeks.

90 mg may be used in patients with a body weight greater than 100 kg.

Pediatric Psoriasis (6 years of age or older):
The recommended dose of Stelara based on body weight (as shown below) is given at Week 0 and 4, and then every 12 weeks thereafter.

Weight	Recommended dose of Stelara	Dosage Form
< 60kg	0.75 mg/kg*	Vial
≥ 60 to ≤ 100 kg	45 mg	Pre-filled syringe, vial
> 100 kg	90 mg	Pre-filled syringe

* For patients with body weight < 60 kg, use the vial presentation only. To calculate the volume of injection (mL) for patients < 60 kg, use the following formula: body weight (kg) x 0.0083 (mL/kg). The calculated volume should be rounded to the nearest 0.01 mL and administered using a 1 mL graduated syringe. The calculated volume of injection per kg body weight at time of dosing are also provided in table below. A 45 mg vial is available for pediatric patients who need to receive less than the full 45 mg dose.

Injection volumes of Stelara for pediatric psoriasis patients < 60 kg		
Body weight at time of dosing (kg)	**Dose (mg)**	**Volume of injection (mL)**
15	11.3	0.12
16	12.0	0.13
17	12.8	0.14
18	13.5	0.15
19	14.3	0.16
20	15.0	0.17
21	15.8	0.17
22	16.5	0.18
23	17.3	0.19
24	18.0	0.20
25	18.8	0.21
26	19.5	0.22
27	20.3	0.22
28	21.0	0.23
29	21.8	0.24
30	22.5	0.25
31	23.3	0.26
32	24.0	0.27
33	24.8	0.27
34	25.5	0.28
35	26.3	0.29
36	27.0	0.30
37	27.8	0.31
38	28.5	0.32
39	29.3	0.32
40	30.0	0.33
41	30.8	0.34
42	31.5	0.35
43	32.3	0.36
44	33.0	0.37
45	33.8	0.37
46	34.5	0.38
47	35.3	0.39
48	36.0	0.40
49	36.8	0.41
50	37.5	0.42
51	38.3	0.42
52	39.0	0.43
53	39.8	0.44
54	40.5	0.45
55	41.3	0.46
56	42.0	0.46
57	42.8	0.47
58	43.5	0.48
59	44.3	0.49

In children 6 to 17 of age with psoriasis, it is recommended that Stelara be administered by a health care provider. If your healthcare professional determines that it is appropriate, your caregiver or you may be able to administer Stelara to yourself, after proper training in injection technique using the right type of syringe and the amount (volume) to be injected (see the "**Instructions for injecting Stelara under the skin yourself**".)

Psoriatic Arthritis
For treatment of psoriatic arthritis, Stelara is given by injection under the skin. The recommended dose of Stelara is 45 mg at Weeks 0 and 4 then every 12 weeks thereafter. Alternatively, 90 mg may be used in patients with a body weight greater than 100 kg.

Crohn's disease and ulcerative colitis
For treatment of Crohn's disease or ulcerative colitis, the recommended dose is a single intravenous dose of Stelara I.V. based on body weight (as shown below) followed by 90 mg Stelara given by injection under the skin (subcutaneous).

Weight	Recommended Dose of Stelara I.V.
≤ 55 kg	260 mg
> 55 kg to ≤ 85 kg	390 mg
> 85 kg	520 mg

The recommended dosing schedule for Crohn's disease and ulcerative colitis is as follows:

Treatment number	Time of treatment Route of administration
Treatment 1	Week 0 Intravenous infusion (Stelara I.V.)
Treatment 2	8 weeks after Treatment 1 Subcutaneous injection (Stelara)
Further treatment	Every 8 weeks* Subcutaneous injection (Stelara)

* your healthcare professional will decide whether the treatment interval between injections should be maintained at every 8 weeks or may be extended to every 12 weeks

The BioAdvance® Network has been established to facilitate the administration of Stelara. This network consists of clinics located across Canada that are staffed by qualified healthcare professionals specially trained in the administration of Stelara. Contact your healthcare professional if you have any questions.

Overdose:

Call your healthcare professional if you accidentally inject Stelara more frequently than instructed.

If you think you, or a person you are caring for, have taken too much Stelara, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

If you miss a dose, contact your healthcare provider for guidance.

What are possible side effects from using Stelara?

These are not all the possible side effects you may have when taking Stelara. If you have any side effects not listed here, tell your healthcare professional.

The most common side effects of Stelara are:

- Upper respiratory tract infections such as the common cold
- Infection of the nose and throat
- Dizziness
- Headache
- Sore throat
- Diarrhea
- Nausea
- Vomiting
- Itching
- Back pain
- Muscle aches
- Joint pain
- Feeling very tired
- Redness of the skin where the injection is given
- Pain where the injection is given
- Sinus infection

Stelara is a medicine that affects your immune system. It can increase your risk of getting serious side effects including:

Serious Infections

- Stelara may lower your ability to fight infections. Some infections could become serious and lead to hospitalization. If you have an infection or have any open cuts, tell your healthcare provider before you start using Stelara. If you get an infection, have any sign of an infection such as fever, feel very tired, cough, flu-like symptoms, or warm, red, or painful skin or sores on your body, tell your healthcare provider right away. These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications.
- Your healthcare professional will examine you for tuberculosis (TB) and perform a test to see if you have TB. If your healthcare professional feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with Stelara and during treatment with Stelara.

Cancers

- Stelara may decrease the activity of your immune system, and increase the risk for certain types of cancer. Tell your healthcare professional if you notice any unusual changes to your skin or health status while receiving Stelara treatment.

Serious Skin Conditions

Shedding of skin – increase in redness and shedding of skin over a larger area of the body may be symptoms of erythrodermic psoriasis or exfoliative dermatitis, which are serious skin conditions. You should contact your healthcare professional immediately if you notice any of these signs.

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
VERY COMMON (>10%)			
Infected nose, sinuses or throat (cold)	✓		
COMMON (≥1% and <10%)			
Sore throat, nasal congestion	✓		
Allergic reaction (skin rash)		✓	
UNCOMMON (≥0.1% and <1%)			
Cellulitis (skin infection)		✓	
Vaginal yeast infections	✓		
Tooth abscess/tooth infection		✓	
RARE (≥0.01% and <0.1%)			
Serious allergic reactions (e.g.: swollen face or trouble breathing; symptoms such as cough, shortness of breath, and fever may also be a sign of an allergic lung reaction)			✓
Increase in redness and shedding of skin		✓	

In general, the side effects of Stelara seen in children 6 to 17 years of age are similar to those in adults.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

If you are using Stelara at home, it is important to store the product in your refrigerator at 2-8°C although not in the freezer compartment. Stelara should not be frozen. Keep the product in the original carton to protect from light until the time of use. Do not shake.

If needed, individual Stelara pre-filled syringes may also be stored at room temperature up to 30°C for a maximum single period of up to 30 days in the original carton with protection from light. Record the date when the pre-filled syringe is first removed from the refrigerator and the new expiry date on the carton in the spaces provided. The new expiry date must not exceed the original expiry date printed on the carton. Once a syringe has been stored at room temperature, it should not be returned to the refrigerator. Discard the syringe if not used within 30 days at room temperature storage.

Always keep medicine out of the reach and sight of children.

If you want more information about Stelara:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; https://www.canada.ca/en/health-canada/services/drugs-health-products/drugproducts/drug-product-database.html, the manufacturer's website www.janssen.com/canada or contact the manufacturer, Janssen Inc., at 1-800-567-3331, or 1-800-387-8781.

This leaflet was prepared by Janssen Inc., Toronto, Ontario M3C 1L9

Last revised: January 5, 2023

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr STELARA® I.V.
'stel ar' a'
ustekinumab for injection
Solution for Intravenous Infusion

Read this carefully before you start taking **Stelara I.V.** This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Stelara I.V.**

What is Stelara I.V. used for?

- **Adults with Crohn's disease or ulcerative colitis**

Stelara I.V./Stelara is a prescription medicine that is approved for adults with moderately to severely active Crohn's disease or adults with moderately to severely active ulcerative colitis. For patients with Crohn's disease or ulcerative colitis, the first dose, Stelara I.V., is given by an intravenous infusion, through a needle placed in a vein. Subsequent doses of Stelara are given by injection under the skin.

Crohn's disease (CD) is a chronic inflammatory bowel disorder. Ulcerative colitis is an inflammatory disease of the colon. If you have moderately to severely active Crohn's disease or ulcerative colitis that has not responded to other medications and you are an adult, you may be given Stelara I.V./Stelara to help relieve your symptoms and keep the disease under control. Stelara I.V./ Stelara may help reduce or stop the use of your corticosteroid medication.

How does Stelara I.V. work?

Stelara I.V. blocks the action of two proteins in your body called interleukin 12 (IL-12) and interleukin 23 (IL-23). In people with Crohn's disease and ulcerative colitis, their immune system may attack parts of their body and that attack uses IL-12 and IL-23. Ustekinumab can block the IL-12 and IL-23 from causing the immune system to attack the digestive tract.

What are the ingredients in Stelara I.V.?

Medicinal ingredients: ustekinumab

Non-medicinal ingredients: EDTA disodium salt dihydrate, L-histidine and L-histidine hydrochloride monohydrate, L-methionine, polysorbate 80 and sucrose. No preservatives are present.

Stelara I.V. comes in the following dosage forms:

Stelara I.V. is available as a sterile solution in single-use vials. Each vial contains 130 mg ustekinumab in 26 mL.

Do not use Stelara I.V. if:

- you have a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- you have had an allergic reaction to Stelara I.V. or Stelara or any of the other ingredients in Stelara I.V. See below for a complete list of ingredients in Stelara I.V.
- after the expiration date on the label.
- the seal is broken.
- the liquid is discoloured, cloudy or you can see other particulate matter floating in it.
- you know or think that it may have been exposed to extreme temperatures (such as accidentally frozen or heated).

<u>You should not receive a live vaccine when taking Stelara I.V.</u>

If you used Stelara I.V. while pregnant, tell your baby's healthcare professional about your Stelara I.V. use before the baby receives any vaccine, including live vaccines, such as the BCG vaccine (used to prevent tuberculosis), rotavirus vaccine, or any other live vaccines.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Stelara I.V. Talk about any health conditions or problems you may have, including if you:

- ever had an allergic reaction to Stelara I.V. or Stelara. Ask your healthcare professional if you are not sure.
- have any kind of infection even if it is very minor.
- have an infection that won't go away or a history of infection that keeps coming back.
- have burning when you urinate.
- have diarrhea or abdominal pain.
- have had TB (tuberculosis), notice blood in your phlegm or if you have recently been near anyone who might have TB.
- have or have had any type of cancer.
- have any new or changing skin lesions.
- have recently received or are scheduled to receive a vaccine. Tell your healthcare professional if anyone in your house needs a vaccine. The viruses in some vaccines can spread to people with a weakened immune system and can cause serious problems.
- are receiving or have received "allergy shots", especially for serious allergic reactions.
- are pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding. Stelara I.V. may pass into your breast milk in small amounts.

<u>Contact your healthcare professional immediately:</u>

- if you develop signs of a serious allergic reaction such as skin rash, swollen face, lips, mouth, throat, wheezing, dizziness, trouble swallowing or breathing.
- if you develop headache, vision problems, seizures or change in mental status (for example, confusion).

There is limited experience with Stelara I.V./Stelara in pregnant and breastfeeding women. If you are a woman of childbearing potential, you should use effective contraception when starting Stelara I.V. and talk to your healthcare professional before planning to conceive a child. If you are pregnant or breastfeeding, your healthcare professional will help you decide whether or not to use Stelara I.V./Stelara.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Know the medicines you take. Keep a list of your medicines and show them to your healthcare professionals when you get a new medicine.

The following may interact with Stelara I.V.:

- Stelara I.V. may change the way the body responds to live vaccines.
- Stelara I.V. may interact with other medications that decrease the activity of the immune system.

Your healthcare professional will assess your health before each treatment.

If you have questions, ask your health care provider.

How to take Stelara I.V.:

Usual dose:

Crohn's disease and ulcerative colitis
For treatment of Crohn's disease or ulcerative colitis, the recommended dose is a single intravenous dose of Stelara I.V. based on body weight (as shown below) followed by 90 mg Stelara given by injection under the skin (subcutaneous).

Weight	Recommended Dose of Stelara I.V.
≤ 55 kg	260 mg
> 55 kg to ≤ 85 kg	390 mg
> 85 kg	520 mg

The recommended dosing schedule for Crohn's disease and ulcerative colitis is as follows:

Treatment number	Time of treatment Route of administration
Treatment 1	Week 0 Intravenous infusion (Stelara I.V.)
Treatment 2	8 weeks after Treatment 1 Subcutaneous injection (Stelara)
Further treatment	Every 8 weeks* Subcutaneous injection (Stelara)

* your healthcare professional will decide whether the treatment interval between injections should be maintained at every 8 weeks or may be extended to every 12 weeks

The initial dose of Stelara I.V. for intravenous infusion for Crohn's disease or ulcerative colitis will be given over a period of at least one hour.

The BioAdvance® Network has been established to facilitate the administration of Stelara I.V. This network consists of clinics located across Canada that are staffed by qualified healthcare professionals specially trained in the administration of Stelara I.V. infusions. Contact your healthcare professional if you have any questions.

Overdose:

In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse effects and appropriate symptomatic treatment be instituted immediately.

If you think you, or a person you are caring for, have taken too much Stelara I.V., contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using Stelara I.V.?

These are not all the possible side effects you may have when taking Stelara. If you have any side effects not listed here, tell your healthcare professional.

The most common side effects of Stelara I.V. are:

- Upper respiratory tract infections such as the common cold
- Infection of the nose and throat
- Dizziness
- Headache
- Sore throat
- Diarrhea
- Nausea
- Vomiting
- Itching
- Back pain
- Muscle aches
- Joint pain
- Feeling very tired
- Redness of the skin where the injection is given
- Pain where the injection is given
- Sinus infection

Stelara I.V. is a medicine that affects your immune system. It can increase your risk of getting serious side effects including:

Serious Infections

- Stelara I.V. may lower your ability to fight infections. Some infections could become serious and lead to hospitalization. If you have an infection or have any open cuts, tell your healthcare provider before you start using Stelara I.V. If you get an infection, have any sign of an infection such as fever, feel very tired, cough, flu-like symptoms, or warm, red, or painful skin or sores on your body, tell your healthcare provider right away. These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications.
- Your healthcare professional will examine you for tuberculosis (TB) and perform a test to see if you have TB. If your healthcare professional feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with Stelara I.V.

Cancers

- Stelara I.V. may decrease the activity of your immune system, and increase the risk for certain types of cancer. Tell your healthcare professional if you notice any unusual changes to your skin or health status while receiving Stelara I.V. treatment.

Serious Skin Conditions

Shedding of skin – increase in redness and shedding of skin over a larger area of the body may be symptoms of erythrodermic psoriasis or exfoliative dermatitis, which are serious skin conditions. You should contact your healthcare professional immediately if you notice any of these signs.

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
VERY COMMON (>10%)			
Infected nose, sinuses or throat (cold)	✓		
COMMON (≥1% and <10%)			
Sore throat, nasal congestion	✓		
Allergic reaction (skin rash)		✓	
UNCOMMON (≥0.1% and <1%)			
Cellulitis (skin infection)		✓	
Vaginal yeast infections	✓		
Tooth abscess/tooth infection		✓	
RARE (≥0.01% and <0.1%)			
Serious allergic reactions (e.g.: swollen face or trouble breathing; symptoms such as cough, shortness of breath, and fever may also be a sign of an allergic lung reaction)			✓
Increase in redness and shedding of skin		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Stelara I.V. must be stored in the original package in the refrigerator at 2-8°C (36-46°F) before use. Stelara I.V. should not be frozen. Keep the product in its original carton to protect from light until the time of use. Do not shake. It must be kept out of the reach and sight of children.

If you want more information about Stelara I.V.:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; https://www.canada.ca/en/health-canada/services/drugs-health-products/drugproducts/drug-product-database.html, the manufacturer's website www.janssen.com/canada or contact the manufacturer, Janssen Inc., at 1-800-567-3331, or 1-800-387-8781.

This leaflet was prepared by Janssen Inc., Toronto, Ontario M3C 1L9

Last revised: January 5, 2023

Exhibit “J10”

This is Exhibit “J10” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

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Description of the Company and Business Segments

Johnson & Johnson and its subsidiaries (the Company) have approximately 127,600 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices and Diagnostics. The Consumer segment includes a broad range of products used in the baby care, skin care, oral care, wound care and women's health fields, as well as nutritional and over-the-counter pharmaceutical products and wellness and prevention platforms. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world. The Pharmaceutical segment includes products in the following areas: anti-infective, antipsychotic, contraceptive, gastrointestinal, hematology, immunology, infectious diseases, neurology, oncology, pain management, thrombosis and vaccines. These products are distributed directly to retailers, wholesalers and health care professionals for prescription use. The Medical Devices and Diagnostics segment includes a broad range of products distributed to wholesalers, hospitals and retailers, used principally in the professional fields by physicians, nurses, hospitals and clinics. These include products to treat cardiovascular disease; orthopaedic and neurological products; blood glucose monitoring and insulin delivery products; general surgery, biosurgical, and energy products; professional diagnostic products; infection prevention products; and disposable contact lenses.

The Company's structure is based upon the principle of decentralized management. The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Consumer, Pharmaceutical and Medical Devices and Diagnostics business segments.

In all of its product lines, the Company competes with companies both locally and globally, throughout the world. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products is important to the Company's success in all areas of its business. This also includes protecting the Company's portfolio of intellectual property. The competitive environment requires substantial investments in continuing research and in maintaining sales forces. In addition, the development and maintenance of customer demand for the Company's consumer products involves significant expenditures for advertising and promotion.

Management's Objectives

The Company manages within a strategic framework aimed at achieving sustainable growth. To accomplish this, the Company's management operates the business consistent with certain strategic principles that have proven successful over time. To this end, the Company participates in growth areas in human health care and is committed to attaining leadership positions in these growth areas through the development of high quality, innovative products and services. New products introduced within the past five years accounted for approximately 25% of 2012 sales. In 2012, $7.7 billion, or 11.4% of sales, was invested in research and development. This investment reflects management's commitment to the importance of ongoing development of new and differentiated products and services to sustain long-term growth.

With more than 275 operating companies located in 60 countries, the Company views its principle of decentralized management as an asset and fundamental to the success of a broadly based business. It also fosters an entrepreneurial spirit, combining the extensive resources of a large organization with the ability to anticipate and react quickly to local market changes and challenges.

The Company is committed to developing global business leaders who can achieve growth objectives. Businesses are managed for the long-term in order to sustain leadership positions and achieve growth that provides an enduring source of value to our shareholders.

Our Credo unifies the management team and the Company's dedicated employees in achieving these objectives, and provides a common set of values that serve as a constant reminder of the Company's responsibilities to its customers, employees, communities and shareholders. The Company believes that these basic principles, along with its overall mission of improving the quality of life for people everywhere, will enable Johnson & Johnson to continue to be among the leaders in the health care industry.

Results of Operations

Analysis of Consolidated Sales

In 2012, worldwide sales increased 3.4% to $67.2 billion, compared to an increase of 5.6% in 2011 and a decrease of 0.5% in 2010. These sales changes consisted of the following:

Sales increase/(decrease) due to:	2012	2011	2010
Volume	5.7%	3.1	(0.5)
Price	0.4	(0.3)	(0.8)
Currency	(2.7)	2.8	0.8
Total	**3.4%**	**5.6**	**(0.5)**

Sales by U.S. companies were $29.8 billion in 2012, $28.9 billion in 2011 and $29.5 billion in 2010. This represents an increase of 3.2% in 2012, and decreases of 1.8% in 2011 and 4.7% in 2010. Sales by international companies were $37.4 billion in 2012, $36.1 billion in 2011 and $32.1 billion in 2010. This represents increases of 3.5% in 2012, 12.4% in 2011 and 3.6% in 2010. The acquisition of Synthes, Inc., net of the related divestiture, increased both total worldwide sales growth and operational growth by 3.1%.

The five-year compound annual growth rates for worldwide, U.S. and international sales were 1.9%, (1.7)% and 5.5%, respectively. The ten-year compound annual growth rates for worldwide, U.S. and international sales were 6.4%, 2.9% and 10.4%, respectively.

Sales in Europe experienced a decline of 1.1% as compared to the prior year, including operational growth of 5.8% offset by a negative currency impact of 6.9%. Sales in the Western Hemisphere (excluding the U.S.) achieved growth of 12.3% as compared to the prior year, including operational growth of 19.0% and a negative currency impact of 6.7%. Sales in the Asia-Pacific, Africa region achieved growth of 5.3% as compared to the prior year, including operational growth of 6.7% and a negative currency impact of 1.4%.

In 2012, 2011 and 2010, the Company did not have a customer that represented 10% or more of total consolidated revenues.

U.S. Health Care Reform

Under the provisions of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, beginning in 2011, companies that sold branded prescription drugs to specified U.S. Government programs pay an annual non-tax deductible fee based on an allocation of each company's market share of total branded prescription drug sales from the prior year. The full-year impact to selling, marketing and administrative expenses was approximately $115 million in 2012 and $140 million in 2011. Under the current law, beginning in 2013, the Company will be required to pay a tax deductible 2.3% excise tax imposed on the sale of certain medical devices. The 2013 excise tax is estimated to be between $200 -$300 million and will be recorded in cost of products sold within the statement of earnings.

The net trade sales impact of the health care reform legislation was an annual reduction of approximately $450 million and $425 million in 2012 and 2011, respectively, due to an increase in sales rebates and discounts.

Analysis of Sales by Business Segments

Consumer Segment

Consumer segment sales in 2012 were $14.4 billion, a decrease of 2.9% from 2011, which included 0.5% operational growth offset by a negative currency impact of 3.4%. U.S. Consumer segment sales were $5.0 billion, a decrease of 2.0%. International sales were $9.4 billion, a decrease of 3.4%, which included 1.9% operational growth offset by a negative currency impact of 5.3%.

Major Consumer Franchise Sales:

				% Change	
(Dollars in Millions)	2012	2011	2010	'12 vs. '11	'11 vs. '10
OTC Pharmaceuticals & Nutritionals	$ 4,354	4,402	4,549	(1.1)%	(3.2)
Skin Care	3,618	3,715	3,452	(2.6)	7.6
Baby Care	2,254	2,340	2,209	(3.7)	5.9
Women's Health	1,625	1,792	1,844	(9.3)	(2.8)
Oral Care	1,624	1,624	1,526	0.0	6.4
Wound Care/Other	972	1,010	1,010	(3.8)	0.0
Total Consumer Sales	**$ 14,447**	**14,883**	**14,590**	**(2.9)%**	**2.0**

The Over-the-Counter (OTC) Pharmaceuticals and Nutritionals franchise sales were $4.4 billion, a decrease of 1.1% from 2011. Sales in the U.S. decreased primarily due to lower sales of analgesics as a result of supply constraints and competitive pressures in nutritional products. Strong growth of upper respiratory, digestive health and analgesics products outside the U.S. was offset by negative currency.

McNEIL-PPC, Inc. continues to operate under a consent decree signed in 2011, with the U.S. Food and Drug Administration (FDA), which governs certain McNeil Consumer Healthcare manufacturing operations. McNeil continues to

operate the manufacturing facilities in Las Piedras, Puerto Rico and Lancaster, Pennsylvania; however, production volumes from these facilities continue to be impacted by additional review and approval processes required under the consent decree. The Company expects this to continue throughout most of 2013. Plants operating under the consent decree will produce a simplified portfolio focused on key brands. The Fort Washington, Pennsylvania manufacturing site is not in operation at this time. McNeil continues to work on the re-siting of the products previously produced at the Fort Washington facility to other facilities.

The Skin Care franchise sales were $3.6 billion in 2012, a decrease of 2.6% from 2011. Increased sales of NEUTROGENA® products in the U.S. were offset by competition and economic conditions outside the U.S. The Baby Care franchise sales were $2.3 billion, a decrease of 3.7% from 2011. The decline in U.S. sales and the impact of negative currency was partially offset by increased sales of haircare and wipes outside the U.S. The Women's Health franchise sales were $1.6 billion, a decrease of 9.3% primarily due to the impact of the divestiture of certain brands. The Oral Care franchise sales were flat as compared to the prior year. Increased sales of LISTERINE® products outside the U.S. were partially offset by competitive pressures in the U.S. The Wound Care/Other franchise sales were $1.0 billion in 2012, a decrease of 3.8% from 2011 due to divestitures and competitive pressures. Negative currency impacted all of the franchises.

Consumer segment sales in 2011 were $14.9 billion, an increase of 2.0% from 2010, a 0.7% operational decline was offset by a positive currency impact of 2.7%. U.S. Consumer segment sales were $5.2 billion, a decrease of 6.7%. International sales were $9.7 billion, an increase of 7.3%, which included 2.9% operational growth and a positive currency impact of 4.4%.

Pharmaceutical Segment

The Pharmaceutical segment achieved sales of $25.4 billion in 2012, representing an increase of 4.0% over the prior year, with operational growth of 6.8% and a negative currency impact of 2.8%. U.S. sales were $12.4 billion, an increase of 0.3%. International sales were $12.9 billion, an increase of 7.9%, which included 13.6% operational growth and a negative currency impact of 5.7%.

Major Pharmaceutical Therapeutic Area Sales:*

(Dollars in Millions)	2012	2011	2010	% Change '12 vs. '11	% Change '11 vs. '10
Total Immunology	**$ 7,874**	**6,798**	**5,398**	**15.8 %**	**25.9**
REMICADE®	6,139	5,492	4,610	11.8	19.1
SIMPONI®	607	410	226	48.0	81.4
STELARA®	1,025	738	393	38.9	87.8
Other Immunology	103	158	169	(34.8)	(6.5)
Total Infectious Diseases	**3,194**	**3,189**	**3,033**	**0.2**	**5.1**
INTELENCE®	349	314	243	11.1	29.2
LEVAQUIN®/FLOXIN®	75	623	1,357	(88.0)	(54.1)
PREZISTA®	1,414	1,211	857	16.8	41.3
Other Infectious Diseases	1,356	1,041	576	30.3	80.7
Total Neuroscience	**6,718**	**6,948**	**6,644**	**(3.3)**	**4.6**
CONCERTA®/methylphenidate	1,073	1,268	1,319	(15.4)	(3.9)
INVEGA®	550	499	424	10.2	17.7
INVEGA® SUSTENNA®/XEPLION®	796	378	152	**	**
RISPERDAL® CONSTA®	1,425	1,583	1,500	(10.0)	5.5
Other Neuroscience	2,874	3,220	3,249	(10.7)	(0.9)
Total Oncology	**2,629**	**2,048**	**1,465**	**28.4**	**39.8**
DOXIL®/CAELYX®	83	402	320	(79.4)	25.6
VELCADE®	1,500	1,274	1,080	17.7	18.0
ZYTIGA®	961	301	—	**	100.0
Other Oncology	85	71	65	19.7	9.2
Total Other	**4,936**	**5,385**	**5,856**	**(8.3)**	**(8.0)**
ACIPHEX®/PARIET®	835	975	1,006	(14.4)	(3.1)
PROCRIT®/EPREX®	1,462	1,623	1,934	(9.9)	(16.1)
Other	2,639	2,787	2,916	(5.3)	(4.4)
Total Pharmaceutical Sales	**$ 25,351**	**24,368**	**22,396**	**4.0 %**	**8.8**

* Prior year amounts have been reclassified to conform to current year presentation.
** Percentage greater than 100%

Immunology products achieved sales of $7.9 billion in 2012, representing an increase of 15.8% as compared to the prior year. The increased sales of SIMPONI® (golimumab) and REMICADE® (infliximab) were primarily due to market growth and the impact of the agreement with Merck & Co. Inc. (Merck). Effective July 1, 2011, distribution rights to REMICADE® and SIMPONI® in certain territories were relinquished to the Company by Merck. Additional contributors to the increase were sales of STELARA® (ustekinumab).

Infectious disease products achieved sales of $3.2 billion in 2012, representing an increase of 0.2% as compared to the prior year. Major contributors were INCIVO® (telaprevir), the continued momentum in market share growth of PREZISTA® (darunavir), EDURANT® (rilpivirine) and INTELENCE® (etravirine) partially offset by lower sales of LEVAQUIN® (levofloxacin)/FLOXIN® (ofloxacin), due to the loss of market exclusivity in the U.S. in June 2011.

Neuroscience products sales were $6.7 billion, a decline of 3.3% as compared to the prior year. Growth was impacted by generic competition for CONCERTA®/methylphenidate, RAZADYNE® (galantamine), RISPERDAL® (risperidone) and DURAGESIC®/Fentanyl Transdermal (fentanyl transdermal system). A decline in the Company's long-acting injectable

antipsychotic, RISPERDAL® CONSTA®(risperidone), was offset by strong sales of INVEGA® SUSTENNA®/XEPLION® (paliperidone palmitate) and INVEGA® (paliperidone palmitate). The Company's U.S. Supply and Distribution Agreement with Watson Laboratories, Inc. to distribute an authorized generic version of CONCERTA® became effective May 1, 2011. The original CONCERTA® patent expired in 2004, and the parties have received approval from the FDA to manufacture and market a generic version of CONCERTA®. Another generic version of CONCERTA® was launched on December 31, 2012. This will result in a further reduction in CONCERTA® sales.

Oncology products achieved sales of $2.6 billion in 2012, representing an increase of 28.4% as compared to the prior year. This growth was primarily due to sales of ZYTIGA®(abiraterone acetate) and VELCADE® (bortezomib). This growth was partially offset by lower sales of DOXIL®(doxorubicin HCl liposome injection)/CAELYX®(pegylated liposomal doxorubicin hydrochloride), due to supply constraints from the Company's third-party manufacturer. The Company has been working to restore a reliable supply of DOXIL®/CAELYX®. Full access in the U.S. has been restored. An alternate manufacturing approach was approved in the European Union (EU) and Japan late in 2012 and in Canada in January of 2013. In the European Union, the CAELYX® managed access program was put in place to ensure patients can complete their full course of treatment. It will remain in place until a full supply of CAELYX® has been restored. In February 2013, the FDA approved a generic version of DOXIL®.

Other Pharmaceutical sales were $4.9 billion, a decline of 8.3% as compared to the prior year primarily due to divestitures and lower sales of ACIPHEX®/PARIET®(rabeprazole sodium) and EPREX® (Epoetin alfa), primarily due to the impact of generic competition. These results were partially offset by sales growth of XARELTO®(rivaroxaban).

During 2012, the Company received several regulatory approvals including: U.S. approval of a new 800mg tablet of PREZISTA® (darunavir) for once daily oral administration for the treatment of human immunodeficiency virus (HIV-1) in treatment-naive and treatment-experienced adult patients with no darunavir resistance-associated mutations; FDA approval for the expanded use of XARELTO®(rivaroxaban) to treat deep-vein thrombosis, or DVT, and pulmonary embolism, or PE and to reduce the risk of recurrent DVT and PE following initial treatment; and the FDA granted accelerated approval for SIRTURO™ (bedaquiline) tablets for the treatment of pulmonary multi-drug resistant tuberculosis as part of combination therapy in adults. The FDA approved the supplemental New Drug Application (NDA) for NUCYNTA® ER (tapentadol) extended-release tablets, an oral analgesic taken twice daily, for the management of neuropathic pain associated with diabetic peripheral neuropathy in adults. The FDA and the European Commission also approved an expanded indication for ZYTIGA® (abiraterone acetate), in combination with prednisone, allowing for the use before chemotherapy in the treatment of metastatic castration-resistant prostate cancer. In addition, the European Commission approved the marketing authorizations for DACOGEN® (decitabine) for the treatment of adult patients (age 65 years and above) with newly diagnosed de novo or secondary acute myeloid leukemia who are not candidates for standard induction chemotherapy, and for the subcutaneous administration of VELCADE® (bortezomib) for the treatment of multiple myeloma.

The Company submitted several New Drug Applications, including an NDA to the FDA and Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) seeking approval for the use of canagliflozin, an oral, once-daily, selective sodium glucose co-transporter 2 (SGLT2) inhibitor, for the treatment of adult patients with type 2 diabetes, and an NDA seeking approval for a fixed-dose therapy combining canagliflozin and immediate release metformin to treat patients with type 2 diabetes. Additional submissions included a supplemental Biologics License Application to the FDA and a Type II Variation to the EMA requesting approval of STELARA® (ustekinumab) for the treatment of adult patients with active psoriatic arthritis, and a Biologics License Application to the FDA requesting approval of an investigational intravenous formulation of the anti-tumor necrosis factor (TNF)-alpha SIMPONI® (golimumab) for the treatment of adults with moderately to severely active rheumatoid arthritis. In addition, a supplemental Biologics License Application was submitted to the FDA and a Type II Variation was submitted to the EMA requesting approval of SIMPONI® (golimumab) for the treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. Finally, an MAA was submitted to the EMA seeking conditional approval for the use of bedaquiline (TMC207) as an oral treatment, to be used as part of combination therapy for pulmonary, multi-drug resistant tuberculosis in adults.

Pharmaceutical segment sales in 2011 were $24.4 billion, an increase of 8.8% from 2010, with operational growth of 6.2% and a positive currency impact of 2.6%. U.S. sales were $12.4 billion, a decrease of 1.1%. International sales were $12.0 billion, an increase of 21.3%, which included 15.5% operational growth and a positive currency impact of 5.8%.

Medical Devices and Diagnostics Segment

The Medical Devices and Diagnostics segment achieved sales of $27.4 billion in 2012, representing an increase of 6.4% over the prior year, with operational growth of 8.7% and a negative currency impact of 2.3%. U.S. sales were $12.4 billion, an increase of 8.7% as compared to the prior year. International sales were $15.1 billion, an increase of 4.5% over the prior year, with operational growth of 8.6% and a negative currency impact of 4.1%. The acquisition of Synthes, Inc., net of the related divestiture, increased both total sales growth and operational growth for the Medical Devices and Diagnostics segment by 7.9%.

Major Medical Devices and Diagnostics Franchise Sales:*

(Dollars in Millions)	2012	2011	2010	% Change '12 vs. '11	% Change '11 vs. '10
Orthopaedics	$ 7,799	5,809	5,585	34.3 %	4.0
Surgical Care	6,483	6,637	6,272	(2.3)	5.8
Vision Care	2,996	2,916	2,680	2.7	8.8
Diabetes Care	2,616	2,652	2,470	(1.4)	7.4
Specialty Surgery	2,526	2,407	2,186	4.9	10.1
Diagnostics	2,069	2,164	2,053	(4.4)	5.4
Cardiovascular Care	1,985	2,288	2,552	(13.2)	(10.3)
Infection Prevention/Other	952	906	803	5.1	12.8
Total Medical Devices and Diagnostics Sales	**$ 27,426**	**25,779**	**24,601**	**6.4 %**	**4.8**

* Prior year amounts have been reclassified to conform to current year presentation.

The Orthopaedics franchise achieved sales of $7.8 billion in 2012, a 34.3% increase over the prior year. Growth was primarily due to sales of newly acquired products from Synthes, Inc., and sales of joint reconstruction and Mitek sports medicine products. Sales were impacted by the divestitures of the surgical instruments business of Codman & Shurtleff, Inc. in the fiscal fourth quarter of 2011, and the divestiture of certain rights and assets related to the DePuy trauma business. The positive impact on the Orthopaedics franchise total sales growth and operational growth due to the newly acquired products from Synthes, Inc. net of the related trauma business divestiture was 34.7%.

The Surgical Care franchise sales were $6.5 billion in 2012, a decrease of 2.3% from the prior year. Lower sales of mechanical, breast care and pelvic floor products were partially offset by increased sales of sutures and endoscopy products with the success of the ECHELON FLEX™ powered ENDOPATH® Stapler.

The Vision Care franchise achieved sales of $3.0 billion in 2012, a 2.7% increase over the prior year. The growth was driven by ACUVUE® TruEye®, 1-DAY ACUVUE® MOIST® for Astigmatism and 1-DAY ACUVUE® MOIST®.

The Diabetes Care franchise sales were $2.6 billion, a decrease of 1.4% versus the prior year. Sales growth in Asia and Latin America was offset by the negative impact of currency.

The Specialty Surgery franchise achieved sales of $2.5 billion in 2012, a 4.9% increase over the prior year. Incremental sales from the acquisition of SterilMed Inc., sales of biosurgery products and international sales of energy products were the major contributors to the growth.

The Diagnostics franchise sales were $2.1 billion, a decline of 4.4% versus the prior year. The decline was primarily due to lower sales in donor screening due to competitive pressures, and the divestiture of the RhoGAM® business during the third quarter of 2012. In January 2013, the Company announced it is exploring strategic alternatives for the Ortho-Clinical Diagnostics business, including a possible divestiture.

The Cardiovascular Care franchise sales were $2.0 billion, a decline of 13.2% versus the prior year. Sales were impacted by the Company's decision to exit the drug-eluting stent market in the second quarter of 2011, and lower sales of endovascular products, impacted by competitive launches and a disruption in supply that was resolved late in the third quarter. The decline in sales was partially offset by strong growth in Biosense Webster's electrophysiology business primarily due to the success of the THERMOCOOL® catheter launches.

The Infection Prevention/Other franchise achieved sales of $1.0 billion in 2012, a 5.1% increase over the prior year primarily due to growth in the advanced sterilization business.

The Medical Devices and Diagnostics segment achieved sales of $25.8 billion in 2011, representing an increase of 4.8% over the prior year, with operational growth of 1.7% and a positive currency impact of 3.1%. U.S. sales were $11.4 billion, a decrease of 0.4% as compared to the prior year. International sales were $14.4 billion, an increase of 9.2% over the prior year, with operational growth of 3.4% and a positive currency impact of 5.8%.

Analysis of Consolidated Earnings Before Provision for Taxes on Income

Consolidated earnings before provision for taxes on income increased by $1.4 billion to $13.8 billion in 2012 as compared to $12.4 billion in 2011, an increase of 11.4%. Earnings before provision for taxes on income were favorable due to increased gross profit of $0.9 billion, a $0.1 billion decrease in selling, marketing and administrative expenses due to cost containment initiatives across many of the businesses, lower litigation expense of $2.1 billion and lower charges of $0.4 billion related to the DePuy ASR™ Hip program versus the prior year. This was partially offset by $2.1 billion of charges attributable to asset write-downs and impairment of in-process research and development, primarily related to the Crucell vaccine business and the discontinuation of the Phase III clinical development of bapineuzumab IV and $0.2 billion of integration and currency costs related to the acquisition of Synthes, Inc. versus the prior year. Included in 2011 was a $0.6 billion restructuring charge, net of

inventory write-offs which are included in cost of products sold, related to the Cardiovascular Care business. Additionally, 2011 included higher gains from divestitures and other items of $0.3 billion, recorded in other (income) expense, net.

The 2011 decrease of 27.1% as compared to 2010 was primarily due to costs associated with litigation, which includes product liability, the impact of the OTC and DePuy ASR™ Hip recalls and the restructuring expense related to the Cardiovascular Care business. Additionally, investment spending, the fee on branded pharmaceutical products incurred due to the U.S. health care reform legislation, and the integration costs, including an inventory step-up charge, associated with the acquisition of Crucell contributed to the decrease in earnings. This was partially offset by gains from divestitures.

As a percent to sales, consolidated earnings before provision for taxes on income in 2012 was 20.5% versus 19.0% in 2011.

Cost of Products Sold and Selling, Marketing and Administrative Expenses: Cost of products sold and selling, marketing and administrative expenses as a percent to sales were as follows:

% of Sales	2012	2011	2010
Cost of products sold	32.2%	31.3	30.5
Percent point increase over the prior year	0.9	0.8	0.7
Selling, marketing and administrative expenses	31.0	32.3	31.5
Percent point (decrease)/increase over the prior year	(1.3)	0.8	(0.5)

In 2012, cost of products sold as a percent to sales increased compared to the prior year. This was primarily the result of the amortization of the inventory step-up charge of $0.4 billion and amortization of intangibles related to the Synthes, Inc. acquisition of $0.3 billion and ongoing remediation costs in the McNeil OTC business. There was a decrease in the percent to sales of selling, marketing and administrative expenses in 2012 compared to the prior year primarily due to cost containment initiatives across many of the businesses. The prior year period included higher investment spending in the Pharmaceutical business for new products.

In 2011, cost of products sold as a percent to sales increased compared to the prior year. This was primarily attributable to ongoing remediation costs in the McNeil OTC business and inventory write-offs due to the restructuring of the Cardiovascular Care business. In addition, lower margins and integration costs, including an inventory step-up charge, associated with the acquisition of Crucell negatively impacted cost of products sold. Percent to sales of selling, marketing and administrative expenses increased in 2011 compared to the prior year primarily due to investment spending, as well as the fee on branded pharmaceutical products incurred due to the U.S. health care reform legislation.

Research and Development Expense: Research and development expense by segment of business was as follows:

	2012		2011		2010	
(Dollars in Millions)	Amount	% of Sales*	Amount	% of Sales*	Amount	% of Sales*
Consumer	$ 622	4.3%	659	4.4	609	4.2
Pharmaceutical	5,362	21.2	5,138	21.1	4,432	19.8
Medical Devices and Diagnostics	1,681	6.1	1,751	6.8	1,803	7.3
Total research and development expense	$ 7,665	11.4%	7,548	11.6	6,844	11.1
Percent increase/(decrease) over the prior year	1.6%		10.3		(2.0)	

* As a percent to segment sales

Research and development activities represent a significant part of the Company's business. These expenditures relate to the processes of discovering, testing and developing new products, improving existing products, as well as ensuring product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products. In 2012, worldwide costs of research and development activities increased by 1.6% compared to 2011. The decrease in the Medical Devices and Diagnostics segment was primarily due to the discontinuation of the clinical development program for the NEVO™ Sirolimus-Eluting Coronary Stent.

In-Process Research and Development (IPR&D): In 2012, the Company recorded a charge of $1.2 billion, which included $0.7 billion for the impairment of the IPR&D related to the discontinuation of the Phase III clinical development of bapineuzumab IV and the partial impairment of the IPR&D related to the Crucell vaccine business in the amount of $0.4 billion. Of the $0.7 billion impairment of the IPR&D related to the discontinuation of the Phase III clinical development of bapineuzumab IV, $0.3 billion

is attributable to noncontrolling interest. These charges relate to development projects which have been recently discontinued or delayed.

Other (Income) Expense, Net: Other (income) expense, net includes royalty income; gains and losses related to the sale and write-down of certain investments in equity securities held by Johnson & Johnson Development Corporation; gains and losses on the disposal of property, plant and equipment; currency gains and losses; and litigation settlements. In 2012, the favorable change of $1.1 billion in other (income) expense, net, was primarily due to lower expenses of $2.1 billion related to litigation, including product liability, and $0.4 billion for costs related to the DePuy ASR™ Hip program. This was partially offset by $0.9 billion attributed to asset write-downs, primarily related to the Crucell vaccine business, and $0.2 billion of higher integration/transaction and currency costs related to the acquisition of Synthes, Inc.

In 2011, the unfavorable change of $3.5 billion in other (income) expense, net, was primarily due to net litigation, which includes product liability of $3.3 billion in 2011 as compared to a $0.4 billion net gain from litigation in 2010. Additionally, 2011 as compared to 2010 included higher expenses of $0.2 billion for costs related to the DePuy ASR™ Hip program and an adjustment of $0.5 billion to the value of the currency option and deal costs related to the acquisition of Synthes, Inc. Included in 2011 were higher gains on the divestitures of businesses of $0.6 billion as compared to 2010.

Restructuring: In 2011, Cordis Corporation, a subsidiary of Johnson & Johnson, announced the discontinuation of its clinical development program for the NEVO™ Sirolimus-Eluting Coronary Stent and cessation of the manufacture and marketing of CYPHER® and CYPHER SELECT® Plus Sirolimus-Eluting Coronary Stents by the end of 2011. The Company recorded a pre-tax charge of $0.7 billion, of which $0.1 billion was included in the cost of products sold. There was no restructuring charge in 2012. See Note 22 to the Consolidated Financial Statements for additional details related to the restructuring.

Interest (Income) Expense: Interest income in 2012 decreased by $27 million as compared to the prior year due to lower rates of interest earned and lower average cash balances. Cash, cash equivalents and marketable securities totaled $21.1 billion at the end of 2012, and averaged $26.7 billion as compared to the $30.0 billion average cash balance in 2011. The decline in the average cash balance was due to the acquisition of Synthes, Inc. partially offset by cash generated from operating activities.

Interest expense in 2012 decreased by $39 million as compared to 2011 due to a lower average debt balance. The average debt balance was $17.9 billion in 2012 versus $18.2 billion in 2011. The total debt balance at the end of 2012 was $16.2 billion as compared to $19.6 billion at the end of 2011. The reduction in debt of approximately $3.4 billion was primarily due to a reduction in commercial paper.

Interest income in 2011 decreased by $16 million as compared to the prior year due to lower rates of interest earned despite higher average cash balances. Cash, cash equivalents and marketable securities totaled $32.3 billion at the end of 2011, and averaged $30.0 billion as compared to the $23.6 billion average cash balance in 2010. The increase in the average cash balance was primarily due to cash generated from operating activities and net cash proceeds from divestitures.

Interest expense in 2011 increased by $116 million as compared to 2010 due to a higher average debt balance. The total debt balance at the end of 2011 was $19.6 billion as compared to $16.8 billion at the end of 2010. The higher average debt balance of $18.2 billion in 2011 versus $15.7 billion in 2010 was due to increased borrowings. The Company increased borrowings, capitalizing on favorable terms in the capital markets. The proceeds of the borrowings were used for general corporate purposes.

Segment Pre-Tax Profit

Pre-tax profits by segment of business were as follows:

			Percent of Segment Sales	
(Dollars in Millions)	**2012**	**2011**	**2012**	**2011**
Consumer	$ 1,693	2,096	11.7%	14.1
Pharmaceutical	6,075	6,406	24.0	26.3
Medical Devices and Diagnostics	7,187	5,263	26.2	20.4
Total [1]	14,955	13,765	22.2	21.2
Less: Expenses not allocated to segments [2]	1,180	1,404		
Earnings before provision for taxes on income	$ 13,775	12,361	20.5%	19.0

(1) See Note 18 to the Consolidated Financial Statements for more details.

(2) Amounts not allocated to segments include interest (income) expense, noncontrolling interests, and general corporate (income) expense. A $0.2 billion and $0.5 billion currency related expense for the acquisition of Synthes, Inc. was included in 2012 and 2011, respectively.

Consumer Segment: In 2012, Consumer segment pre-tax profit as a percent to sales was 11.7% versus 14.1%, in 2011. Pre-tax profit was unfavorably impacted by $0.3 billion attributed to intangible asset write-downs and approximately $0.3 billion due to unfavorable product mix and remediation costs associated with the McNEIL-PPC, Inc. consent decree. This was partially offset by cost containment initiatives realized in selling, marketing and administrative expenses. In addition, 2011 included higher gains on divestitures. In 2011, Consumer segment pre-tax profit decreased 10.5% from 2010. The primary drivers of the decline in operating profit were unfavorable product mix and remediation costs associated with the recall of certain OTC products, partially offset by the gain on the divestiture of MONISTAT®.

Pharmaceutical Segment: In 2012, Pharmaceutical segment pre-tax profit as a percent to sales was 24.0% versus 26.3%, in 2011. Pre-tax profit was unfavorably impacted by charges of $1.6 billion attributed to the write-down of assets and impairment of in-process research and development assets, related to the Crucell vaccine business, and to the discontinuation of the Phase III clinical development of bapineuzumab IV. This was partially offset by lower litigation expense of $1.1 billion versus the prior year and favorable operating expenses of $0.3 billion. Additionally, 2012 included the gain on the divestiture of BYSTOLIC®(nebivolol) IP rights. In 2011, Pharmaceutical segment pre-tax profit decreased 9.6% from 2010. The primary drivers of the decrease in the pre-tax profit margin were higher litigation expenses recorded in 2011, the impact of the U.S. health care reform fee, and lower margins and integration costs, including an inventory step-up charge, associated with the Crucell acquisition. This was partially offset by gains on the divestitures of the Animal Health Business and Ortho Dermatologics, the gain related to the Company's earlier investment in Crucell, and lower manufacturing costs.

Medical Devices and Diagnostics Segment: In 2012, Medical Devices and Diagnostics segment pre-tax profit as a percent to sales was 26.2% versus 20.4%, in 2011. The Medical Devices and Diagnostics segment pre-tax profit was favorably impacted by profits from Synthes sales, lower expenses of $1.4 billion for litigation, including product liability, and the DePuy ASR™ Hip program and $0.1 billion for research & development primarily due to the discontinuation of its clinical development program for the NEVO™ Sirolimus-Eluting Coronary Stent. This was partially offset by an increase in integration costs and amortization of the inventory step-up of $0.8 billion associated with the acquisition of Synthes, Inc. and $0.1 billion attributed to the write-down of intangible assets. In addition, 2012 included higher gains on divestitures versus the prior year due to the divestitures of the Therakos business and RhoGAM®. Additionally, 2011 included a $0.7 billion restructuring charge related to the discontinuation of the clinical development program for the NEVO™ Sirolimus-Eluting Coronary Stent. In 2011, Medical Devices and Diagnostics segment pre-tax profit decreased 36.4% from 2010. The primary drivers of the decline in the pre-tax profit margin in the Medical Devices and Diagnostics segment were litigation expenses, including product liability, costs associated with the DePuy ASR™ Hip program, restructuring expense, costs incurred related to the acquisition of Synthes, Inc. and increased investment spending.

Provision for Taxes on Income: The worldwide effective income tax rate was 23.7% in 2012, 21.8% in 2011 and 21.3% in 2010. The increase in the 2012 effective tax rate of 1.9% as compared to 2011 was due to lower tax benefits on the impairment of in-process research and development intangible assets in low tax jurisdictions, increases in taxable income in higher tax jurisdictions relative to lower tax jurisdictions and the exclusion of the benefit of the U.S. Research & Development (R&D) tax credit and the CFC look-through provisions from the 2012 fiscal year financial results. The R&D tax credit and the CFC look-through provisions were enacted into law in 2013 and were retroactive to January 1, 2012. The entire benefit of the R&D tax credit and the CFC look-through provisions will be reflected in the 2013 fiscal year financial results.

The 2011 tax rate increased as compared to 2010 due to certain U.S. expenses which are not fully tax deductible and higher U.S. state taxes partially offset by increases in taxable income in lower tax jurisdictions relative to higher tax jurisdictions.

Noncontrolling Interest: A charge of $0.7 billion for the impairment of the IPR&D related to the discontinuation of the Phase III clinical development of bapineuzumab IV was recorded in 2012. Of the $0.7 billion impairment, $0.3 billion is attributable to noncontrolling interest.

Liquidity and Capital Resources

Liquidity & Cash Flows

Cash and cash equivalents were $14.9 billion at the end of 2012 as compared with $24.5 billion at the end of 2011. The primary uses of cash that contributed to the $9.6 billion decrease versus the prior year were approximately $4.5 billion net cash used by investing activities and $20.6 billion net cash used by financing activities partially offset by $15.4 billion of cash generated from operating activities.

Cash flow from operations of $15.4 billion was the result of $10.5 billion of net earnings and $6.9 billion of non-cash charges primarily related to depreciation and amortization, asset write-downs (primarily in-process research and development), stock-based compensation, noncontrolling interest and deferred tax provision reduced by $2.0 billion related to changes in assets and liabilities, net of effects from acquisitions.

Investing activities use of $4.5 billion was primarily for $2.9 billion for additions to property, plant and equipment and acquisitions, net of cash acquired of $4.5 billion partially offset by net sales of investments in marketable securities of

$1.4 billion and $1.5 billion of proceeds from the disposal of assets.

Financing activities use of $20.6 billion was for the repurchase of common stock of $12.9 billion primarily for the acquisition of Synthes, Inc., dividends to shareholders of $6.6 billion and net retirement of short and long-term debt of $3.7 billion, partially offset by $2.7 billion of net proceeds from stock options exercised/excess tax benefits.

In 2012, the Company continued to have access to liquidity through the commercial paper market. For additional details on borrowings, see Note 7 to the Consolidated Financial Statements.

The Company anticipates that operating cash flows, existing credit facilities and access to the commercial paper markets will provide sufficient resources to fund operating needs in 2013.

Concentration of Credit Risk

Global concentration of credit risk with respect to trade accounts receivables continues to be limited due to the large number of customers globally and adherence to internal credit policies and credit limits. Recent economic challenges in Italy, Spain, Greece and Portugal (the Southern European Region) have impacted certain payment patterns, which have historically been longer than those experienced in the U.S. and other international markets. The total net trade accounts receivable balance in the Southern European Region was approximately $2.1 billion as of December 30, 2012 and approximately $2.4 billion as of January 1, 2012. Approximately $1.2 billion as of December 30, 2012 and approximately $1.4 billion as of January 1, 2012 of the Southern European Region net trade accounts receivable balance related to the Company's Consumer, Vision Care and Diabetes Care businesses as well as certain Pharmaceutical and Medical Devices and Diagnostics customers which are in line with historical collection patterns.

The remaining balance of net trade accounts receivable in the Southern European Region has been negatively impacted by the timing of payments from certain government owned or supported health care customers as well as certain distributors of the Pharmaceutical and Medical Devices and Diagnostics local affiliates. The total net trade accounts receivable balance for these customers were approximately $0.9 billion at December 30, 2012 and $1.0 billion at January 1, 2012. The Company continues to receive payments from these customers and in some cases late payment premiums. For customers where payment is expected over periods of time longer than one year, revenue and trade receivables have been discounted over the estimated period of time for collection. Allowances for doubtful accounts have been increased for these customers, but have been immaterial to date. The Company will continue to work closely with these customers on payment plans, monitor the economic situation and take appropriate actions as necessary.

Financing and Market Risk

The Company uses financial instruments to manage the impact of foreign exchange rate changes on cash flows. Accordingly, the Company enters into forward foreign exchange contracts to protect the value of certain foreign currency assets and liabilities and to hedge future foreign currency transactions primarily related to product costs. Gains or losses on these contracts are offset by the gains or losses on the underlying transactions. A 10% appreciation of the U.S. Dollar from the December 30, 2012 market rates would increase the unrealized value of the Company’s forward contracts by $91 million. Conversely, a 10% depreciation of the U.S. Dollar from the December 30, 2012 market rates would decrease the unrealized value of the Company’s forward contracts by $112 million. In either scenario, the gain or loss on the forward contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated earnings and cash flows.

The Company hedges the exposure to fluctuations in currency exchange rates, and the effect on certain assets and liabilities in foreign currency, by entering into currency swap contracts. A 1% change in the spread between U.S. and foreign interest rates on the Company’s interest rate sensitive financial instruments would either increase or decrease the unrealized value of the Company’s swap contracts by approximately $190 million. In either scenario, at maturity, the gain or loss on the swap contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated cash flows.

The Company does not enter into financial instruments for trading or speculative purposes. Further, the Company has a policy of only entering into contracts with parties that have at least an “A” (or equivalent) credit rating. The counter-parties to these contracts are major financial institutions and there is no significant concentration of exposure with any one counter-party. Management believes the risk of loss is remote.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2012, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 19, 2013. Interest charged on borrowings under the credit line agreement is based on either bids provided by banks, the prime rate or London Interbank Offered Rates (LIBOR), plus applicable margins. Commitment fees under the agreement are not material.

Total borrowings at the end of 2012 and 2011 were $16.2 billion and $19.6 billion, respectively. The reduction in debt in 2012 of approximately $3.4 billion was primarily due to a reduction in commercial paper.

In 2012, net cash (cash and current marketable securities, net of debt) was $4.9 billion compared to net cash of $12.6 billion in 2011. Total debt represented 20.0% of total capital (shareholders’ equity and total debt) in 2012 and 25.6% of total capital in 2011. Shareholders’ equity per share at the end of 2012 was $23.33 compared to $20.95 at year-end 2011, an

increase of 11.4%.

A summary of borrowings can be found in Note 7 to the Consolidated Financial Statements.

Contractual Obligations and Commitments

The Company's contractual obligations are primarily for leases, debt and unfunded retirement plans. There are no other significant obligations. To satisfy these obligations, the Company will use cash from operations. The following table summarizes the Company's contractual obligations and their aggregate maturities as of December 30, 2012 (see Notes 7, 10 and 16 to the Consolidated Financial Statements for further details):

(Dollars in Millions)		Long-Term Debt Obligations	Interest on Debt Obligations	Unfunded Retirement Plans	Operating Leases	Total
	2013	$ 1,512	497	68	251	2,328
	2014	1,789	483	66	192	2,530
	2015	—	477	71	149	697
	2016	898	471	76	115	1,560
	2017	1,000	436	80	90	1,606
After 2017		7,802	4,232	502	128	12,664
Total		**$ 13,001**	**6,596**	**863**	**925**	**21,385**

For tax matters, see Note 8 to the Consolidated Financial Statements.

Share Repurchase and Dividends

On July 9, 2007, the Company announced that its Board of Directors approved a stock repurchase program authorizing the Company to buy back up to $10.0 billion of the Company's Common Stock. As of January 2, 2011, the Company repurchased an aggregate of 158.3 million shares of Johnson & Johnson Common Stock at a cost of $10.0 billion and the stock repurchase program was completed. The Company funded the share repurchase program through a combination of available cash and debt.

Pursuant to the accelerated stock repurchase agreements in connection with the acquisition of Synthes, Inc., the Company has not made any purchases of Common Stock on the open market during the fiscal third and fourth quarters of 2012.

The Company increased its dividend in 2012 for the 50th consecutive year. Cash dividends paid were $2.40 per share in 2012 compared with dividends of $2.25 per share in 2011, and $2.11 per share in 2010. The dividends were distributed as follows:

	2012	2011	2010
First quarter	$ 0.57	0.54	0.49
Second quarter	0.61	0.57	0.54
Third quarter	0.61	0.57	0.54
Fourth quarter	0.61	0.57	0.54
Total	**$ 2.40**	**2.25**	**2.11**

On January 2, 2013, the Board of Directors declared a regular quarterly cash dividend of $0.61 per share, payable on March 12, 2013, to shareholders of record as of February 26, 2013. The Company expects to continue the practice of paying regular cash dividends.

Other Information

Critical Accounting Policies and Estimates

Management's discussion and analysis of results of operations and financial condition are based on the Company's consolidated financial statements that have been prepared in accordance with accounting principles generally accepted in the U.S. (GAAP). The preparation of these financial statements requires that management make estimates and assumptions that affect the amounts reported for revenues, expenses, assets, liabilities and other related disclosures. Actual results may or may not differ from these estimates. The Company believes that the understanding of certain key accounting policies and estimates are essential in achieving more insight into the Company's operating results and financial condition. These key accounting policies include revenue recognition, income taxes, legal and self-insurance contingencies, valuation of long-lived assets, assumptions used to determine the amounts recorded for pensions and other employee benefit plans and accounting for stock

options.

Revenue Recognition: The Company recognizes revenue from product sales when goods are shipped or delivered, and title and risk of loss pass to the customer. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns and discounts to customers are accounted for as reductions in sales in the same period the related sales are recorded.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including prices charged by competitors. Rebates, the largest being the Medicaid rebate provision, are estimated based on contractual terms, historical experience, trend analysis and projected market conditions in the various markets served. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns are generally estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales return accruals.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices and Diagnostics segment are typically resalable but are not material. The Company rarely exchanges products from inventory for returned products. The sales returns reserve for the total Company has ranged between 1.0% and 1.2% of annual net trade sales during the fiscal reporting years 2012, 2011 and 2010.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the year incurred. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on estimated sales volumes for the incentive period and are recorded as products are sold. The Company also earns service revenue for co-promotion of certain products. For all years presented, service revenues were less than 2% of total revenues and are included in sales to customers. These arrangements are evaluated to determine the appropriate amounts to be deferred.

In addition, the Company enters into collaboration arrangements that contain multiple revenue generating activities. Amounts due from collaborative partners for these arrangements are recognized as each activity is performed or delivered, based on the relative fair value. Upfront fees received as part of these arrangements are deferred and recognized over the performance period. See Note 1 to the Consolidated Financial Statements for additional disclosures on collaborations.

Reasonably likely changes to assumptions used to calculate the accruals for rebates, returns and promotions are not anticipated to have a material effect on the financial statements. The Company currently discloses the impact of changes to assumptions in the quarterly or annual filing in which there is a material financial statement impact.

Below are tables that show the progression of accrued rebates, returns, promotions, reserve for doubtful accounts and reserve for cash discounts by segment of business for the fiscal years ended December 30, 2012 and January 1, 2012.

Consumer Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits	Balance at End of Period
2012				
Accrued rebates [1]	$ 127	438	(433)	132
Accrued returns	114	131	(137)	108
Accrued promotions	240	1,392	(1,351)	281
Subtotal	$ 481	1,961	(1,921)	521
Reserve for doubtful accounts	43	6	(11)	38
Reserve for cash discounts	22	214	(215)	21
Total	$ 546	2,181	(2,147)	580
2011				
Accrued rebates[1]	$ 131	346	(350)	127
Accrued returns	145	103	(134)	114
Accrued promotions	294	1,520	(1,574)	240
Subtotal	$ 570	1,969	(2,058)	481
Reserve for doubtful accounts	57	3	(17)	43
Reserve for cash discounts	21	226	(225)	22
Total	$ 648	2,198	(2,300)	546

[1] Includes reserve for customer rebates of $33 million at December 30, 2012 and $34 million at January 1, 2012, recorded as a contra asset.

Pharmaceutical Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits	Balance at End of Period
2012				
Accrued rebates [1]	$ 1,591	4,732	(4,556)	1,767
Accrued returns	384	49	(36)	397
Accrued promotions	83	142	(131)	94
Subtotal	$ 2,058	4,923	(4,723)	2,258
Reserve for doubtful accounts	157	47	(13)	191
Reserve for cash discounts	45	425	(408)	62
Total	$ 2,260	5,395	(5,144)	2,511
2011				
Accrued rebates [1]	$ 1,520	4,732	(4,661)	1,591
Accrued returns	294	105	(15)	384
Accrued promotions	83	187	(187)	83
Subtotal	$ 1,897	5,024	(4,863)	2,058
Reserve for doubtful accounts	145	20	(8)	157
Reserve for cash discounts	54	392	(401)	45
Total	$ 2,096	5,436	(5,272)	2,260

[1] Includes reserve for customer rebates of $269 million at December 30, 2012 and $298 million at January 1, 2012, recorded as a contra asset.

Medical Devices and Diagnostics Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits	Balance at End of Period
2012				
Accrued rebates[1]	$ 497	3,803	(3,733)	567
Accrued returns	184	369	(348)	205
Accrued promotions	73	49	(62)	60
Subtotal	$ 754	4,221	(4,143)	832
Reserve for doubtful accounts	161	74	2	237
Reserve for cash discounts	32	371	(381)	22
Total	$ 947	4,666	(4,522)	1,091
2011				
Accrued rebates[1]	$ 495	3,253	(3,251)	497
Accrued returns	201	352	(369)	184
Accrued promotions	50	67	(44)	73
Subtotal	$ 746	3,672	(3,664)	754
Reserve for doubtful accounts	138	54	(31)	161
Reserve for cash discounts	35	342	(345)	32
Total	$ 919	4,068	(4,040)	947

(1) Includes reserve for customer rebates of $340 million at December 30, 2012 and $324 million at January 1, 2012, recorded as a contra asset.

Income Taxes: Income taxes are recorded based on amounts refundable or payable for the current year and include the results of any difference between U.S. GAAP accounting and tax reporting, recorded as deferred tax assets or liabilities. The Company estimates deferred tax assets and liabilities based on current tax regulations and rates. Changes in tax laws and rates may affect recorded deferred tax assets and liabilities in the future.

The Company has unrecognized tax benefits for uncertain tax positions. The Company follows U.S. GAAP which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Management believes that changes in these estimates would not have a material effect on the Company's results of operations, cash flows or financial position.

At December 30, 2012 and January 1, 2012, the cumulative amounts of undistributed international earnings were approximately $49.0 billion and $41.6 billion, respectively. At December 30, 2012 and January 1, 2012, the Company's foreign subsidiaries held balances of cash and cash equivalents in the amounts of $14.8 billion and $24.5 billion, respectively. The Company has not provided deferred taxes on the undistributed earnings from certain international subsidiaries where the earnings are considered to be permanently reinvested. The Company intends to continue to reinvest these earnings in international operations. If the Company decided at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company does not determine the deferred tax liability associated with these undistributed earnings, as such determination is not practical.

See Note 8 to the Consolidated Financial Statements for further information regarding income taxes.

Legal and Self Insurance Contingencies: The Company records accruals for various contingencies including legal proceedings and product liability claims as these arise in the normal course of business. The accruals are based on management's judgment as to the probability of losses and, where applicable, actuarially determined estimates. The Company has self insurance through a wholly-owned captive insurance company and is insured up to certain limits. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated. Additionally, the Company records insurance receivable amounts from third-party insurers when recovery is probable. As appropriate, reserves against these receivables are recorded for estimated amounts that may not be collected from third-party insurers.

The Company follows the provisions of U.S. GAAP when recording litigation related contingencies. A liability is recorded when a loss is probable and can be reasonably estimated. The best estimate of a loss within a range is accrued; however, if no estimate in the range is better than any other, the minimum amount is accrued.

Long-Lived and Intangible Assets: The Company assesses changes in economic conditions and makes assumptions regarding estimated future cash flows in evaluating the value of the Company's property, plant and equipment, goodwill and intangible assets. As these assumptions and estimates may change over time, it may or may not be necessary for the Company to record impairment charges.

Employee Benefit Plans: The Company sponsors various retirement and pension plans, including defined benefit, defined contribution and termination indemnity plans, which cover most employees worldwide. These plans are based on assumptions for the discount rate, expected return on plan assets, expected salary increases and health care cost trend rates. See Note 10 to the Consolidated Financial Statements for further details on these rates and the effect a rate change would have on the Company's results of operations.

Stock Based Compensation: The Company recognizes compensation expense associated with the issuance of equity instruments to employees for their services. The fair value of each award is estimated on the date of grant using the Black-Scholes option valuation model and is expensed in the financial statements over the vesting period. The input assumptions used in determining fair value are the expected life, expected volatility, risk-free rate and the dividend yield. See Note 17 to the Consolidated Financial Statements for additional information.

New Accounting Pronouncements

Refer to Note 1 to the Consolidated Financial Statements for recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of December 30, 2012.

Economic and Market Factors

The Company is aware that its products are used in an environment where, for more than a decade, policymakers, consumers and businesses have expressed concerns about the rising cost of health care. In response to these concerns, the Company has a long-standing policy of pricing products responsibly. For the period 2002 - 2012, in the United States, the weighted average compound annual growth rate of the Company's net price increases for health care products (prescription and over-the-counter drugs, hospital and professional products) was below the U.S. Consumer Price Index (CPI).

Inflation rates continue to have an effect on worldwide economies and, consequently, on the way companies operate. The Company accounted for operations in Venezuela as highly inflationary in 2010, 2011 and 2012, as the prior three-year cumulative inflation rate surpassed 100%. In the face of increasing costs, the Company strives to maintain its profit margins through cost reduction programs, productivity improvements and periodic price increases.

On February 8, 2013, the Venezuelan government announced a 32% devaluation of its currency. The effect of the devaluation is not expected to have a material impact on the Company's 2013 full year results.

The Company is exposed to fluctuations in currency exchange rates. A 1% change in the value of the U.S. Dollar as compared to all foreign currencies in which the Company had sales, income or expense in 2012 would have increased or decreased the translation of foreign sales by approximately $375 million and income by $80 million.

The Company faces various worldwide health care changes that may continue to result in pricing pressures that include health care cost containment and government legislation relating to sales, promotions and reimbursement of health care products.

Changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing health care insurance coverage, as a result of the current global economic downturn, may continue to impact the Company's businesses.

The Company also operates in an environment which has become increasingly hostile to intellectual property rights. Generic drug firms have filed Abbreviated New Drug Applications (ANDAs) seeking to market generic forms of most of the Company's key pharmaceutical products, prior to expiration of the applicable patents covering those products. In the event the Company is not successful in defending the patent claims challenged in ANDA filings, the generic firms will then introduce generic versions of the product at issue, resulting in the potential for substantial market share and revenue losses for that product. For further information, see the discussion on "Litigation Against Filers of Abbreviated New Drug Applications" in Note 21 to the Consolidated Financial Statements.

Legal Proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability, intellectual property, commercial and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of business.

The Company records accruals for such contingencies when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. The Company has accrued for certain litigation matters and continues to monitor each related legal issue and adjust accruals for new information and further developments in accordance with Accounting Standards Codification (ASC) 450-20-25. For these and other litigation and regulatory matters currently disclosed for which a loss is probable or reasonably possible, the Company is unable to determine an estimate of the possible loss or range of loss beyond the amounts already accrued. These matters can be affected by various factors, including whether damages sought in the

proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; or there present legal uncertainties; there are significant facts in dispute; or there are numerous parties involved.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution in any reporting period of one or more of these matters, either alone or in the aggregate, may have a material adverse effect on the Company's results of operations and cash flows for that period.

See Note 21 to the Consolidated Financial Statements for further information regarding legal proceedings.

Common Stock Market Prices

The Company's Common Stock is listed on the New York Stock Exchange under the symbol JNJ. As of February 19, 2013, there were 169,820 record holders of Common Stock of the Company. The composite market price ranges for Johnson & Johnson Common Stock during 2012 and 2011 were:

	2012		2011	
	High	Low	High	Low
First quarter	$ 66.32	64.02	63.54	57.50
Second quarter	67.70	61.71	67.37	59.25
Third quarter	69.75	66.85	68.05	59.08
Fourth quarter	72.74	67.80	66.32	60.83
Year-end close	$69.48		65.58	

Cautionary Factors That May Affect Future Results

This Annual Report contains forward-looking statements. Forward-looking statements do not relate strictly to historical or current facts and anticipate results based on management's plans that are subject to uncertainty. Forward-looking statements may be identified by the use of words such as "plans," "expects," "will," "anticipates," "estimates" and other words of similar meaning in conjunction with, among other things, discussions of future operations, financial performance, the Company's strategy for growth, product development, regulatory approval, market position and expenditures.

Forward-looking statements are based on current expectations of future events. The Company cannot guarantee that any forward-looking statement will be accurate, although the Company believes that it has been reasonable in its expectations and assumptions. Investors should realize that if underlying assumptions prove inaccurate or that unknown risks or uncertainties materialize, actual results could vary materially from the Company's expectations and projections. Investors are therefore cautioned not to place undue reliance on any forward-looking statements. The Company does not undertake to update any forward-looking statements as a result of new information or future events or developments.

Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; significant litigation or government action adverse to the Company; impact of business combinations; financial distress and bankruptcies experienced by significant customers and suppliers; changes to governmental laws and regulations and U.S. and foreign health care reforms; trends toward health care cost containment; increased scrutiny of the health care industry by government agencies; changes in behavior and spending patterns of purchasers of health care products and services; financial instability of international economies and sovereign risk; disruptions due to natural disasters; manufacturing difficulties or delays; complex global supply chains with increasing regulatory requirements; and product efficacy or safety concerns resulting in product recalls or regulatory action.

The Company's report on Form 10-K for the year ended December 30, 2012 includes, in Exhibit 99, a discussion of additional factors that could cause actual results to differ from expectations. The Company notes these factors as permitted by the Private Securities Litigation Reform Act of 1995.

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
At December 30, 2012 and January 1, 2012
(Dollars in Millions Except Share and Per Share Amounts) (Note 1)

		2012	2011
Assets			
Current assets			
Cash and cash equivalents (Notes 1 and 2)	$	14,911	24,542
Marketable securities (Notes 1 and 2)		6,178	7,719
Accounts receivable trade, less allowances for doubtful accounts $466 (2011, $361)		11,309	10,581
Inventories (Notes 1 and 3)		7,495	6,285
Deferred taxes on income (Note 8)		3,139	2,556
Prepaid expenses and other receivables		3,084	2,633
Total current assets		**46,116**	**54,316**
Property, plant and equipment, net (Notes 1 and 4)		16,097	14,739
Intangible assets, net (Notes 1 and 5)		28,752	18,138
Goodwill (Notes 1 and 5)		22,424	16,138
Deferred taxes on income (Note 8)		4,541	6,540
Other assets		3,417	3,773
Total assets	**$**	**121,347**	**113,644**
Liabilities and Shareholders' Equity			
Current liabilities			
Loans and notes payable (Note 7)	$	4,676	6,658
Accounts payable		5,831	5,725
Accrued liabilities		7,299	4,608
Accrued rebates, returns and promotions		2,969	2,637
Accrued compensation and employee related obligations		2,423	2,329
Accrued taxes on income		1,064	854
Total current liabilities		**24,262**	**22,811**
Long-term debt (Note 7)		11,489	12,969
Deferred taxes on income (Note 8)		3,136	1,800
Employee related obligations (Notes 9 and 10)		9,082	8,353
Other liabilities		8,552	10,631
Total liabilities		**56,521**	**56,564**
Shareholders' equity			
Preferred stock — without par value (authorized and unissued 2,000,000 shares)		—	—
Common stock — par value $1.00 per share (Note 12) (authorized 4,320,000,000 shares; issued 3,119,843,000 shares)		3,120	3,120
Accumulated other comprehensive income (Note 13)		(5,810)	(5,632)
Retained earnings		85,992	81,251
		83,302	78,739
Less: common stock held in treasury, at cost (Note 12) (341,354,000 shares and 395,480,000 shares)		18,476	21,659
Total shareholders' equity		**64,826**	**57,080**
Total liabilities and shareholders' equity	**$**	**121,347**	**113,644**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EARNINGS
(Dollars and Shares in Millions Except Per Share Amounts) (Note 1)

		2012	2011	2010
Sales to customers	$	67,224	65,030	61,587
Cost of products sold		21,658	20,360	18,792
Gross profit		45,566	44,670	42,795
Selling, marketing and administrative expenses		20,869	20,969	19,424
Research and development expense		7,665	7,548	6,844
In-process research and development (Note 5)		1,163	—	—
Interest income		(64)	(91)	(107)
Interest expense, net of portion capitalized (Note 4)		532	571	455
Other (income) expense, net		1,626	2,743	(768)
Restructuring (Note 22)		—	569	—
Earnings before provision for taxes on income		13,775	12,361	16,947
Provision for taxes on income (Note 8)		3,261	2,689	3,613
Net earnings		10,514	9,672	13,334
Add: Net loss attributable to noncontrolling interest		339	—	—
Net earnings attributable to Johnson & Johnson	**$**	**10,853**	**9,672**	**13,334**
Net earnings per share attributable to Johnson & Johnson (Notes 1 and 15)				
Basic	**$**	**3.94**	**3.54**	**4.85**
Diluted	**$**	**3.86**	**3.49**	**4.78**
Cash dividends per share	**$**	**2.40**	**2.25**	**2.11**
Average shares outstanding (Notes 1 and 15)				
Basic		**2,753.3**	**2,736.0**	**2,751.4**
Diluted		**2,812.6**	**2,775.3**	**2,788.8**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Dollars in Millions) (Note 1)

		2012	2011	2010
Net Earnings	$	10,514	9,672	13,334
Other Comprehensive Income (Loss), net of tax				
Foreign currency translation		1,230	(557)	(461)
Securities:				
Unrealized holding gain (loss) arising during period		(248)	565	99
Reclassifications to earnings		(5)	(141)	(45)
Net change		(253)	424	54
Employee benefit plans:				
Prior service cost amortization during period		2	5	4
Prior service cost - current year		(8)	15	—
Gain (loss) amortization during period		370	246	188
Gain (loss) - current year		(1,643)	(1,984)	(203)
Effect of exchange rates		(52)	18	(10)
Net change		(1,331)	(1,700)	(21)
Derivatives & hedges:				
Unrealized gain (loss) arising during period		52	(500)	(333)
Reclassifications to earnings		124	232	288
Net change		176	(268)	(45)
Other Comprehensive Income (Loss)		(178)	(2,101)	(473)
Comprehensive Income	$	10,336	7,571	12,861
Comprehensive Loss Attributable To Noncontrolling Interest, net of tax		339	—	—
Comprehensive Income Attributable To Johnson & Johnson	$	10,675	7,571	12,861

The tax effects in other comprehensive income for the fiscal years ended 2012, 2011 and 2010 respectively: Securities; $136 million, $228 million and $29 million, Employee Benefit Plans; $653 million $915 million and $11 million, Derivatives & Hedges; $95 million, $144 million and $25 million.

Foreign currency translation is not adjusted for income taxes as it relates to permanent investments in international subsidiaries.

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY
(Dollars in Millions) (Note 1)

	Total	Retained Earnings	Accumulated Other Comprehensive Income	Common Stock Issued Amount	Treasury Stock Amount
Balance, January 3, 2010	**$ 50,588**	**70,306**	**(3,058)**	**3,120**	**(19,780)**
Net earnings attributable to Johnson & Johnson	13,334	13,334			
Cash dividends paid	(5,804)	(5,804)			
Employee compensation and stock option plans	1,731	(63)			1,794
Repurchase of common stock	(2,797)				(2,797)
Other comprehensive income, net of tax:	(473)		(473)		
Balance, January 2, 2011	**$ 56,579**	**77,773**	**(3,531)**	**3,120**	**(20,783)**
Net earnings attributable to Johnson & Johnson	9,672	9,672			
Cash dividends paid	(6,156)	(6,156)			
Employee compensation and stock option plans	1,760	111			1,649
Repurchase of common stock	(2,525)				(2,525)
Other	(149)	(149)			
Other comprehensive income, net of tax:	(2,101)		(2,101)		
Balance, January 1, 2012	**$ 57,080**	**81,251**	**(5,632)**	**3,120**	**(21,659)**
Net earnings attributable to Johnson & Johnson	10,853	10,853			
Cash dividends paid	(6,614)	(6,614)			
Employee compensation and stock option plans	3,269	19			3,250
Issuance of common stock associated with the acquisition of Synthes, Inc.	13,335	483			12,852
Repurchase of common stock[(1)]	(12,919)				(12,919)
Other comprehensive income, net of tax:	(178)		(178)		
Balance, December 30, 2012	**$ 64,826**	**85,992**	**(5,810)**	**3,120**	**(18,476)**

(1) Includes repurchase of common stock associated with the acquisition of Synthes, Inc.

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Dollars in Millions) (Note 1)

	2012	2011	2010
Cash flows from operating activities			
Net earnings	$ 10,514	9,672	13,334
Adjustments to reconcile net earnings to cash flows from operating activities:			
Depreciation and amortization of property and intangibles	3,666	3,158	2,939
Stock based compensation	662	621	614
Noncontrolling interest	339	—	—
Asset write-downs and impairments	2,131	160	—
Deferred tax provision	(39)	(836)	356
Accounts receivable allowances	92	32	12
Changes in assets and liabilities, net of effects from acquisitions:			
Increase in accounts receivable	(9)	(915)	(207)
Increase in inventories	(1)	(715)	(196)
Increase in accounts payable and accrued liabilities	2,768	493	20
Increase in other current and non-current assets	(2,172)	(1,785)	(574)
(Decrease)/increase in other current and non-current liabilities	(2,555)	4,413	87
Net cash flows from operating activities	**15,396**	**14,298**	**16,385**
Cash flows from investing activities			
Additions to property, plant and equipment	(2,934)	(2,893)	(2,384)
Proceeds from the disposal of assets	1,509	1,342	524
Acquisitions, net of cash acquired (Note 20)	(4,486)	(2,797)	(1,269)
Purchases of investments	(13,434)	(29,882)	(15,788)
Sales of investments	14,797	30,396	11,101
Other (primarily intangibles)	38	(778)	(38)
Net cash used by investing activities	**(4,510)**	**(4,612)**	**(7,854)**
Cash flows from financing activities			
Dividends to shareholders	(6,614)	(6,156)	(5,804)
Repurchase of common stock	(12,919)	(2,525)	(2,797)
Proceeds from short-term debt	3,268	9,729	7,874
Retirement of short-term debt	(6,175)	(11,200)	(6,565)
Proceeds from long-term debt	45	4,470	1,118
Retirement of long-term debt	(804)	(16)	(32)
Proceeds from the exercise of stock options/excess tax benefits	2,720	1,246	1,226
Other	(83)	—	—
Net cash used by financing activities	**(20,562)**	**(4,452)**	**(4,980)**
Effect of exchange rate changes on cash and cash equivalents	45	(47)	(6)
(Decrease)/increase in cash and cash equivalents	(9,631)	5,187	3,545
Cash and cash equivalents, beginning of year (Note 1)	24,542	19,355	15,810
Cash and cash equivalents, end of year (Note 1)	**$ 14,911**	**24,542**	**19,355**
Supplemental cash flow data			
Cash paid during the year for:			
Interest	$ 616	576	491
Income taxes	2,507	2,970	2,442
Supplemental schedule of non-cash investing and financing activities			
Issuance of common stock associated with the acquisition of Synthes, Inc.	13,335	—	—
Treasury stock issued for employee compensation and stock option plans, net of cash proceeds	615	433	673
Conversion of debt	—	1	1

Acquisitions				
Fair value of assets acquired	$	19,025	3,025	1,321
Fair value of liabilities assumed and noncontrolling interests		(1,204)	(228)	(52)
Net fair value of acquisitions	$	17,821	2,797	1,269
Less: Issuance of common stock associated with the acquisition of Synthes, Inc.		13,335	—	—
Net cash paid for acquisitions	**$**	**4,486**	**2,797**	**1,269**

See Notes to Consolidated Financial Statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Johnson & Johnson and its subsidiaries (the Company). Intercompany accounts and transactions are eliminated.

Description of the Company And Business Segments

The Company has approximately 127,600 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world and its primary focus is on products related to human health and well-being.

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices and Diagnostics. The Consumer segment includes a broad range of products used in the baby care, skin care, oral care, wound care and women's health fields, as well as nutritional and over-the-counter pharmaceutical products and wellness and prevention platforms. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world. The Pharmaceutical segment includes products in the following areas: anti-infective, antipsychotic, contraceptive, gastrointestinal, hematology, immunology, infectious diseases, neurology, oncology, pain management, thrombosis and vaccines. These products are distributed directly to retailers, wholesalers and health care professionals for prescription use. The Medical Devices and Diagnostics segment includes a broad range of products distributed to wholesalers, hospitals and retailers, used principally in the professional fields by physicians, nurses, hospitals and clinics. These include products to treat cardiovascular disease; orthopaedic and neurological products; blood glucose monitoring and insulin delivery products; general surgery, biosurgical, and energy products; professional diagnostic products; infection prevention products; and disposable contact lenses.

New Accounting Pronouncements

Recently Adopted Accounting Pronouncements

During the fiscal first quarter of 2012, the Company adopted the Financial Accounting Standards Board (FASB) guidance and amendments issued related to goodwill impairment testing. Under the amendments in this update, an entity has the option to first assess qualitative factors to determine whether the existence of events or circumstances leads to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If, after assessing the totality of events or circumstances, an entity determines it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing the two-step impairment test is unnecessary. However, if an entity concludes otherwise, then it is required to perform the first step of the two-step impairment test. This update became effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. The adoption of this standard did not have a material impact on the Company's results of operations, cash flows or financial position.

During the fiscal first quarter of 2012, the Company adopted the FASB amendment to the disclosure requirements for presentation of comprehensive income. The amendment requires that all non-owner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This guidance became effective retrospectively for the interim periods and annual periods beginning after December 15, 2011.

During the fiscal first quarter of 2012, the Company adopted the FASB amendments to disclosure requirements for fair value measurement. These amendments result in convergence of fair value measurement and disclosure requirements between U.S. Generally Accepted Accounting Principles (GAAP) and International Financial Reporting Standards (IFRS). This guidance became effective prospectively for the interim periods and annual periods beginning after December 15, 2011. The adoption of this standard did not have a material impact on the Company's results of operations, cash flows or financial position.

Recently Issued Accounting Standards

Not Adopted as of December 30, 2012

During the fiscal third quarter of 2012, the FASB issued guidance and amendments related to testing indefinite lived intangible assets for impairment. Under the amendments in this update, an entity has the option to first assess qualitative factors to determine whether the existence of events or circumstances indicates that it is more likely than not that the indefinite-lived intangible asset is impaired. If, after assessing the totality of events and circumstances, an entity concludes that it is not more likely than not that the indefinite-lived intangible asset is impaired, then the entity is not required to determine the fair value. However, if an entity concludes otherwise, then it is required to determine the fair value of the indefinite-lived intangible asset and perform the quantitative impairment test. An entity also has the option to bypass the qualitative assessment for any indefinite-lived intangible asset in any period and proceed directly to performing the quantitative impairment test. This update became effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012.

However, early adoption is permitted. The adoption of this standard is not expected to have a material impact on the Company's results of operations, cash flows or financial position.

In February 2013, the FASB issued guidance related to additional reporting and disclosure of amounts reclassified out of accumulated other comprehensive income (OCI). Under this new guidance, companies will be required to disclose the amount of income (or loss) reclassified out of OCI to each respective line item on the income statement of where net income is presented. The guidance allows companies to elect whether to disclose the reclassification either in the notes to the financial statements, or on the face of the income statement. This update is effective for annual and interim reporting periods for fiscal years beginning after December 15, 2012. The adoption of this standard is not expected have a material impact on the Company's results of operations, cash flows or financial position.

Cash Equivalents

The Company considers securities with maturities of three months or less, when purchased, to be cash equivalents.

Investments

Short-term marketable securities are carried at cost, which approximates fair value. Investments classified as available-for-sale are carried at estimated fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income. Long-term debt securities that the Company has the ability and intent to hold until maturity are carried at amortized cost. Management determines the appropriate classification of its investment in debt and equity securities at the time of purchase and re-evaluates such determination at each balance sheet date. The Company periodically reviews its investments in equity securities for impairment and adjusts these investments to their fair value when a decline in market value is deemed to be other than temporary. If losses on these securities are considered to be other than temporary, the loss is recognized in earnings.

Property, Plant and Equipment and Depreciation

Property, plant and equipment are stated at cost. The Company utilizes the straight-line method of depreciation over the estimated useful lives of the assets:

Building and building equipment	20 - 30 years
Land and leasehold improvements	10 - 20 years
Machinery and equipment	2 - 13 years

The Company capitalizes certain computer software and development costs, included in machinery and equipment, when incurred in connection with developing or obtaining computer software for internal use. Capitalized software costs are amortized over the estimated useful lives of the software, which generally range from 3 to 8 years.

The Company reviews long-lived assets to assess recoverability using undiscounted cash flows. When certain events or changes in operating or economic conditions occur, an impairment assessment may be performed on the recoverability of the carrying value of these assets. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows.

Revenue Recognition

The Company recognizes revenue from product sales when the goods are shipped or delivered and title and risk of loss pass to the customer. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns and discounts to customers are accounted for as reductions in sales in the same period the related sales are recorded.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including prices charged by competitors. Rebates, the largest being the Medicaid rebate provision, are estimated based on contractual terms, historical experience, trend analysis and projected market conditions in the various markets served. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns are generally estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales returns accruals.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices and Diagnostics segment are typically resalable but are not material. The Company rarely exchanges products from inventory

for returned products. The sales returns reserve for the total Company has ranged between 1.0% and 1.2% of annual sales to customers during the fiscal reporting years 2012, 2011 and 2010.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the year incurred. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. The Company also earns service revenue for co-promotion of certain products and includes it in sales to customers. These arrangements are evaluated to determine the appropriate amounts to be deferred.

Shipping and Handling

Shipping and handling costs incurred were $1,051 million, $1,022 million and $945 million in 2012, 2011 and 2010, respectively, and are included in selling, marketing and administrative expense. The amount of revenue received for shipping and handling is less than 0.5% of sales to customers for all periods presented.

Inventories

Inventories are stated at the lower of cost or market determined by the first-in, first-out method.

Intangible Assets and Goodwill

The authoritative literature on U.S. GAAP requires that goodwill and intangible assets with indefinite lives be assessed annually for impairment. The Company completed the annual impairment test for 2012 in the fiscal fourth quarter. Future impairment tests will be performed annually in the fiscal fourth quarter, or sooner if warranted, as was the case for certain indefinite lived intangible assets in the fiscal second and third quarters of 2012. Purchased in-process research and development is accounted for as an indefinite lived intangible asset until the underlying project is completed, at which point the intangible asset will be accounted for as a definite lived intangible asset, or abandoned, at which point the intangible asset will be written off or partially impaired.

Intangible assets that have finite useful lives continue to be amortized over their useful lives, and are reviewed for impairment when warranted by economic conditions. See Note 5 for further details on Intangible Assets and Goodwill.

Financial Instruments

As required by U.S. GAAP, all derivative instruments are recorded on the balance sheet at fair value. Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value, with Level 1 having the highest priority and Level 3 having the lowest. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The Company documents all relationships between hedged items and derivatives. The overall risk management strategy includes reasons for undertaking hedge transactions and entering into derivatives. The objectives of this strategy are: (1) minimize foreign currency exposure's impact on the Company's financial performance; (2) protect the Company's cash flow from adverse movements in foreign exchange rates; (3) ensure the appropriateness of financial instruments; and (4) manage the enterprise risk associated with financial institutions. See Note 6 for additional information on Financial Instruments.

Product Liability

Accruals for product liability claims are recorded, on an undiscounted basis, when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated based on existing information. The accruals are adjusted periodically as additional information becomes available.

As a result of cost and availability factors, effective November 1, 2005, the Company ceased purchasing third-party product liability insurance. The Company has self insurance through a wholly-owned captive insurance company and is insured up to certain limits. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated. Based on the availability of prior coverage, receivables for insurance recoveries related to product liability claims are recorded on an undiscounted basis, when it is probable that a recovery will be realized. As appropriate, reserves against these receivables are recorded for estimated amounts that may not be collected from third-party insurers.

Concentration of Credit Risk

Global concentration of credit risk with respect to trade accounts receivables continues to be limited due to the large number of customers globally and adherence to internal credit policies and credit limits. Recent economic challenges in Italy, Spain, Greece and Portugal (the Southern European Region) have impacted certain payment patterns, which have historically been longer than those experienced in the U.S. and other international markets. The total net trade accounts receivable balance in the

Southern European Region was approximately $2.1 billion as of December 30, 2012 and approximately $2.4 billion as of January 1, 2012. Approximately $1.4 billion as of December 30, 2012 and approximately $1.4 billion as of January 1, 2012 of the Southern European Region net trade accounts receivable balance related to the Company's Consumer, Vision Care and Diabetes Care businesses as well as certain Pharmaceutical and Medical Devices and Diagnostics customers which are in line with historical collection patterns.

The remaining balance of net trade accounts receivable in the Southern European Region has been negatively impacted by the timing of payments from certain government owned or supported health care customers as well as certain distributors of the Pharmaceutical and Medical Devices and Diagnostics local affiliates. The total net trade accounts receivable balance for these customers were approximately $0.9 billion at December 30, 2012 and $1.0 billion at January 1, 2012. The Company continues to receive payments from these customers and in some cases late payment premiums. For customers where payment is expected over periods of time longer than one year, revenue and trade receivables have been discounted over the estimated period of time for collection. Allowances for doubtful accounts have been increased for these customers, but have been immaterial to date. The Company will continue to work closely with these customers on payment plans, monitor the economic situation and take appropriate actions as necessary.

Research and Development

Research and development expenses are expensed as incurred. Upfront and milestone payments made to third parties in connection with research and development collaborations are expensed as incurred up to the point of regulatory approval. Payments made to third parties subsequent to regulatory approval are capitalized and amortized over the remaining useful life of the related product. Amounts capitalized for such payments are included in other intangibles, net of accumulated amortization.

The Company enters into collaborative arrangements, typically with other pharmaceutical or biotechnology companies, to develop and commercialize drug candidates or intellectual property. These arrangements typically involve two (or more) parties who are active participants in the collaboration and are exposed to significant risks and rewards dependent on the commercial success of the activities. These collaborations usually involve various activities by one or more parties, including research and development, marketing and selling and distribution. Often, these collaborations require upfront, milestone and royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development. Amounts due from collaborative partners related to development activities are generally reflected as a reduction of research and development expense because the performance of contract development services is not central to the Company's operations. In general, the income statement presentation for these collaborations is as follows:

Nature/Type of Collaboration	Statement of Earnings Presentation
Third-party sale of product	Sales to customers
Royalties/milestones paid to collaborative partner (post-regulatory approval)*	Cost of goods sold
Royalties received from collaborative partner	Other income (expense), net
Upfront payments & milestones paid to collaborative partner (pre-regulatory approval)	Research and development expense
Research and development payments to collaborative partner	Research and development expense
Research and development payments received from collaborative partner	Reduction of Research and development expense

* Milestones are capitalized as intangible assets and amortized to cost of goods sold over the useful life.

For all years presented, there was no individual project that represented greater than 5% of the total annual consolidated research and development expense.

Advertising

Costs associated with advertising are expensed in the year incurred and are included in selling, marketing and administrative expenses. Advertising expenses worldwide, which comprised television, radio, print media and Internet advertising, were $2.3 billion, $2.6 billion and $2.5 billion in 2012, 2011 and 2010, respectively.

Income Taxes

Income taxes are recorded based on amounts refundable or payable for the current year and include the results of any difference between U.S. GAAP accounting and tax reporting, recorded as deferred tax assets or liabilities. The Company estimates deferred tax assets and liabilities based on current tax regulations and rates. Changes in tax laws and rates may affect recorded deferred tax assets and liabilities in the future.

The Company has unrecognized tax benefits for uncertain tax positions. The Company follows U.S. GAAP which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Management believes that changes in these estimates would not have a material effect on the Company's results of operations, cash flows or financial position.

At December 30, 2012 and January 1, 2012, the cumulative amounts of undistributed international earnings were approximately $49.0 billion and $41.6 billion, respectively. At December 30, 2012 and January 1, 2012, the Company's foreign subsidiaries held balances of cash and cash equivalents in the amounts of $14.8 billion and $24.5 billion, respectively. The Company has not provided deferred taxes on the undistributed earnings from certain international subsidiaries where the earnings are considered to be permanently reinvested. The Company intends to continue to reinvest these earnings in international operations. If the Company decided at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company does not determine the deferred tax liability associated with these undistributed earnings, as such determination is not practicable.

See Note 8 to the Consolidated Financial Statements for further information regarding income taxes.

Net Earnings Per Share

Basic earnings per share is computed by dividing net earnings available to common shareholders by the weighted average number of common shares outstanding for the period. Diluted earnings per share reflects the potential dilution that could occur if securities were exercised or converted into common stock using the treasury stock method.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the amounts reported. Estimates are used when accounting for sales discounts, rebates, allowances and incentives, product liabilities, income taxes, depreciation, amortization, employee benefits, contingencies and intangible asset and liability valuations. Actual results may or may not differ from those estimates.

The Company follows the provisions of U.S. GAAP when recording litigation related contingencies. A liability is recorded when a loss is probable and can be reasonably estimated. The best estimate of a loss within a range is accrued; however, if no estimate in the range is better than any other, the minimum amount is accrued.

Annual Closing Date

The Company follows the concept of a fiscal year, which ends on the Sunday nearest to the end of the month of December. Normally each fiscal year consists of 52 weeks, but every five or six years the fiscal year consists of 53 weeks, as was the case in 2009, and will be the case again in 2015.

Reclassification

Certain prior period amounts have been reclassified to conform to current year presentation.

2. Cash, Cash Equivalents and Current Marketable Securities

At the end of 2012 and 2011, cash, cash equivalents and current marketable securities were comprised of:

(Dollars in Millions)	2012	2011
Cash	$ 3,032	2,709
Government securities and obligations	15,323	27,017
Corporate debt securities	622	489
Money market funds	1,406	1,590
Time deposits	706	456
Total cash, cash equivalents and current marketable securities	**$ 21,089**	**32,261**

The estimated fair value was the same as the amortized cost as of December 30, 2012. The estimated fair value was $32,262 million as of January 1, 2012 reflecting a $1 million unrealized gain in government securities and obligations.

As of December 30, 2012, current marketable securities consisted of $5,726 million and $452 million of government securities and obligations, and corporate debt securities, respectively.

As of January 1, 2012, current marketable securities consisted of $7,545 million and $174 million of government securities and obligations, and corporate debt securities, respectively.

Fair value of government securities and obligations and corporate debt securities were estimated using quoted broker prices and significant other observable inputs.

The Company invests its excess cash in both deposits with major banks throughout the world and other high-quality money market instruments. The Company has a policy of making investments only with commercial institutions that have at least an A

(or equivalent) credit rating.

3. Inventories

At the end of 2012 and 2011, inventories were comprised of:

(Dollars in Millions)		2012	2011
Raw materials and supplies	$	1,416	1,206
Goods in process		2,262	1,637
Finished goods		3,817	3,442
Total inventories	**$**	**7,495**	**6,285**

As of December 30, 2012, the remaining inventory step-up related to the Synthes, Inc. acquisition is approximately $150 million.

4. Property, Plant and Equipment

At the end of 2012 and 2011, property, plant and equipment at cost and accumulated depreciation were:

(Dollars in Millions)		2012	2011
Land and land improvements	$	793	754
Buildings and building equipment		10,046	9,389
Machinery and equipment		21,075	19,182
Construction in progress		2,740	2,504
Total property, plant and equipment, gross	$	34,654	31,829
Less accumulated depreciation		18,557	17,090
Total property, plant and equipment, net	**$**	**16,097**	**14,739**

The Company capitalizes interest expense as part of the cost of construction of facilities and equipment. Interest expense capitalized in 2012, 2011 and 2010 was $115 million, $84 million and $73 million, respectively.

Depreciation expense, including the amortization of capitalized interest in 2012, 2011 and 2010, was $2.5 billion, $2.3 billion and $2.2 billion, respectively.

Upon retirement or other disposal of property, plant and equipment, the costs and related amounts of accumulated depreciation or amortization are eliminated from the asset and accumulated depreciation accounts, respectively. The difference, if any, between the net asset value and the proceeds are recorded in earnings.

5. Intangible Assets and Goodwill

At the end of 2012 and 2011, the gross and net amounts of intangible assets were:

(Dollars in Millions)		2012	2011
Intangible assets with definite lives:			
Patents and trademarks — gross	$	8,890	7,947
Less accumulated amortization		3,416	2,976
Patents and trademarks — net	**$**	**5,474**	**4,971**
Customer relationships and other intangibles — gross	$	18,755	8,716
Less accumulated amortization		4,030	3,432
Customer relationships and other intangibles — net	**$**	**14,725**	**5,284**
Intangible assets with indefinite lives:			
Trademarks	$	7,648	6,034
Purchased in-process research and development		905	1,849
Total intangible assets with indefinite lives	**$**	**8,553**	**7,883**
Total intangible assets — net	**$**	**28,752**	**18,138**

Goodwill as of December 30, 2012 and January 1, 2012, as allocated by segment of business, was as follows:

(Dollars in Millions)	Consumer	Pharmaceuticals	Med Devices and Diagnostics	Total
Goodwill at January 2, 2011	$ 8,144	1,225	5,925	15,294
Acquisitions	251	538	198	987
Currency translation/other	(97)	(42)	(4)	(143)
Goodwill at January 1, 2012	$ 8,298	1,721	6,119	16,138
Acquisitions	10	46	6,045	6,101
Currency translation/other	211	25	(51)	185
Goodwill at December 30, 2012	**$ 8,519**	**1,792**	**12,113**	**22,424**

The weighted average amortization periods for patents and trademarks and customer relationships and other intangible assets are 17 years and 24 years, respectively. The amortization expense of amortizable assets was $1,146 million, $852 million and $748 million before tax, for the fiscal years ended December 30, 2012, January 1, 2012 and January 2, 2011, respectively. The estimated amortization expense for the five succeeding years approximates $1,350 million before tax, per year. Amortization expense is included in cost of products sold.

Intangible assets and goodwill increased by $12.9 billion and $6.0 billion, respectively, based on the purchase price allocation for the Synthes, Inc. acquisition. See Note 20 to the Consolidated Financial Statements for additional details on the Synthes, Inc. acquisition. The increase in intangible assets was partially offset by $0.8 billion in intangible asset write-downs and a $1.2 billion impairment of purchased in-process research and development, primarily related to the discontinuation of the Phase III clinical development of bapineuzumab IV and the partial impairment related to the Crucell vaccine business.

6. Fair Value Measurements

The Company uses forward exchange contracts to manage its exposure to the variability of cash flows, primarily related to the foreign exchange rate changes of future intercompany product and third-party purchases of raw materials denominated in foreign currency. The Company also uses cross currency interest rate swaps to manage currency risk primarily related to borrowings. Both types of derivatives are designated as cash flow hedges. The Company also uses forward exchange contracts to manage its exposure to the variability of cash flows for repatriation of foreign dividends. These contracts are designated as net investment hedges. Additionally, the Company uses forward exchange contracts to offset its exposure to certain foreign currency assets and liabilities. These forward exchange contracts are not designated as hedges and therefore, changes in the fair values of these derivatives are recognized in earnings, thereby offsetting the current earnings effect of the related foreign currency assets and liabilities. The Company does not enter into derivative financial instruments for trading or speculative purposes, or contain credit risk related contingent features or requirements to post collateral. On an ongoing basis, the Company monitors counterparty credit ratings. The Company considers credit non-performance risk to be low, because the Company enters into agreements with commercial institutions that have at least an A (or equivalent) credit rating. As of December 30, 2012, the Company had notional amounts outstanding for forward foreign exchange contracts and cross currency interest rate swaps of $26.0 billion and $2.4 billion, respectively.

All derivative instruments are recorded on the balance sheet at fair value. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The designation as a cash flow hedge is made at the entrance date into the derivative contract. At inception, all derivatives are expected to be highly effective. Changes in the fair value of a derivative that is designated as a cash flow hedge and is highly effective are recorded in accumulated other comprehensive income until the underlying transaction affects earnings, and are then reclassified to earnings in the same account as the hedged transaction. Gains/losses on net investment hedges are accounted for through the currency translation account and are insignificant. On an ongoing basis, the Company assesses whether each derivative continues to be highly effective in offsetting changes in the cash flows of hedged items. If and when a derivative is no longer expected to be highly effective, hedge accounting is discontinued. Hedge ineffectiveness, if any, is included in current period earnings in Other (income) expense, net.

As of December 30, 2012, the balance of deferred net gains on derivatives included in accumulated other comprehensive income was $8 million after-tax. For additional information, see the Consolidated Statements of Comprehensive Income and Note 13. The Company expects that substantially all of the amount related to foreign exchange contracts will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months, excluding interest rate swaps. The amount ultimately realized in earnings will differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity of the derivative.

The following table is a summary of the activity related to designated derivatives for the fiscal years ended December 30,

2012 and January 1, 2012:

(Dollars in Millions)	Gain/(Loss) recognized in Accumulated OCI[1]		Gain/(Loss) reclassified from Accumulated OCI into income[1]		Gain/(Loss) Recognized in Other income/expense[2]	
Cash Flow Hedges by Income Statement Caption	**2012**	**2011**	**2012**	**2011**	**2012**	**2011**
Sales to customers [3]	$ 45	(60)	(58)	(9)	(1)	(1)
Cost of products sold [3]	103	(103)	(98)	(154)	(4)	2
Research and development expense [3]	(42)	24	19	(22)	(1)	(1)
Interest (income)/Interest expense, net [4]	11	(406)	(16)	(45)	—	—
Other (income) expense, net [3]	(65)	45	29	(2)	—	1
Total	**$ 52**	**(500)**	**(124)**	**(232)**	**(6)**	**1**

All amounts shown in the table above are net of tax.

(1) Effective portion

(2) Ineffective portion

(3) Foreign exchange contracts

(4) Cross currency interest rate swaps

For the fiscal years ended December 30, 2012 and January 1, 2012, a gain of $48 million and a loss of $23 million, respectively, was recognized in Other (income) expense, net, relating to foreign exchange contracts not designated as hedging instruments.

Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described below with Level 1 having the highest priority and Level 3 having the lowest.

The fair value of a derivative financial instrument (i.e., forward exchange contract, currency swap) is the aggregation by currency of all future cash flows discounted to its present value at the prevailing market interest rates and subsequently converted to the U.S. Dollar at the current spot foreign exchange rate. The Company does not believe that fair values of these derivative instruments materially differ from the amounts that could be realized upon settlement or maturity, or that the changes in fair value will have a material effect on the Company's results of operations, cash flows or financial position. The Company also holds equity investments that are classified as Level 1 as they are traded in an active exchange market. The Company did not have any other significant financial assets or liabilities which would require revised valuations under this standard that are recognized at fair value.

The following three levels of inputs are used to measure fair value:

Level 1 — Quoted prices in active markets for identical assets and liabilities.

Level 2 — Significant other observable inputs.

Level 3 — Significant unobservable inputs.

The Company's significant financial assets and liabilities measured at fair value as of December 30, 2012 and January 1, 2012 were as follows:

				2012	2011
(Dollars in Millions)	Level 1	Level 2	Level 3	Total	Total [1]
Derivatives designated as hedging instruments:					
Assets:					
Foreign exchange contracts	$ —	423	—	423	442
Cross currency interest rate swaps [2]	—	98	—	98	15
Total	—	**521**	—	**521**	**457**
Liabilities:					
Foreign exchange contracts	—	252	—	252	452
Cross currency interest rate swaps [3]	—	10	—	10	594
Total	—	**262**	—	**262**	**1,046**
Derivatives not designated as hedging instruments:					
Assets:					
Foreign exchange contracts	—	75	—	75	29
Swiss Franc Option [4]	—	—	—	—	17
Total	—	**75**	—	**75**	**46**
Liabilities:					
Foreign exchange contracts	—	23	—	23	34
Other investments [5]	$ 1,247	—	—	1,247	1,563

(1) 2011 assets and liabilities are all classified as Level 2 with the exception of Other investments of $1,563 million, which are classified as Level 1.
(2) Includes $96 million and $15 million of non-current assets for the fiscal years ending December 30, 2012 and January 1, 2012, respectively.
(3) Includes $4 million and $594 million of non-current liabilities for the fiscal years ending December 30, 2012 and January 1, 2012, respectively. Cross currency interest rate swaps related to outstanding EUR and GBP notes, matured in November 2012. The swaps were settled at fair market value and replaced with new swaps.
(4) Currency option related to the acquisition of Synthes, Inc., which expired in January 2012.
(5) Classified as non-current other assets.

See Notes 2 and 7 for financial assets and liabilities held at carrying amount on the Consolidated Balance Sheet.

7. Borrowings

The components of long-term debt are as follows:

(Dollars in Millions)	2012	Effective Rate %	2011	Effective Rate %
5.15% Debentures due 2012	$ —	—%	599	5.18
0.70% Notes due 2013	500	0.75	500	0.75
3.80% Debentures due 2013	500	3.82	500	3.82
3 month LIBOR+0% FRN due 2013	500	0.31	500	0.46
3 month LIBOR+0.09% FRN due 2014	750	0.40	750	0.55
1.20% Notes due 2014	999	1.24	999	1.24
2.15% Notes due 2016	898	2.22	898	2.22
5.55% Debentures due 2017	1,000	5.55	1,000	5.55
5.15% Debentures due 2018	898	5.15	898	5.15
4.75% Notes due 2019 (1B Euro 1.3275) (2)/ (1B Euro 1.2892) (3)	1,321 (2)	5.83	1,282 (3)	5.35
3% Zero Coupon Convertible Subordinated Debentures due 2020	205	3.00	199	3.00
2.95% Debentures due 2020	542	3.15	541	3.15
3.55% Notes due 2021	446	3.67	446	3.67
6.73% Debentures due 2023	250	6.73	250	6.73
5.50% Notes due 2024 (500MM GBP 1.6169)(2)/(500MM GBP 1.5421) (3)	803 (2)	6.75	765 (3)	5.71
6.95% Notes due 2029	296	7.14	294	7.14
4.95% Debentures due 2033	500	4.95	500	4.95
5.95% Notes due 2037	995	5.99	995	5.99
5.85% Debentures due 2038	700	5.86	700	5.86
4.50% Debentures due 2040	539	4.63	539	4.63
4.85% Notes due 2041	298	4.89	298	4.89
Other	61	—	132	—
	13,001 (4)	**4.14** (1)	**13,585** (4)	**4.08** (1)
Less current portion	1,512		616	
	$ 11,489		**12,969**	

(1) Weighted average effective rate.
(2) Translation rate at December 30, 2012.
(3) Translation rate at January 1, 2012.
(4) The excess of the fair value over the carrying value of debt was $2.2 billion in 2012 and $2.0 billion in 2011.

Fair value of the non-current debt was estimated using market prices, which were corroborated by quoted broker prices and significant other observable inputs.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2012 , the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 19, 2013. Interest charged on borrowings under the credit line agreements is based on either bids provided by banks, the prime rate or London Interbank Offered Rates (LIBOR), plus applicable margins. Commitment fees under the agreements are not material.

Throughout 2012, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $4.7 billion at the end of 2012, of which $2.4 billion was borrowed under the Commercial Paper Program. The remainder principally represents local borrowing by international subsidiaries.

The Company has a shelf registration with the U.S. Securities and Exchange Commission that enables the Company to issue debt securities and warrants to purchase debt securities on a timely basis.

Aggregate maturities of long-term obligations commencing in 2012 are:

(Dollars in Millions)					
2013	2014	2015	2016	2017	After 2017
$1,512	1,789	—	898	1,000	7,802

8. Income Taxes

The provision for taxes on income consists of:

(Dollars in Millions)	2012	2011	2010
Currently payable:			
U.S. taxes	$ 2,023	2,392	2,063
International taxes	1,277	1,133	1,194
Total currently payable	3,300	3,525	3,257
Deferred:			
U.S. taxes	(120)	(690)	(4)
International taxes	81	(146)	360
Total deferred	(39)	(836)	356
Provision for taxes on income	**$ 3,261**	**2,689**	**3,613**

A comparison of income tax expense at the U.S. statutory rate of 35% in 2012, 2011 and 2010, to the Company's effective tax rate is as follows:

(Dollars in Millions)	2012	2011	2010
U.S.	$ 4,664	3,634	6,392
International	9,111	8,727	10,555
Earnings before taxes on income:	$ 13,775	12,361	16,947
Tax rates:			
U.S. statutory rate	35.0 %	35.0	35.0
International operations excluding Ireland	(9.8)	(14.0)	(7.5)
Ireland and Puerto Rico operations	(3.9)	(1.8)	(5.1)
Research and orphan drug tax credits	—	(0.8)	(0.6)
U.S. state and local	1.3	2.1	1.0
U.S. manufacturing deduction	(0.9)	(0.8)	(0.5)
U.S. tax on international income	1.1	(0.4)	(0.6)
All other[1]	0.9	2.5	(0.4)
Effective tax rate	23.7 %	21.8	21.3

[1] Includes U.S. expenses not fully tax deductible primarily related to litigation expense.

The increase in the 2012 effective tax rate as compared to 2011 was due to lower tax benefits on the impairment of in-process research and development intangible assets in low tax jurisdictions, increases in taxable income in higher tax jurisdictions relative to lower tax jurisdictions and the exclusion of the benefit of the U.S. Research & Development (R&D) tax credit and the CFC look-through provisions from the 2012 fiscal year financial results. The R&D tax credit and the CFC look-through provisions were enacted into law in 2013 and were retroactive to January 1, 2012. The entire benefit of the R&D tax credit and the CFC look-through provisions will be reflected in the 2013 fiscal year financial results. The increase in the 2011 tax rate as compared to 2010 was primarily due to certain U.S. expenses which are not fully tax deductible and higher U.S. state taxes partially offset by increases in taxable income in lower tax jurisdictions relative to higher tax jurisdictions.

Temporary differences and carryforwards for 2012 and 2011 were as follows:

	2012 Deferred Tax		2011 Deferred Tax	
(Dollars in Millions)	**Asset**	**Liability**	**Asset**	**Liability**
Employee related obligations	$ 3,343		3,028	
Stock based compensation	1,199		1,358	
Depreciation		(933)		(865)
Non-deductible intangibles		(6,261)		(2,997)
International R&D capitalized for tax	1,599		1,509	
Reserves & liabilities	1,908		1,527	
Income reported for tax purposes	726		903	
Net operating loss carryforward international	1,117		1,183	
Miscellaneous international	1,291	(371)	1,261	(422)
Miscellaneous U.S.	915		817	
Total deferred income taxes	**$ 12,098**	**(7,565)**	**11,586**	**(4,284)**

The difference between the net deferred tax on income per the balance sheet and the net deferred tax above is included in taxes on income on the balance sheet. The Company has wholly-owned international subsidiaries that have cumulative net losses. The Company believes that it is more likely than not that these subsidiaries will realize future taxable income sufficient to utilize these deferred tax assets.

The following table summarizes the activity related to unrecognized tax benefits:

(Dollars in Millions)	**2012**	**2011**	**2010**
Beginning of year	$ 2,699	2,307	2,403
Increases related to current year tax positions	538	402	465
Increases related to prior period tax positions	57	87	68
Decreases related to prior period tax positions	(41)	(77)	(431)
Settlements	(120)	(16)	(186)
Lapse of statute of limitations	(79)	(4)	(12)
End of year	**$ 3,054**	**2,699**	**2,307**

The unrecognized tax benefits of $3.1 billion at December 30, 2012, if recognized, would affect the Company's annual effective tax rate. The Company conducts business and files tax returns in numerous countries and currently has tax audits in progress with a number of tax authorities. The U.S. Internal Revenue Service (IRS) has completed its audit for the tax years through 2005; however, there are a limited number of issues remaining open for prior tax years going back to 1999. In other major jurisdictions where the Company conducts business, the years remain open generally back to the year 2003. The Company believes it is possible that audits may be completed by tax authorities in some jurisdictions over the next twelve months. However, the Company is not able to provide a reasonably reliable estimate of the timing of any other future tax payments relating to uncertain tax positions.

The Company classifies liabilities for unrecognized tax benefits and related interest and penalties as long-term liabilities. Interest expense and penalties related to unrecognized tax benefits are classified as income tax expense. The Company recognized after tax interest of $41 million expense, $47 million expense and $34 million income in 2012, 2011 and 2010, respectively. The total amount of accrued interest was $422 million and $350 million in 2012 and 2011, respectively.

9. Employee Related Obligations

At the end of 2012 and 2011, employee related obligations recorded on the Consolidated Balance Sheets were:

(Dollars in Millions)	2012	2011
Pension benefits	$ 4,488	3,937
Postretirement benefits	2,789	2,843
Postemployment benefits	1,452	1,129
Deferred compensation	747	863
Total employee obligations	9,476	8,772
Less current benefits payable	394	419
Employee related obligations — non-current	**$ 9,082**	**8,353**

Prepaid employee related obligations of $194 million and $249 million for 2012 and 2011, respectively, are included in other assets on the Consolidated Balance Sheets.

10. Pensions and Other Benefit Plans

The Company sponsors various retirement and pension plans, including defined benefit, defined contribution and termination indemnity plans, which cover most employees worldwide. The Company also provides post-retirement benefits, primarily health care, to all eligible U.S. retired employees and their dependents.

Many international employees are covered by government-sponsored programs and the cost to the Company is not significant.

Retirement plan benefits are primarily based on the employee's compensation during the last three to five years before retirement and the number of years of service. International subsidiaries have plans under which funds are deposited with trustees, annuities are purchased under group contracts, or reserves are provided.

The Company does not fund retiree health care benefits in advance and has the right to modify these plans in the future.

The Company uses the date of its consolidated financial statements (December 30, 2012 and January 1, 2012, respectively) as the measurement date for all U.S. and international retirement and other benefit plans.

Net periodic benefit costs for the Company's defined benefit retirement plans and other benefit plans for 2012, 2011 and 2010 include the following components:

	Retirement Plans			Other Benefit Plans		
(Dollars in Millions)	2012	2011	2010	2012	2011	2010
Service cost	$ 722	638	550	175	149	134
Interest cost	878	853	791	165	188	202
Expected return on plan assets	(1,236)	(1,108)	(1,005)	(4)	(1)	(1)
Amortization of prior service cost (credit)	6	9	10	(3)	(3)	(4)
Amortization of net transition obligation	1	1	1	—	—	—
Recognized actuarial losses	494	388	236	76	45	48
Curtailments and settlements	—	—	1	—	—	—
Net periodic benefit cost	**$ 865**	**781**	**584**	**409**	**378**	**379**

Amounts expected to be recognized in net periodic benefit cost in the coming year for the Company's defined benefit retirement plans and other post-retirement plans:

(Dollars in Millions)	
Amortization of net transition obligation	$ 1
Amortization of net actuarial losses	775
Amortization of prior service cost	6

Unrecognized gains and losses for the U.S. pension plans are amortized over the average remaining future service for each plan. For plans with no active employees, they are amortized over the average life expectancy. The amortization of gains and

losses for the other U.S. benefit plans is determined by using a 10% corridor of the greater of the market value of assets or the projected benefit obligation. Total unamortized gains and losses in excess of the corridor are amortized over the average remaining future service.

Prior service costs/benefits for the U.S. pension plans are amortized over the remaining future service of plan participants at the time of the plan amendment. Prior service cost/benefit for the other U.S. benefit plans is amortized over the average remaining service to full eligibility age of plan participants at the time of the plan amendment.

The weighted-average assumptions in the following table represent the rates used to develop the actuarial present value of projected benefit obligation for the year listed and also the net periodic benefit cost for the following year.

	Retirement Plans			Other Benefit Plans		
	2012	2011	2010	2012	2011	2010
Worldwide Benefit Plans						
Discount rate	4.25%	5.13%	5.71%	4.55%	5.25%	6.00%
Expected long-term rate of return on plan assets	8.45%	8.62%	8.68%			
Rate of increase in compensation levels	4.08%	4.19%	4.19%	4.28%	4.28%	4.29%

The Company's discount rates are determined by considering current yield curves representing high quality, long-term fixed income instruments. The resulting discount rates are consistent with the duration of plan liabilities.

The expected rates of return on plan asset assumptions represent the Company's assessment of long-term returns on diversified investment portfolios globally. The assessment is determined using projections from external financial sources, long-term historical averages, actual returns by asset class and the various asset class allocations by market.

The following table displays the assumed health care cost trend rates, for all individuals:

Health Care Plans	2012	2011
Health care cost trend rate assumed for next year	6.50%	7.50%
Rate to which the cost trend rate is assumed to decline (ultimate trend)	4.50%	5.00%
Year the rate reaches the ultimate trend rate	2032	2018

A one-percentage-point change in assumed health care cost trend rates would have the following effect:

(Dollars in Millions)	One-Percentage-Point Increase	One-Percentage-Point Decrease
Health Care Plans		
Total interest and service cost	$ 42	$ (33)
Post-retirement benefit obligation	496	(394)

The following table sets forth information related to the benefit obligation and the fair value of plan assets at year-end 2012 and 2011 for the Company's defined benefit retirement plans and other post-retirement plans:

	Retirement Plans		Other Benefit Plans	
(Dollars in Millions)	**2012**	**2011**	**2012**	**2011**
Change in Benefit Obligation				
Projected benefit obligation — beginning of year	$ 17,424	14,993	3,790	3,572
Service cost	722	638	175	149
Interest cost	878	853	165	188
Plan participant contributions	35	54	—	—
Amendments	12	(24)	—	—
Actuarial losses	2,662	1,698	459	213
Divestitures & acquisitions	629	14	—	—
Curtailments & settlements & restructuring	(6)	(6)	—	—
Benefits paid from plan	(697)	(659)	(432)	(320)
Effect of exchange rates	170	(137)	2	(12)
Projected benefit obligation — end of year	**$ 21,829**	**17,424**	**4,159**	**3,790**
Change in Plan Assets				
Plan assets at fair value — beginning of year	$ 13,736	13,433	8	14
Actual return (loss) on plan assets	1,926	(102)	3	(1)
Company contributions	1,838	1,135	543	315
Plan participant contributions	35	54	—	—
Settlements	(2)	(2)	—	—
Divestitures & acquisitions	593	(2)	—	—
Benefits paid from plan assets	(697)	(659)	(432)	(320)
Effect of exchange rates	107	(121)	—	—
Plan assets at fair value — end of year	**$ 17,536**	**13,736**	**122**	**8**
Funded status — end of year	**$ (4,293)**	**(3,688)**	**(4,037)**	**(3,782)**
Amounts Recognized in the Company's Balance Sheet consist of the following:				
Non-current assets	$ 194	249	$ —	—
Current liabilities	(65)	(59)	(307)	(346)
Non-current liabilities	(4,422)	(3,878)	(3,730)	(3,436)
Total recognized in the consolidated balance sheet — end of year	**$ (4,293)**	**(3,688)**	**$ (4,037)**	**(3,782)**
Amounts Recognized in Accumulated Other Comprehensive Income consist of the following:				
Net actuarial loss	$ 7,586	6,030	$ 1,601	1,218
Prior service cost (credit)	9	6	(14)	(18)
Unrecognized net transition obligation	2	3	—	1
Total before tax effects	**$ 7,597**	**6,039**	**$ 1,587**	**1,201**
Accumulated Benefit Obligations — end of year	**$ 19,267**	**15,452**		

(Dollars in Millions)	Retirement Plans 2012	Retirement Plans 2011	Other Benefit Plans 2012	Other Benefit Plans 2011
Changes in Plan Assets and Benefit Obligations Recognized in Other Comprehensive Income				
Net periodic benefit cost	**$ 865**	**781**	**$ 409**	**378**
Net actuarial loss	2,007	2,903	458	197
Amortization of net actuarial (loss) gain	(494)	(388)	(76)	8
Prior service cost	12	(24)	—	—
Amortization of prior service (cost) credit	(6)	(9)	3	3
Effect of exchange rates	79	(25)	1	(3)
Total recognized in other comprehensive income, before tax	**$ 1,598**	**2,457**	**$ 386**	**205**
Total recognized in net periodic benefit cost and other comprehensive income	**$ 2,463**	**3,238**	**$ 795**	**583**

The Company plans to continue to fund its U.S. Qualified Plans to comply with the Pension Protection Act of 2006. International Plans are funded in accordance with local regulations. Additional discretionary contributions are made when deemed appropriate to meet the long-term obligations of the plans. For certain plans, funding is not a common practice, as funding provides no economic benefit. Consequently, the Company has several pension plans that are not funded.

In 2012, the Company contributed $1,399 million and $439 million to its U.S. and international pension plans, respectively.

The following table displays the funded status of the Company's U.S. Qualified & Non-Qualified pension plans and international funded and unfunded pension plans at December 30, 2012 and January 1, 2012, respectively:

	U.S. Plans				International Plans			
	Qualified Plans		Non-Qualified Plans		Funded Plans		Unfunded Plans	
(Dollars in Millions)	2012	2011	2012	2011	2012	2011	2012	2011
Plan Assets	$ 11,464	9,132	—	—	6,072	4,604	—	—
Projected Benefit Obligation	12,420	10,283	1,343	1,155	7,586	5,626	480	360
Accumulated Benefit Obligation	11,001	9,147	1,070	903	6,774	5,078	422	324
Over (Under) Funded Status								
Projected Benefit Obligation	$ (956)	(1,151)	(1,343)	(1,155)	(1,514)	(1,022)	(480)	(360)
Accumulated Benefit Obligation	463	(15)	(1,070)	(903)	(702)	(474)	(422)	(324)

Plans with accumulated benefit obligations in excess of plan assets have an accumulated benefit obligation, projected benefit obligation and plan assets of $6.5 billion, $7.4 billion and $4.0 billion, respectively at the end of 2012 and $13.8 billion, $15.4 billion and $11.7 billion, respectively, at the end of 2011.

The following table displays the projected future benefit payments from the Company's retirement and other benefit plans:

(Dollars in Millions)	2013	2014	2015	2016	2017	2018-2022
Projected future benefit payments						
Retirement plans	$ 695	715	736	775	820	4,934
Other benefit plans — gross	327	221	220	220	220	1,121
Medicare rebates	(11)	—	—	—	—	—
Other benefit plans — net	$ 316	221	220	220	220	1,121

The following table displays the projected future minimum contributions to the Company's U.S. and international unfunded retirement plans. These amounts do not include any discretionary contributions that the Company may elect to make in the future.

(Dollars in Millions)	2013	2014	2015	2016	2017	2018-2022
Projected future contributions						
Unfunded U.S. retirement plans	$ 43	46	49	52	56	354
Unfunded international retirement plans	$ 25	20	22	24	24	148

Each pension plan is overseen by a local committee or board that is responsible for the overall administration and investment of the pension plans. In determining investment policies, strategies and goals, each committee or board considers factors including, local pension rules and regulations; local tax regulations; availability of investment vehicles (separate accounts, commingled accounts, insurance funds, etc.); funded status of the plans; ratio of actives to retirees; duration of liabilities; and other relevant factors including; diversification, liquidity of local markets and liquidity of base currency. A majority of the Company's pension funds are open to new entrants and are expected to be on-going plans. Permitted investments are primarily liquid and/or listed, with little reliance on illiquid and non-traditional investments such as hedge funds.

The Company's retirement plan asset allocation at the end of 2012 and 2011 and target allocations for 2013 are as follows:

	Percent of Plan Assets		Target Allocation
	2012	2011	2013
Worldwide Retirement Plans			
Equity securities	75%	70%	71%
Debt securities	25	30	29
Total plan assets	**100%**	**100%**	**100%**

Determination of Fair Value of Plan Assets

The Plan has an established and well-documented process for determining fair values. Fair value is based upon quoted market prices, where available. If listed prices or quotes are not available, fair value is based upon models that primarily use, as inputs, market-based or independently sourced market parameters, including yield curves, interest rates, volatilities, equity or debt prices, foreign exchange rates and credit curves.

While the Plan believes its valuation methods are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

Valuation Hierarchy

The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described in the table below with Level 1 having the highest priority and Level 3 having the lowest.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Following is a description of the valuation methodologies used for the investments measured at fair value.

- *Short-term investments* — Cash and quoted short-term instruments are valued at the closing price or the amount held on deposit by the custodian bank. Other investments are through investment vehicles valued using the Net Asset Value (NAV) provided by the administrator of the fund. The NAV is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding. The NAV is a quoted price in a market that is not active and classified as Level 2.
- *Government and agency securities* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified within Level 1 of the valuation hierarchy. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows. When quoted market prices for a security are not available in an active market, they are classified as Level 2.
- *Debt instruments* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified as Level 1. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows and are classified as Level 2. Level 3 debt instruments are priced based on unobservable inputs.

- *Equity securities* — Common stocks are valued at the closing price reported on the major market on which the individual securities are traded. Substantially all common stock is classified within Level 1 of the valuation hierarchy.
- *Commingled funds* — The investments are public investment vehicles valued using the NAV provided by the fund administrator. The NAV is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding. Assets in the Level 2 category have a quoted market price in a market that is not active.
- *Insurance contracts* — The instruments are issued by insurance companies. The fair value is based on negotiated value and the underlying investments held in separate account portfolios as well as considering the credit worthiness of the issuer. The underlying investments are government, asset-backed and fixed income securities. In general, insurance contracts are classified as Level 3 as there are no quoted prices nor other observable inputs for pricing.
- *Other assets* — Other assets are represented primarily by limited partnerships and real estate investments, as well as commercial loans and commercial mortgages that are not classified as corporate debt. Other assets that are exchange listed and actively traded are classified as Level 1, while inactively traded assets are classified as Level 2. Most limited partnerships represent investments in private equity and similar funds that are valued by the general partners. These, as well as any other assets valued using unobservable inputs, are classified as Level 3.

The following table sets forth the Retirement Plans' trust investments measured at fair value as of December 30, 2012 and January 1, 2012:

	Quoted Prices in Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobserv-able Inputs (Level 3)		Total Assets	
(Dollars in Millions)	**2012**	**2011**	**2012**	**2011**	**2012**	**2011**	**2012**	**2011**
Short-term investment funds	$ 155	161	627	632	—	—	782	793
Government and agency securities	53	59	1,706	1,528	—	—	1,759	1,587
Debt instruments	2	1	1,641	1,106	3	9	1,646	1,116
Equity securities	8,104	6,682	1	2	4	16	8,109	6,700
Commingled funds	11	8	4,985	3,375	50	33	5,046	3,416
Insurance contracts	—	—	—	—	24	25	24	25
Other assets	—	1	101	33	69	65	170	99
Trust investments at fair value	**$ 8,325**	**6,912**	**9,061**	**6,676**	**150**	**148**	**17,536**	**13,736**

The Company's Other Benefit Plans are unfunded except for U.S. commingled funds (Level 2) of $67 million and $8 million at December 30, 2012 and January 1, 2012, respectively, and $55 million of U.S. short-term-investment funds (Level 2) at December 30, 2012.

The fair value of Johnson & Johnson Common Stock directly held in plan assets was $512 million (2.9% of total plan assets) at December 30, 2012 and $476 million (3.5% of total plan assets) at January 1, 2012.

Level 3 Gains and Losses

The table below sets forth a summary of changes in the fair value of the Plan's Level 3 assets for the years ended December 30, 2012 and January 1, 2012:

(Dollars in Millions)	**Debt Instruments**	**Equity Securities**	**Commingled Funds**	**Insurance Contracts**	**Other Assets**	**Total Level 3**
Balance January 2, 2011	$ 13	24	35	29	82	183
Realized gains (losses)	—	3	—	1	—	4
Unrealized gains (losses)	1	(2)	(6)	(2)	(17)	(26)
Purchases, sales, issuances and settlements, net	(5)	(9)	4	(3)	—	(13)
Balance January 1, 2012	9	16	33	25	65	148
Realized gains (losses)	—	(1)	—	—	(5)	(6)
Unrealized gains (losses)	—	—	—	—	—	—
Purchases, sales, issuances and settlements, net	(6)	(11)	17	(1)	9	8
Balance December 30, 2012	**$ 3**	**4**	**50**	**24**	**69**	**150**

11. Savings Plan

The Company has voluntary 401(k) savings plans designed to enhance the existing retirement programs covering eligible employees. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which he/she is eligible. Total Company matching contributions to the plans were $160 million, $157 million and $157 million in 2012, 2011 and 2010, respectively.

12. Capital and Treasury Stock

Changes in treasury stock were:

	Treasury Stock	
(Amounts in Millions Except Treasury Stock Shares in Thousands)	Shares	Amount
Balance at January 3, 2010	365,522	$ 19,780
Employee compensation and stock option plans	(28,866)	(1,794)
Repurchase of common stock	45,090	2,797
Balance at January 2, 2011	381,746	20,783
Employee compensation and stock option plans	(26,007)	(1,649)
Repurchase of common stock	39,741	2,525
Balance at January 1, 2012	395,480	21,659
Employee compensation and stock option plans	(55,170)	(3,250)
Issuance of common stock associated with the acquisition of Synthes, Inc.	(203,740)	(12,852)
Repurchase of common stock [1]	204,784	12,919
Balance at December 30, 2012	341,354	$ 18,476

Aggregate shares of Common Stock issued were approximately 3,119,843,000 shares at the end of 2012, 2011 and 2010.

Cash dividends paid were $2.40 per share in 2012, compared with dividends of $2.25 per share in 2011, and $2.11 per share in 2010.

(1) Includes repurchase of common stock associated with the acquisition of Synthes, Inc.

13. Accumulated Other Comprehensive Income

Components of other comprehensive income/(loss) consist of the following:

(Dollars in Millions)	Foreign Currency Translation	Gains/ (Losses) on Securities	Employee Benefit Plans	Gains/ (Losses) on Derivatives & Hedges	Total Accumulated Other Comprehensive Income/(Loss)
January 3, 2010	$ (508)	(30)	(2,665)	145	(3,058)
Net 2010 changes	(461)	54	(21)	(45)	(473)
January 2, 2011	(969)	24	(2,686)	100	(3,531)
Net 2011 changes	(557)	424	(1,700)	(268)	(2,101)
January 1, 2012	(1,526)	448	(4,386)	(168)	(5,632)
Net 2012 changes	1,230	(253)	(1,331)	176	(178)
December 30, 2012	**$ (296)**	**195**	**(5,717)**	**8**	**(5,810)**

Amounts in accumulated other comprehensive income are presented net of the related tax impact. Foreign currency translation is not adjusted for income taxes as it relates to permanent investments in international subsidiaries. For additional details on comprehensive income see the Consolidated Statements of Comprehensive Income.

14. International Currency Translation

For translation of its subsidiaries operating in non-U.S. Dollar currencies, the Company has determined that the local currencies of its international subsidiaries are the functional currencies except those in highly inflationary economies, which are defined as those which have had compound cumulative rates of inflation of 100% or more during the past three years, or where a substantial portion of its cash flows are not in the local currency.

In consolidating international subsidiaries, balance sheet currency effects are recorded as a component of accumulated

other comprehensive income. This equity account includes the results of translating all balance sheet assets and liabilities at current exchange rates, except for those located in highly inflationary economies. The translation of balance sheet accounts for highly inflationary economies are reflected in the operating results.

A rollforward of the changes during 2012, 2011 and 2010 for foreign currency translation adjustments is included in Note 13.

Net currency transaction gains and losses included in Other (income) expense were losses of $58 million, $10 million and $130 million in 2012, 2011 and 2010, respectively.

15. Earnings Per Share

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal years ended December 30, 2012, January 1, 2012 and January 2, 2011:

(In Millions Except Per Share Amounts)	2012	2011	2010
Basic net earnings per share attributable to Johnson & Johnson	$ 3.94	3.54	4.85
Average shares outstanding — basic	2,753.3	2,736.0	2,751.4
Potential shares exercisable under stock option plans	164.6	158.3	156.1
Less: shares repurchased under treasury stock method	(128.2)	(122.6)	(122.3)
Convertible debt shares	3.6	3.6	3.6
Accelerated share repurchase program	19.3	—	—
Adjusted average shares outstanding — diluted	2,812.6	2,775.3	2,788.8
Diluted net earnings per share attributable to Johnson & Johnson	$ 3.86	3.49	4.78

The diluted net earnings per share calculation includes the dilutive effect of convertible debt that is offset by the related reduction in interest expense of $4 million after-tax for years 2012, 2011 and 2010.

Diluted net earnings per share excludes 0.2 million, 50.7 million and 66.3 million shares underlying stock options for 2012, 2011 and 2010, respectively, as the exercise price of these options was greater than their average market value, which would result in an anti-dilutive effect on diluted earnings per share.

The diluted earnings per share calculation for the fiscal year ended December 30, 2012 included the dilutive effect of 19.3 million shares related to the accelerated share repurchase program, associated with the acquisition of Synthes, Inc. See Note 20 to the Consolidated Financial Statements for additional details. A $1 increase/decrease in the volume weighted average share price would impact this estimate by approximately 2.6 million shares.

16. Rental Expense and Lease Commitments

Rentals of space, vehicles, manufacturing equipment and office and data processing equipment under operating leases were approximately $375 million, $313 million and $299 million in 2012, 2011 and 2010, respectively.

The approximate minimum rental payments required under operating leases that have initial or remaining non-cancelable lease terms in excess of one year at December 30, 2012 are:

(Dollars in Millions)

2013	2014	2015	2016	2017	After 2017	Total
$251	192	149	115	90	128	925

Commitments under capital leases are not significant.

17. Common Stock, Stock Option Plans and Stock Compensation Agreements

At December 30, 2012, the Company had 4 stock-based compensation plans. The shares outstanding are for contracts under the Company's 2000 Stock Option Plan, the 2005 Long-Term Incentive Plan, the 2012 Long-Term Incentive Plan, and the Scios, Inc. Stock Option Plans. The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan.

The compensation cost that has been charged against income for these plans was $662 million, $621 million and $614 million for 2012, 2011 and 2010, respectively. The total income tax benefit recognized in the income statement for share-based compensation costs was $220 million, $207 million and $205 million for 2012, 2011 and 2010, respectively. The total unrecognized compensation cost was $565 million, $562 million and $613 million for 2012, 2011 and 2010, respectively. The weighted average period for this cost to be recognized was 1.02 years, 0.97 years and 1.05 years for 2012, 2011, and 2010, respectively. Share-based compensation costs capitalized as part of inventory were insignificant in all periods.

Stock Options

Stock options expire 10 years from the date of grant and vest over service periods that range from 6 months to 4 years. All options are granted at the average of the high and low prices of the Company's Common Stock on the New York Stock Exchange on the date of grant. Under the 2012 Long-Term Incentive Plan, the Company may issue up to 200 million shares of common stock, plus any shares canceled, expired, forfeited, or not issued from the 2005 Long-Term Incentive Plan subsequent to April 26, 2012. Shares available for future grants under the 2012 Long-Term Incentive Plan were 201.8 million at the end of 2012.

The Company settles employee stock option exercises with treasury shares. Previously, treasury shares were replenished throughout the year for the number of shares used to settle employee stock option exercises. However, pursuant to the accelerated stock repurchase agreements in connection with the acquisition of Synthes, Inc., the Company has not made any purchases of Common Stock on the open market during the fiscal third and fourth quarters of 2012.

The fair value of each option award was estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the following table. Expected volatility represents a blended rate of 4-year daily historical average volatility rate, and a 5-week average implied volatility rate based on at-the-money traded Johnson & Johnson options with a life of 2 years. Historical data is used to determine the expected life of the option. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant.

The average fair value of options granted was $6.39, $7.47 and $8.03, in 2012, 2011, and 2010, respectively. The fair value was estimated based on the weighted average assumptions of:

	2012	2011	2010
Risk-free rate	1.06%	2.41%	2.78%
Expected volatility	18.38%	18.20%	17.40%
Expected life (in years)	6.0	6.0	6.0
Dividend yield	3.60%	3.60%	3.30%

A summary of option activity under the Plan as of December 30, 2012, January 1, 2012 and January 2, 2011 and changes during the years ending on those dates is presented below:

(Shares in Thousands)	Outstanding Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (Dollars in Millions)
Shares at January 3, 2010	212,719	$ 58.66	$ 1,310
Options granted	13,996	62.62	
Options exercised	(25,020)	51.84	
Options canceled/forfeited	(8,005)	62.36	
Shares at January 2, 2011	193,690	59.68	648
Options granted	9,530	62.21	
Options exercised	(20,160)	56.65	
Options canceled/forfeited	(3,601)	62.38	
Shares at January 1, 2012	179,459	60.10	1,004
Options granted	8,661	65.36	
Options exercised	(49,388)	56.73	
Options canceled/forfeited	(4,381)	62.97	
Shares at December 30, 2012	**134,351**	**$ 61.58**	**$ 1,061**

The total intrinsic value of options exercised was $547 million, $167 million and $278 million in 2012, 2011 and 2010, respectively.

The following table summarizes stock options outstanding and exercisable at December 30, 2012:

(Shares in Thousands)	Outstanding			Exercisable	
Exercise Price Range	Options	Average Life[1]	Average Exercise Price	Options	Average Exercise Price
$49.66-$53.77	3,600	0.1	$52.19	3,599	$52.19
$53.93-$58.33	29,134	3.6	$56.13	28,076	$56.04
$58.34-$61.75	29,604	4.0	$60.01	29,556	$60.01
$61.86-65.37	28,817	7.8	$63.29	464	$63.88
$65.62-$68.37	43,196	2.9	$65.97	43,165	$65.97
	134,351	**4.3**	**$61.58**	**104,860**	**$61.15**

[1] *Average contractual life remaining in years.*

Stock options exercisable at January 1, 2012 and January 2, 2011 were 138,126 at an average price of $59.94 and an average life of 4.2 years and 141,275 at an average price of $59.25 and an average life of 4.7 years, respectively.

Restricted Share Units and Performance Share Units

The Company grants restricted share units with a vesting period of three years. The Company also grants performance share units, which are paid in shares of Johnson & Johnson Common Stock after the end of a three-year performance period. Whether any performance share units vest, and the amount that does vest, is tied to the achievement, over a three-year period, of three equally-weighted goals that directly align with or help drive long-term total shareholder return: sales, adjusted operational earnings per share, and relative total shareholder return. The number of shares actually earned at the end of the three-year period will vary, based only on actual performance, from 0% to 200% of the target number of performance share units granted.

The Company settles employee stock issuances with treasury shares. Previously, treasury shares were replenished throughout the year for the number of shares used to settle employee stock issuances. However, pursuant to the accelerated stock repurchase agreements in connection with the acquisition of Synthes, Inc., the Company has not made any purchases of Common Stock on the open market during the fiscal third and fourth quarters of 2012.

A summary of the restricted share units and performance share units activity under the Plans as of December 30, 2012 is presented below:

(Shares in Thousands)	Outstanding Restricted Share Units	Outstanding Performance Share Units
Shares at January 3, 2010	26,324	
Granted	12,003	
Issued	(6,297)	
Canceled/forfeited	(2,296)	
Shares at January 2, 2011	29,734	
Granted	11,478	
Issued	(8,300)	
Canceled/forfeited	(1,886)	
Shares at January 1, 2012	31,026	—
Granted	12,197	327
Issued	(9,278)	—
Canceled/forfeited	(2,111)	(42)
Shares at December 30, 2012	31,834	285

The average fair value of the restricted share units granted was $58.93, $55.90 and $56.69 in 2012, 2011 and 2010, respectively, using the fair market value at the date of grant. The fair value of restricted share units was discounted for dividends, which are not paid on the restricted share units during the vesting period. The fair value of restricted share units settled was $483.2 million, $458.9 million and $375.0 million in 2012, 2011 and 2010, respectively.

The weighted average fair value of the performance share units was $55.01 in 2012, calculated using the weighted average fair market value for each of the three component goals at the date of grant.

The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. No performance share units were issued in 2012.

18. Segments of Business and Geographic Areas

(Dollars in Millions)	Sales to Customers 2012	2011	2010
Consumer —			
United States	$ 5,046	5,151	5,519
International	9,401	9,732	9,071
Total	**14,447**	**14,883**	**14,590**
Pharmaceutical —			
United States	12,421	12,386	12,519
International	12,930	11,982	9,877
Total	**25,351**	**24,368**	**22,396**
Medical Devices and Diagnostics —			
United States	12,363	11,371	11,412
International	15,063	14,408	13,189
Total	**27,426**	**25,779**	**24,601**
Worldwide total	**$ 67,224**	**65,030**	**61,587**

(Dollars in Millions)	Pre-Tax Profit 2012 [3]	2011 [4]	2010 [5]	Identifiable Assets 2012	2011	2010
Consumer	$ 1,693	2,096	2,342	$ 24,131	24,210	23,753
Pharmaceutical	6,075	6,406	7,086	23,219	23,747	19,961
Medical Devices and Diagnostics	7,187	5,263	8,272	42,926	23,609	23,277
Total	14,955	13,765	17,700	90,276	71,566	66,991
Less: Expense not allocated to segments [1]	1,180	1,404	753			
General corporate [2]				31,071	42,078	35,917
Worldwide total	**$ 13,775**	**12,361**	**16,947**	**$ 121,347**	**113,644**	**102,908**

(Dollars in Millions)	Additions to Property, Plant & Equipment 2012	2011	2010	Depreciation and Amortization 2012	2011	2010
Consumer	$ 468	670	526	$ 575	631	532
Pharmaceutical	737	729	508	1,010	958	912
Medical Devices and Diagnostics	1,230	1,095	1,113	1,857	1,331	1,270
Segments total	2,435	2,494	2,147	3,442	2,920	2,714
General corporate	499	399	237	224	238	225
Worldwide total	**$ 2,934**	**2,893**	**2,384**	**$ 3,666**	**3,158**	**2,939**

(Dollars in Millions)	Sales to Customers 2012	2011	2010	Long-Lived Assets [6] 2012	2011	2010
United States	$ 29,830	28,908	29,450	$ 35,115	23,529	23,315
Europe	16,945	17,129	15,510	25,261	19,056	16,791
Western Hemisphere excluding U.S.	7,207	6,418	5,550	3,636	3,517	3,653
Asia-Pacific, Africa	13,242	12,575	11,077	2,362	2,163	2,089
Segments total	67,224	65,030	61,587	66,374	48,265	45,848
General corporate				899	750	715
Other non long-lived assets				54,074	64,629	56,345
Worldwide total	**$ 67,224**	**65,030**	**61,587**	**$ 121,347**	**113,644**	**102,908**

See Note 1 for a description of the segments in which the Company operates.

Export sales are not significant. In 2012, 2011 and 2010, the Company did not have a customer that represented 10% of total revenues.

(1) Amounts not allocated to segments include interest (income) expense, noncontrolling interests and general corporate (income) expense. Includes expense of $0.2 billion and $0.5 billion of currency related expense related to the acquisition of Synthes, Inc. in 2012 and 2011, respectively.

(2) General corporate includes cash and marketable securities.

(3) Includes $1,218 million of net litigation expense, which includes product liability, comprised of $658 million and $560 million in the Pharmaceutical and Medical Devices and Diagnostics segments, respectively. Includes $1,163 million of in-process research and development expense, comprised of $1,111 million and $52 million in the Pharmaceutical and Medical Devices and Diagnostics segments, respectively. Includes $795 million of Synthes integration/transaction costs in the Medical Devices and Diagnostics segment. Includes $909 million of asset write-downs and other adjustments, comprised of $499 million, $264 million and $146 million in the Pharmaceutical, Consumer and Medical Devices and Diagnostics segments, respectively. The Medical Devices and Diagnostics segment also includes $110 million expense for the cost associated with the DePuy ASR™Hip program.

(4) Includes $3,310 million of net litigation expense, which includes product liability, comprised of $1,741 million and $1,569 million in the Pharmaceutical and Medical Devices and Diagnostics segments, respectively. Includes $656 million of net restructuring expense, comprised of $676 million expense in the Medical Devices and Diagnostics segment and a gain of $20 million in the Pharmaceutical segment. The Medical Devices and Diagnostics segment also includes $521 million expense for the cost associated with the DePuy ASR™Hip program.

(5) Includes $397 million of net litigation gain, which includes product liability expense, comprised of $447 million expense in the Pharmaceutical segment and a gain of $844 million in the Medical Devices and Diagnostics segment. The Medical Devices and Diagnostics segment also includes $280 million expense for the cost associated with the DePuy ASR™Hip program.

(6) Long-lived assets include property, plant and equipment, net for 2012, 2011 and 2010 of $16,097, $14,739 and $14,553, respectively, and intangible assets and goodwill, net for 2012, 2011 and 2010 of $51,176, $34,276 and $32,010, respectively.

19. Selected Quarterly Financial Data (unaudited)

Selected unaudited quarterly financial data for the years 2012 and 2011 are summarized below:

	2012				2011			
(Dollars in Millions Except Per Share Data)	First Quarter [1]	Second Quarter [2]	Third Quarter [3]	Fourth Quarter [4]	First Quarter [5]	Second Quarter [6]	Third Quarter [7]	Fourth Quarter [8]
Segment sales to customers								
Consumer	$ 3,595	3,619	3,581	3,652	3,682	3,793	3,740	3,668
Pharmaceutical	6,133	6,291	6,402	6,525	6,059	6,233	5,982	6,094
Med Devices & Diagnostics	6,411	6,565	7,069	7,381	6,432	6,571	6,283	6,493
Total sales	16,139	16,475	17,052	17,558	16,173	16,597	16,005	16,255
Gross profit	11,224	11,332	11,455	11,555	11,395	11,425	10,933	10,917
Earnings before provision for taxes on income	5,045	2,035	3,595	3,100	4,510	3,422	4,111	318
Net earnings attributable to Johnson & Johnson	3,910	1,408	2,968	2,567	3,476	2,776	3,202	218
Basic net earnings per share attributable to Johnson & Johnson	$ 1.43	0.51	1.08	0.93	1.27	1.01	1.17	0.08
Diluted net earnings per share attributable to Johnson & Johnson	$ 1.41	0.50	1.05	0.91	1.25	1.00	1.15	0.08

(1) The first quarter of 2012 includes an after-tax gain of $106 million from currency and costs associated with the acquisition of Synthes, Inc.

(2) The second quarter of 2012 includes after-tax charges of $717 million for asset write-downs, $611 million from net litigation, $564 million associated with the acquisition of Synthes, Inc. and $344 million from impairment of in-process research and development.

(3) The third quarter of 2012 includes after-tax charges of $135 million associated with the acquisition of Synthes, Inc., $340 million from impairment of in-process research and development, $70 million associated with litigation, including product liability, and $24 million associated with the DePuy ASR™ Hip program.

(4) The fourth quarter of 2012 includes after-tax charges of $371 million from net litigation, including product liability, $306 million associated with the acquisition of Synthes, Inc., $73 million associated with the DePuy ASR™ Hip program and $59 million from impairment of in-process research and development.

(5) The first quarter of 2011 includes an after-tax charge of $271 million from net litigation, including product liability, and the DePuy ASR™ Hip program.

(6) The second quarter of 2011 includes after-tax charges of $549 million for restructuring, $325 million from litigation, including product liability, and the DePuy ASR™ Hip program, partially offset by a $102 million after-tax gain associated with an adjustment to the value of the currency option related to the acquisition of Synthes, Inc.

(7) The third quarter of 2011 includes a $241 million after-tax charge associated with an adjustment to the value of the currency option and deal costs related to the acquisition of Synthes, Inc.

(8) The fourth quarter of 2011 includes after-tax charges of $2,239 million from net litigation, including product liability, $336 million for the cost associated with the DePuy ASR™ Hip program and $338 million associated with an adjustment to the value of the currency option and deal costs related to the acquisition of Synthes, Inc.

20. Business Combinations and Divestitures

Certain businesses were acquired for $17,821 million in cash and stock and $1,204 million of liabilities assumed during 2012. These acquisitions were accounted for by the purchase method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2012 acquisitions included: Synthes Inc., a global developer and manufacturer of orthopaedics devices; Guangzhou Biosesal Biotech Co. Ltd, a developer of biologic combinations addressing moderate to severe hemostasis; Angiotech Pharmaceuticals, Inc., intellectual property and know how related to the Quill™ Knotless Tissue-Closure Device; Corlmmun Inc., a developer of a phase II treatment for CHF; Calibra Medical, Inc., developer of a unique, wearable three-day insulin patch for convenient and discreet mealtime dosing for people with diabetes who take multiple daily injections of insulin; Spectrum Vision LLC, a full service distributor of contact lenses serving Russia with facilities in the Ukraine and Kazakhstan; marketing authorizations, trademarks, and patents extending ZYRTEC® related market rights in Australia and Canada.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $15,785 million and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately $208 million has been identified as the value of IPR&D associated with the acquisitions of Corlmmun Inc. and Synthes Inc.

The IPR&D related to the acquisition of Synthes, Inc. of $63 million is associated with orthopaedic devices, and the IPR&D associated with Corlmmun of $145 million is related to a CHF treatment. These IPR&D values were calculated using the cash flow projections discounted for the risk inherent in such projects. Synthes Inc. had a probability of success factor of 100%, discounted using a 14% rate. Corlmmun had a probability of success factor of 38%, discounted using a 25% rate.

During the fiscal second quarter, the Company completed the acquisition of Synthes, Inc., a global developer and manufacturer of orthopaedics devices, for a purchase price of $20.2 billion in cash and stock. The net acquisition cost of the transaction is $17.5 billion based on cash on hand at closing of $2.7 billion.

Under the terms of the agreement, each share of Synthes, Inc. common stock was exchanged for CHF 55.65 in cash and 1.717 shares of Johnson & Johnson common stock, based on the calculated exchange ratio. The exchange ratio was calculated on June 12, 2012 and based on the relevant exchange rate and closing price of Johnson & Johnson common stock on that date, the total fair value of consideration transferred was $19.7 billion. When the acquisition was completed on June 14, 2012, based on the relevant exchange rate and closing price of Johnson & Johnson common stock on that date, the total fair value of the consideration transferred was $20.2 billion. Janssen Pharmaceutical, a company organized under the laws of Ireland and a wholly-owned subsidiary of Johnson & Johnson, used cash on hand to satisfy the cash portion of the merger consideration.

The stock portion of the merger consideration consisted of shares of Johnson & Johnson common stock purchased by Janssen Pharmaceutical, from two banks, pursuant to two accelerated share repurchase (ASR) agreements dated June 12, 2012. On June 13, 2012, Janssen Pharmaceutical purchased an aggregate of approximately 203.7 million shares of Johnson & Johnson common stock at an initial purchase price of $12.9 billion under the ASR agreements, with all of the shares delivered to Janssen Pharmaceutical on June 13, 2012. Final settlement of the transactions under each ASR agreement is expected to occur in the first half of 2013, and may occur earlier at the option of the two banks, as applicable, or later under certain circumstances. Based on the theoretical settlement of the ASR agreements, an additional 19.3 million shares would be issued to settle the ASR agreements as of December 30, 2012.

In addition, while the Company believes that the transactions under each ASR agreement and a series of related internal transactions were consummated in a tax efficient manner in accordance with applicable law, it is possible that the Internal Revenue Service could assert one or more contrary positions to challenge the transactions from a tax perspective. If challenged, an amount up to the total purchase price for the Synthes shares could be treated as subject to applicable U.S. tax at approximately the statutory rate to the Company, plus interest.

The following table summarizes the consideration transferred to acquire Synthes, Inc. valued on the acquisition date of June 14, 2012:

(Dollars in Millions)		
Cash (multiply 55.65CHF by shares of Synthes common stock outstanding by the exchange rate)(A)	$	6,902
Common Stock (multiply 1.717 by shares of Synthes common stock outstanding by J&J stock price)(B)	$	13,335
Total fair value of consideration transferred	$	20,237

(A) Synthes common stock outstanding of 118.7 million shares as of the acquisition date and CHF/USD exchange rate of .95674

(B) Johnson & Johnson closing stock price on the New York Stock Exchange as of acquisition date of $65.45 per share.

The Company is still finalizing the allocation of the purchase price to the individual assets acquired and liabilities assumed. The allocation of the purchase price included in the current period balance sheet is based on the best estimate of management. To assist management in the allocation, the Company engaged valuation specialists to prepare independent appraisals. Certain estimated values surrounding litigation loss contingencies are not yet finalized and are subject to change. We will finalize the amounts recognized as we obtain the information necessary to complete the analysis. We expect to finalize these amounts as soon as possible but no later than one year from the acquisition date.

The following table presents the amounts recognized for assets acquired and liabilities assumed as of the acquisition date, as well as the adjustments made up to December 30, 2012:

(Dollars in Millions)		June 14, 2012	December 30, 2012
Cash & Cash equivalents	$	2,749	2,749
Inventory		889	1,194
Accounts Receivable, net		738	738
Other current assets		249	238
Property, plant and equipment		1,253	1,253
Goodwill		5,371	6,011
Intangible assets		12,929	12,861
Other non-current assets		46	46
Total Assets Acquired		**24,224**	**25,090**
Current liabilities		825	1,053
Deferred Taxes		2,731	3,471
Other non-current liabilities		431	329
Total Liabilities Assumed		**3,987**	**4,853**
Net Assets Acquired	**$**	**20,237**	**20,237**

The adjustments made since the date of acquisition were to account for changes to inventory, based on the results of the physical inventory counts and deferred taxes, to reflect the statutory tax rate that is being applied to the intangible assets. The revisions to the purchase price allocation were not material to the Statements of Consolidated Earnings for the prior fiscal quarters of 2012.

The assets acquired are recorded in the Medical Devices and Diagnostics segment. The acquisition of Synthes, Inc. resulted in $6.0 billion of goodwill. The goodwill is primarily attributable to synergies expected to arise from the acquisition of Synthes, Inc. The goodwill is not expected to be deductible for tax purposes.

The purchase price allocation to the identifiable intangible assets included in the June 14, 2012 and December 30, 2012 balance sheets were as follows:

(Dollars in Millions)		June 14, 2012	December 30, 2012
Intangible assets with definite lives:			
Customer relationships	$	9,950	9,870
Patents and technology		1,495	1,508
Total amortizable intangibles		11,445	11,378
Trademark and Trade name		1,420	1,420
In-process research and development		64	63
Total intangible assets	**$**	**12,929**	**12,861**

The weighted average life for the $11.4 billion of total amortizable intangibles is approximately 21 years.

The trade name asset values were determined to have an indefinite life based on a number of factors, including trade name history, the competitive environment, market share and future operating plans. The intangible assets with definite lives were assigned asset lives ranging from 7 to 22 years.

The majority of the intangible asset valuation relates to customer relationships, patents and technology and trade name intangible assets in the Company's trauma, cranio maxillofacial, spine and power tools business lines. Additionally, in-process research and development intangible assets were valued for technology programs for unapproved products.

The value of the IPR&D was calculated using cash flow projections discounted for the risk inherent in such projects. The discount rate applied was 14%.

The Company is in the process of executing the integration plans to combine businesses, sales organizations, systems and locations as a result of which the Company has and will continue to incur integration costs.

The operating results of Synthes were reported in the Company's financial statements beginning on June 14, 2012. Total sales and net earnings for Synthes for the fiscal year ended December 30, 2012 were $2,159 million and $324 million, respectively.

The following table provides pro forma results of operations for the fiscal year ended December 30, 2012 and January 1, 2012, as if Synthes, Inc. had been acquired as of January 3, 2011. The pro forma results include the effect of divestitures and certain purchase accounting adjustments such as the estimated changes in depreciation and amortization expense on the acquired tangible and intangible assets. However, pro forma results do not include any anticipated cost savings or other effects of the integration of Synthes, Inc. Accordingly, such amounts are not necessarily indicative of the results if the acquisition had occurred on the dates indicated or which may occur in the future.

		Unaudited Pro forma consolidated results	
(Dollars in Millions Except Per Share Amounts)		2012	2011
Net Sales	$	68,894	68,741
Net Earnings attributable to Johnson & Johnson	$	11,564	9,427
Diluted Net Earnings per share attributable to Johnson & Johnson	$	4.11	3.40

In 2012, the Company recorded acquisition related costs of $1,028 million before tax, which were recorded in Cost of products sold and Other (income) expense.

In connection with the Synthes acquisition, DePuy Orthopaedics, Inc. agreed to divest certain rights and assets related to its trauma business to Biomet, Inc. and completed the initial closing for this transaction in the fiscal second quarter of 2012, including those countries that represented the majority of sales. As of December 30, 2012, the transaction had closed worldwide.

Certain businesses were acquired for $2,797 million in cash and $228 million of liabilities assumed during 2011. These acquisitions were accounted for by the purchase method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2011 acquisitions included: Crucell N.V., a global biopharmaceutical company focused on the research & development, production and marketing of vaccines and antibodies against infectious disease worldwide; the over-the-counter brands of J.B. Chemicals & Pharmaceuticals Limited, including RINZA®, Russia's leading multi-symptom cough and cold brand, and DOKTOR MOM®, Russia's number two selling cough brand, as well as several other brands; full ownership of the Johnson & Johnson-Merck Consumer Pharmaceuticals Co. joint venture in the U.S. from Merck Sharp & Dohme Corp; and SterilMed, Inc., a leader in the reprocessing and re-manufacturing of medical devices in the U.S.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $2,657 million and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately $982 million has been identified as the value of IPR&D associated with the acquisition of Crucell N.V.

The IPR&D related to the acquisition of Crucell N.V. of $982 million is associated with vaccines and antibodies that prevent and/or treat infectious diseases. The value of the IPR&D was calculated using cash flow projections discounted for the risk inherent in such projects. Probability of success factors ranging from 14-81% were used to reflect inherent clinical and regulatory risk. The discount rate applied was 16%. During the fiscal second quarter of 2012, the Company recorded a charge of $0.5 billion for the intangible asset write-down and $0.4 billion for the impairment of the in-process research and development related to the Crucell business.

Certain businesses were acquired for $1,269 million in cash and $52 million of liabilities assumed during 2010. These acquisitions were accounted for by the purchase method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2010 acquisitions included: Acclarent, Inc., a privately held medical technology company dedicated to designing, developing and commercializing devices that address conditions affecting the ear, nose and throat (ENT); RespiVert Ltd., a privately held drug discovery company focused on developing small-molecule, inhaled therapies for the treatment of pulmonary diseases; and Micrus Endovascular LLC, a global developer and manufacturer of minimally invasive devices for hemorrhagic and ischemic stroke.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $1,185 million and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately $213 million has been identified as the value of IPR&D associated with the acquisitions of Acclarent, Inc., RespiVert Ltd. and

Micrus Endovascular LLC.

The IPR&D related to the acquisition of Acclarent, Inc. was $75 million and is associated with novel, endoscopic, catheter-based devices to meet the needs of ENT patients. The value of the IPR&D was calculated using cash flow projections discounted for the risk inherent in such projects. Probability of success factors ranging from 50-53% were used to reflect inherent clinical and regulatory risk. The discount rate applied was 16%.

The IPR&D related to the acquisition of RespiVert Ltd. was $100 million and is associated with narrow spectrum kinase inhibitors with a unique profile of anti-inflammatory activities as treatments for moderate to severe asthma, Chronic Obstructive Pulmonary Disease (COPD) and Cystic Fibrosis (CF). The value of the IPR&D was calculated using cash flow projections discounted for the risk inherent in such projects. Probability of success factors ranging from 10-12% were used to reflect inherent clinical and regulatory risk. The discount rate applied was 17%.

The IPR&D related to the acquisition of Micrus Endovascular LLC was $38 million and is associated with ischemic and flow diverter technologies. The value of the IPR&D was calculated using cash flow projections discounted for the risk inherent in such projects. Probability of success factors ranging from 50-75% were used to reflect inherent clinical and regulatory risk. The discount rate applied was 14%.

With the exception of the Synthes, Inc. acquisition, supplemental pro forma information for 2012, 2011 and 2010 in accordance with U.S. GAAP standards related to business combinations, and goodwill and other intangible assets, is not provided, as the impact of the aforementioned acquisitions did not have a material effect on the Company's results of operations, cash flows or financial position.

During 2012, the Company divestitures included: BYSTOLIC® (nebivolol) IP rights to Forest Laboratories, Inc.; the trauma business of Depuy Orthopaedics, Inc. to Biomet Inc.; the Therakos business to an affiliate of Gores Capital Partners III, L.P.; the sale of certain consumer brands and the RhoGAM® business. In 2012, the gains on the divestitures of businesses were $0.9 billion. During 2011, the Company divestitures included, the Animal Health Business to Elanco, a Division of Eli Lilly, MONISTAT® in Canada, the U.S. and its territories (including Puerto Rico), assets of the Ortho Dermatologics division in the U.S. to subsidiaries of Valeant Pharmaceuticals International, Inc. and the Surgical Instruments Business of Codman & Shurtleff, Inc. In 2011, the gains on the divestitures of businesses were $1.0 billion. During 2010, the Company divestitures included the Breast Care Business of Ethicon Endo-Surgery Inc. The gains on these divestitures were recognized in Other (income)/expense, net.

21. Legal Proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability, intellectual property, commercial and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of their business.

The Company records accruals for such contingencies when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of December 30, 2012, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals for new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters currently disclosed for which a loss is probable or reasonably possible, the Company is unable to determine an estimate of the possible loss or range of loss beyond the amounts already accrued. These matters can be affected by various factors, including whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; or there are numerous parties involved.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution in any reporting period of one or more of these matters, either alone or in the aggregate, may have a material adverse effect on the Company's results of operations and cash flows for that period.

PRODUCT LIABILITY

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability cases. The damages claimed are substantial, and while these subsidiaries are confident of the adequacy of the warnings and instructions for use that accompany the products at issue, it is not feasible to predict the ultimate outcome of litigation. The Company has established product liability accruals in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. Changes to the accruals may be required in the future as additional information becomes available.

Multiple products of Johnson & Johnson subsidiaries are subject to product liability claims and lawsuits in which claimants seek substantial compensatory and, where available, punitive damages, including LEVAQUIN®, the ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, the PINNACLE® Acetabular Cup System, RISPERDAL®,

pelvic meshes, DURAGESIC®/fentanyl patches and TOPAMAX®. As of December 30, 2012, in the U.S. there were approximately 2,100 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to LEVAQUIN®, 10,750 with respect to the ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, 3,300 with respect to the PINNACLE® Acetabular Cup System, 425 with respect to RISPERDAL®, 4,000 with respect to pelvic meshes, 30 with respect to DURAGESIC®/fentanyl patches and 75 with respect to TOPAMAX®.

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System used in hip replacement surgery. Claims for personal injury have been made against DePuy and Johnson & Johnson, and the number of pending lawsuits continues to increase. Cases filed in Federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada and Australia. The Company continues to receive information with respect to potential costs associated with this recall. During the fiscal third and fourth quarters of 2012, the Company increased its accruals for the DePuy ASR™ Hip recall program and related product liability after the Company completed an analysis of new information, including the number of expected claims, recently updated revision rates of the recalled products and product liability expense per case. Changes to these accruals may be required in the future as additional information becomes available.

Claims for personal injury have also been made against DePuy and Johnson & Johnson relating to DePuy's PINNACLE® Acetabular Cup System. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in Federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Texas. The Company has established a product liability accrual in anticipation of product liability litigation associated with DePuy's PINNACLE® Acetabular Cup System. Changes to this accrual may be required in the future as additional information becomes available.

Claims for personal injury have been made against Ethicon, Inc. (Ethicon) and Johnson & Johnson arising out of Ethicon's pelvic mesh devices used to treat stress urinary incontinence and pelvic organ prolapse. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in Federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Southern District of West Virginia. In addition, a class action and several individual personal injury cases have been commenced in Canada and Australia seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices. The Company has established a product liability accrual in anticipation of product liability litigation associated with Ethicon's pelvic mesh products. Changes to this accrual may be required in the future as additional information becomes available.

The Company believes that the ultimate resolution of these matters based on historical and reasonably likely future trends is not expected to have a material adverse effect on the Company's financial position, annual results of operations and cash flows. The resolution in any interim reporting period could have a material impact on the Company's results of operations and cash flows for that period.

INTELLECTUAL PROPERTY

Certain subsidiaries of Johnson & Johnson are subject, from time to time, to legal proceedings and claims related to patent, trademark and other intellectual property matters arising out of their business. The most significant of these matters are described below.

PATENT INFRINGEMENT

Certain subsidiaries of Johnson & Johnson are involved in lawsuits challenging the coverage and/or validity of the patents on their products. Although these subsidiaries believe that they have substantial defenses to these challenges with respect to all material patents, there can be no assurance as to the outcome of these matters, and a loss in any of these cases could potentially adversely affect the ability of these subsidiaries to sell their products, or require the payment of past damages and future royalties.

Medical Devices and Diagnostics

In October 2004, Tyco Healthcare Group, LP (Tyco) and U.S. Surgical Corporation filed a lawsuit against Ethicon Endo-Surgery, Inc. (EES) in the United States District Court for the District of Connecticut alleging that several features of EES's HARMONIC® Scalpel infringed four Tyco patents. In October 2007, on motions for summary judgment prior to the initial trial, a number of claims were found invalid and a number were found infringed. However, no claim was found both valid and infringed. Trial commenced in December 2007, and the Court dismissed the case without prejudice on grounds that Tyco did not own the patents in suit. The dismissal without prejudice was affirmed on appeal. In January 2010, Tyco filed another complaint in the United States District Court for the District of Connecticut asserting infringement of three of the four patents

from the previous lawsuit and adding new products. Tyco is seeking monetary damages and injunctive relief. The case was tried in July 2012, and the parties are awaiting a decision from the Court.

In October 2007, Bruce Saffran (Saffran) filed a patent infringement lawsuit against Johnson & Johnson and Cordis Corporation (Cordis) in the United States District Court for the Eastern District of Texas alleging infringement on U.S. Patent No. 5,653,760. In January 2011, a jury returned a verdict finding that Cordis's sales of its CYPHER® Stent willfully infringed the '760 patent. The jury awarded Saffran $482 million. In March 2011, the Court entered judgment against Cordis in the amount of $593 million, representing the jury verdict, plus $111 million in pre-judgment interest. Cordis has appealed the judgment. Oral argument was heard in December 2012, and a decision from the Court of Appeals is pending. Because the Company believes that the potential for an unfavorable outcome is not probable, it has not established an accrual with respect to the case.

In November 2007, Roche Diagnostics Operations, Inc., et al. (Roche) filed a patent infringement lawsuit against LifeScan, Inc. (LifeScan) in the United States District Court for the District of Delaware, accusing LifeScan's entire OneTouch® line of blood glucose monitoring systems of infringement of two patents related to the use of microelectrode sensors. In September 2009, LifeScan obtained a favorable ruling on claim construction that precluded a finding of infringement. The Court entered judgment against Roche in July 2010 and Roche appealed. The Court of Appeals reversed the District Court's ruling on claim construction and remanded the case to the District Court for new findings on the issue. The parties are awaiting a ruling on claim construction. Roche is seeking monetary damages and injunctive relief.

In June 2009, Rembrandt Vision Technologies, L.P. (Rembrandt) filed a patent infringement lawsuit against Johnson & Johnson Vision Care, Inc. (JJVC) in the United States District Court for the Eastern District of Texas alleging that JJVC's manufacture and sale of its ACUVUE®ADVANCE® and ACUVUE® OASYS® Hydrogel Contact Lenses infringe their U.S. Patent No. 5,712,327 (the Chang patent). Rembrandt is seeking monetary relief. The case was transferred to the United States District Court for the Middle District of Florida. In May 2012, the jury returned a verdict holding that neither of the accused lenses infringe the '327 patent. Rembrandt has filed an appeal with the United States Court of Appeals for the Federal Circuit.

In November 2011, Howmedica Osteonics Corp. (Howmedica) and Stryker Ireland Ltd. (Stryker) filed a patent infringement lawsuit against DePuy Orthopaedics, Inc. (DePuy) in the United States District Court for the District of New Jersey alleging infringement by DePuy's PINNACLE® Acetabular Cup System and DURALOC® Acetabular Cup System of a patent relating to a dual-locking mechanism feature in an acetabular cup system. Howmedica and Stryker are seeking monetary damages and injunctive relief. DePuy filed its answer in February 2012 and filed a counterclaim asserting that Stryker's Trident Acetabular Hip System infringes DePuy's U.S. Patent No. 6,610,097. DePuy is seeking damages and injunctive relief from Howmedica and Stryker.

In May 2012, Medtronic Minimed, Inc., Medtronic Puerto Rico Operations Co. and MiniMed Distribution Corp. (collectively, Medtronic Minimed) filed a patent infringement lawsuit against Animas Corporation in the United States District Court for the Central District of California alleging that Animas' OneTouch® Ping® Glucose Management System infringes nine of their patents. Medtronic Minimed is seeking monetary damages and injunctive relief.

In June 2012, DePuy Orthopaedics, Inc. (DePuy) filed a declaratory judgment action against Orthopaedic Hospital (OH) in the United States District Court for the Northern District of Indiana seeking a declaration of the parties' rights and obligations under a Patent Rights and License Agreement between the parties related to development of a polyethylene material. OH has claimed that DePuy owes royalties on products made with anti-oxidant polyethylene. DePuy disputes that it owes such royalties to OH and is thus seeking a declaration from the Court on disputed contractual provisions. After DePuy filed the declaratory judgment action, OH filed a separate suit on the same subject matter in the United States District Court for the Central District of California, and moved for consolidation with the California case.

Pharmaceutical

In May 2009, Abbott Biotechnology Ltd. (Abbott) filed a patent infringement lawsuit against Centocor, Inc. (Centocor) (now Janssen Biotech, Inc. (JBI)) in the United States District Court for the District of Massachusetts alleging that SIMPONI® infringes Abbott's U.S. Patent Nos. 7,223,394 and 7,541,031 (the Salfeld patents). Abbott is seeking monetary damages and injunctive relief. In April 2012, the parties participated in an arbitration on the issue of JBI's defense that Abbott is equitably estopped from asserting the patents. In May 2012, the arbitrator rejected JBI's defense. The case has been reinstated in the District Court and fact discovery is ongoing.

In August 2009, Abbott GmbH & Co. (Abbott GmbH) and Abbott Bioresearch Center filed a patent infringement lawsuit against Centocor (now JBI) in the United States District Court for the District of Massachusetts alleging that STELARA® infringes two United States patents assigned to Abbott GmbH. JBI filed a complaint in the United States District Court for the District of Columbia for a declaratory judgment of non-infringement and invalidity of the Abbott GmbH patents, as well as a Complaint for Review of a Patent Interference Decision that granted priority of invention on one of the two asserted patents to Abbott GmbH. The cases have been transferred from the District of Columbia to the District of Massachusetts. Trial was held in September 2012 with a jury verdict in favor of Centocor, invalidating Abbott's patent claims. Post-trial briefing has been completed and the parties are awaiting a decision. Also in August 2009, Abbott GmbH and Abbott Laboratories Limited brought a patent infringement lawsuit in The Federal Court of Canada alleging that STELARA® infringes Abbott GmbH's

Canadian patent. A trial is scheduled for December 2013 in the Canadian Case. In addition to the U.S. and Canadian litigations, in August 2012, Abbott filed patent infringement lawsuits in the Netherlands, Switzerland and Germany. In each of the above cases, Abbott is seeking monetary damages and injunctive relief.

LITIGATION AGAINST FILERS OF ABBREVIATED NEW DRUG APPLICATIONS (ANDAs)

The following summarizes lawsuits pending against generic companies that filed Abbreviated New Drug Applications (ANDAs) seeking to market generic forms of products sold by various subsidiaries of Johnson & Johnson prior to expiration of the applicable patents covering those products. These ANDAs typically include allegations of non-infringement, invalidity and unenforceability of these patents. In the event the subsidiaries are not successful in these actions, or the statutory 30-month stays expire before the United States District Court rulings are obtained, the third-party companies involved will have the ability, upon approval of the United States Food and Drug Administration (FDA), to introduce generic versions of the products at issue, resulting in very substantial market share and revenue losses for those products.

CONCERTA®

A number of generic companies have filed ANDAs seeking approval to market generic versions of CONCERTA®. In September 2011, a settlement agreement was entered into with Kremers-Urban, LLC and KUDCO Ireland, Ltd. (collectively, KUDCO) pursuant to which KUDCO was granted a license under the patent-in-suit to market its generic version of CONCERTA® starting on July 1, 2012, if and when KUDCO obtains FDA approval.

In November 2010, ALZA Corporation (ALZA) and Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI) (now Janssen Pharmaceuticals, Inc. (JPI)) filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Impax Laboratories, Inc. (Impax), Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd. (collectively, Teva) in response to Impax and Teva's filing of a major amendment to its ANDA seeking approval to market a generic version of CONCERTA® before the expiration of ALZA and JPI's patent relating to CONCERTA®. Impax and Teva filed counterclaims alleging non-infringement and invalidity. In May 2011, ALZA and JPI filed a second lawsuit against Teva in response to Teva's filing of a second major amendment to its ANDA seeking approval to market additional dosage strengths of its generic CONCERTA® product before the expiration of ALZA and JPI's patent relating to CONCERTA®. In each of the above cases, ALZA and JPI sought an Order enjoining the defendants from marketing its generic version of CONCERTA® prior to the expiration of ALZA and JPI's CONCERTA® patent. In September 2012, a settlement agreement was entered into with Impax and Teva pursuant to which those parties were granted a license under the patent-in-suit to market their generic version of CONCERTA® starting July 14, 2013 (or earlier under certain circumstances), if and when they obtain FDA approval.

ORTHO TRI-CYCLEN® LO

A number of generic companies have filed ANDAs seeking approval to market generic versions of ORTHO TRI-CYCLEN® LO. In February 2012, JPI and Watson Laboratories, Inc. and Watson Pharmaceuticals, Inc. (collectively, Watson) entered into a settlement agreement. Pursuant to the settlement agreement, the parties entered into a supply agreement whereby JPI will supply to Watson a combinational oral contraceptive containing certain specified compounds from December 31, 2015 (or earlier under certain circumstances) through the expiration of the '815 patent on December 6, 2019. In addition, in the event Watson does not wish to exercise its rights under the supply agreement, JPI has granted Watson a license to market Watson's ANDA product from December 31, 2015 (or earlier under certain circumstances) through December 6, 2019.

In January 2010, OMJPI (now JPI) filed a patent infringement lawsuit against Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, Lupin) in the United States District Court for the District of New Jersey in response to Lupin's ANDA seeking approval to market a generic version of ORTHO TRI-CYCLEN® LO prior to the expiration of JPI's patent relating to ORTHO TRI-CYCLEN® LO (the OTCLO patent). Lupin filed a counterclaim alleging invalidity of the patent. Trial concluded in June 2012, and in September 2012, the Court issued a decision in favor of JPI. In particular, the Court ordered that the effective date of the approval of Lupin's ANDA (which had previously been approved) be not earlier than the expiration of the OTCLO patent. Lupin has appealed the decision to the Court of Appeals for the Federal Circuit. Oral argument was heard in February 2013, and the Court's decision is pending.

In November 2010, OMJPI (now JPI) filed a patent infringement lawsuit against Mylan Inc. and Mylan Pharmaceuticals, Inc. (collectively, Mylan), and Famy Care, Ltd. (Famy Care) in the United States District Court for the District of New Jersey in response to Famy Care's ANDA seeking approval to market a generic version of ORTHO TRI-CYCLEN® LO prior to the expiration of the OTCLO patent. Mylan and Famy Care filed counterclaims alleging invalidity of the patent. In November 2012, JPI and Mylan entered into a settlement agreement pursuant to which Mylan was granted a license under the OTCLO patent to market its generic version of ORTHO TRI-CYCLEN® LO starting December 31, 2015 (or earlier under certain circumstances), if and when they obtain FDA approval.

In October 2011, JPI filed a patent infringement lawsuit against Sun Pharma Global FZE and Sun Pharmaceutical Industries (collectively, Sun) in the United States District Court for the District of New Jersey in response to Sun's ANDA

seeking approval to market a generic version of ORTHO TRI-CYCLEN® LO prior to the expiration of the OTCLO patent.

In May 2012, JPI filed a patent infringement lawsuit against Haupt Pharma, Inc., Ranbaxy Laboratories Limited and Ranbaxy Inc. (collectively, Haupt) in the United States District Court for the District of New Jersey in response to Haupt's ANDA seeking approval to market a generic version of ORTHO TRI-CYCLEN® LO prior to the expiration of the OTCLO patent. In December 2012, JPI and Haupt entered into a settlement agreement pursuant to which Haupt was granted a license under the OTCLO patent to market its generic version of ORTHO TRI-CYCLEN® LO starting December 31, 2015 (or earlier under certain circumstances), if and when they obtain FDA approval.

In August 2012, JPI filed a patent infringement lawsuit against Glenmark Generics Ltd. and Glenmark Generics Inc., USA (collectively, Glenmark) in the United States District Court for the District of New Jersey in response to Glenmark's ANDA seeking approval to market a generic version of ORTHO TRI-CYCLEN® LO prior to the expiration of the OTCLO patent. In November 2012, a settlement agreement was entered into with Glenmark pursuant to which Glenmark was granted a license under the OTCLO patent to market its generic version of ORTHO TRI-CYCLEN® LO starting December 31, 2015 (or earlier under certain circumstances), if and when they obtain FDA approval.

In each of the above cases, JPI sought or is seeking an Order enjoining the defendants from marketing their generic versions of ORTHO TRI-CYLCEN® LO before the expiration of the OTCLO patent.

PREZISTA®

A number of generic companies have filed ANDAs seeking approval to market generic versions of PREZISTA®. In November 2010, Tibotec, Inc. (now Tibotec, LLC) and Tibotec Pharmaceuticals (now Janssen R&D Ireland) (collectively, Tibotec) filed a patent infringement lawsuit against Lupin, Ltd., Lupin Pharmaceuticals, Inc. (collectively, Lupin), Mylan, Inc. and Mylan Pharmaceuticals, Inc. (collectively, Mylan) in the United States District Court for the District of New Jersey in response to Lupin's and Mylan's respective ANDAs seeking approval to market generic versions of Tibotec's PREZISTA® product before the expiration of Tibotec's patent relating to PREZISTA®. Lupin and Mylan each filed counterclaims alleging non-infringement and invalidity. In July 2011, Tibotec filed another patent infringement lawsuit against Lupin in the United States District Court for the District of New Jersey in response to Lupin's supplement to its ANDA to add new dosage strengths for its proposed product. In August 2011, Tibotec and G.D. Searle & Company (G.D. Searle) filed a patent infringement lawsuit against Lupin and Mylan in response to their notice letters advising that their ANDAs are seeking approval to market generic versions of Tibotec's PREZISTA® product before the expiration of two patents relating to PREZISTA® that Tibotec exclusively licenses from G.D. Searle.

In March 2011, Tibotec and G.D. Searle filed a patent infringement lawsuit against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals, Ltd. (collectively, Teva) in the United States District Court for the District of New Jersey in response to Teva's ANDA seeking approval to market a generic version of PREZISTA® before the expiration of certain patents relating to PREZISTA® that Tibotec either owns or exclusively licenses from G.D. Searle.

In March 2011, Tibotec filed a patent infringement lawsuit against Hetero Drugs, Ltd. Unit III and Hetero USA Inc. (collectively, Hetero) in the United States District Court for the District of New Jersey in response to Hetero's ANDA seeking approval to market a generic version of PREZISTA® before the expiration of certain patents relating to PREZISTA® that Tibotec exclusively licenses from G.D. Searle. In July 2011, upon agreement by the parties, the Court entered a stay of the lawsuit pending a final decision in the lawsuit against Teva with respect to the validity and/or enforceability of the patents that Tibotec licenses from G.D. Searle, with Hetero agreeing to be bound by such final decision.

In September 2011, the Court consolidated the above lawsuits, as well as lawsuits brought by the United States Government against each of the defendants for infringement of a United States Government-owned patent relating to PREZISTA®, for purposes of pre-trial discovery and trial, with the proviso that after discovery is completed, any party can move to have the cases de-consolidated for trial.

In May and June 2012, Janssen Products, LP and Janssen R&D Ireland (collectively, Janssen) and G.D. Searle filed a patent infringement lawsuit against Lupin, Teva and Mylan in the United States District Court for the District of New Jersey, alleging infringement of newly issued United States Reissue Patent No. Re42,889, which Janssen exclusively licenses from G.D. Searle. In August 2012, Janssen and G.D. Searle filed a patent infringement lawsuit against Lupin, Teva and Mylan in the United States District Court for the District of New Jersey, alleging infringement of newly issued United States Reissue Patent No. Re43,596, which Janssen exclusively licenses from G.D. Searle. These cases have been consolidated with the above lawsuits. In October 2012, Janssen filed a motion to file a Supplemental Complaint against Lupin, Teva and Mylan in the United States District Court for the District of New Jersey, alleging infringement of United States Patent Nos. 7,772,411 (Mylan only), 7,126,015 (Lupin and Teva only) and 7,595,408 (Lupin and Teva only). In January 2013, the Court permitted these three additional patents to be added to the consolidated action.

In each of the above lawsuits, Tibotec and Janssen are seeking an Order enjoining the defendants from marketing their generic versions of PREZISTA® before the expiration of the relevant patents.

OTHER INTELLECTUAL PROPERTY MATTERS

In September 2009, Centocor Ortho Biotech Products, L.P. (now Janssen Products, LP (JPLP)) intervened in an inventorship lawsuit filed by the University of Kansas Center for Research, Inc. (KUCR) against the United States of America (USA) in the United States District Court for the District of Kansas. KUCR alleges that two KUCR scientists should be added as inventors on two USA-owned patents relating to VELCADE®. The USA licensed the patents (and their foreign counterparts) to Millennium Pharmaceuticals, Inc. (MPI), who in turn sublicensed the patents (and their foreign counterparts) to JPLP for commercial marketing outside the United States. In July 2010, the parties reached a settlement agreement to resolve the disputes in this case and submitted the inventorship issue to arbitration, the outcome of which would determine whether pre-specified payments would be made to KUCR, but will not affect JPLP's right to market VELCADE®. The arbitration took place in December 2011 and a decision in favor of KUCR was issued in March 2012. As a result, JPLP will be required to make the aforementioned pre-specified payments to KUCR.

In December 2009, the State of Israel filed a lawsuit in the District Court in Tel Aviv Jaffa against Omrix Biopharmaceuticals, Inc. and various affiliates (Omrix). In the lawsuit, the State claims that an employee of a government-owned hospital was the inventor on several patents related to fibrin glue technology that the employee developed while he was a government employee. The State claims that he had no right to transfer any intellectual property to Omrix because it belongs to the State. The State is seeking damages plus royalties on QUIXIL™ and EVICEL™ products, or alternatively, transfer of the patents to the State.

In January 2011, Genentech, Inc. (Genentech) initiated an arbitration against UCB Celltech (Celltech) seeking damages for allegedly cooperating with Centocor, Inc. (now Janssen Biotech, Inc. (JBI)) to improperly terminate a prior agreement in which JBI was sublicensed under Genentech's Cabilly patents to sell REMICADE®. JBI has an indemnity agreement with Celltech, and Celltech asserted that JBI would be liable for any damages Celltech may be required to pay Genentech in that arbitration. Following an arbitration hearing in June 2012, the arbitrators issued a decision finding no liability for Celltech, and therefore, JBI is not liable for any potential indemnity claim. JBI has moved to recover its attorneys fees, costs and expenses.

In March 2012, Noramco, Inc. (Noramco) moved to intervene in three patent infringement lawsuits filed in the United States District Court for the Southern District of New York (SDNY) by Purdue Pharma L.P. and others (Purdue) against Noramco oxycodone customers, Impax Laboratories, Inc. (Impax), Teva Pharmaceuticals USA, Inc. (Teva) and Amneal Pharmaceuticals, LLC (Amneal). In February 2013, Noramco appeared on behalf of Noramco customers Watson Laboratories, Inc. - Florida and Andrx Labs, LLC (collectively, Watson/Andrx) in a similar lawsuit filed by Purdue in the SDNY. The lawsuits are in response to the defendants' respective ANDAs seeking approval to market generic extended release oxycodone products before the expiration of certain Purdue patents. Three of the asserted patents relate to oxycodone and processes for making oxycodone, and Noramco has agreed to defend the lawsuits on behalf of Impax, Teva, Amneal and Watson/Andrx. Although Noramco did not participate, in November 2012, a trial in a lawsuit brought by Purdue against another Noramco customer, Actavis Elizabeth, LLC (Actavis), took place. Because the active ingredient at issue in the Actavis lawsuit is the same as the active ingredient at issue in the above lawsuits, the District Court's decision in the Actavis case may affect those lawsuits. A decision from the District Court in the Actavis case is pending.

In August 2012, Dr. James M. Swanson (Swanson) filed a lawsuit against ALZA Corporation (ALZA) in the Northern District of California seeking to be added as an inventor on two ALZA-owned patents relating to CONCERTA®. Alternatively, Dr. Swanson has alleged that the patents-in-suit are invalid and/or unenforceable as a result of ALZA's alleged omission of Dr. Swanson as a named inventor on the patents. Dr. Swanson is seeking damages and an award of unjust enrichment. ALZA filed a motion to dismiss Swanson's claims and oral argument is scheduled for February 2013.

GOVERNMENT PROCEEDINGS

Like other companies in the pharmaceutical and medical devices and diagnostics industries, Johnson & Johnson and certain of its subsidiaries are subject to extensive regulation by national, state and local government agencies in the United States and other countries in which they operate. As a result, interaction with government agencies is ongoing. The most significant litigation brought by, and investigations conducted by, government agencies are listed below. It is possible that criminal charges and substantial fines and/or civil penalties or damages could result from government investigations or litigation.

AVERAGE WHOLESALE PRICE (AWP) LITIGATION

Johnson & Johnson and several of its pharmaceutical subsidiaries (the J&J AWP Defendants), along with numerous other pharmaceutical companies, are defendants in a series of lawsuits in state and federal courts involving allegations that the pricing and marketing of certain pharmaceutical products amounted to fraudulent and otherwise actionable conduct because, among other things, the companies allegedly reported an inflated Average Wholesale Price (AWP) for the drugs at issue. Payors alleged that they used those AWPs in calculating provider reimbursement levels. Many of these cases, both federal actions and state actions removed to federal court, were consolidated for pre-trial purposes in a Multi-District Litigation (MDL) in the

United States District Court for the District of Massachusetts.

The plaintiffs in these cases included three classes of private persons or entities that paid for any portion of the purchase of the drugs at issue based on AWP, and state government entities that made Medicaid payments for the drugs at issue based on AWP. In June 2007, after a trial on the merits, the MDL Court dismissed the claims of two of the plaintiff classes against the J&J AWP Defendants. In March 2011, the Court dismissed the claims of the third class against the J&J AWP Defendants without prejudice.

AWP cases brought by various Attorneys General have proceeded to trial against other manufacturers. Several state cases against certain subsidiaries of Johnson & Johnson have been settled, including Kentucky, which had been set for trial in January 2012 and Kansas which had been set for trial in March 2013. Louisiana and Mississippi are set for trial in October 2013, Illinois is set for trial in May 2014, and Alaska is set for trial in July 2014. Other state cases are likely to be set for trial in due course. In addition, an AWP case against the J&J AWP Defendants brought by the Commonwealth of Pennsylvania was tried in Commonwealth Court in October and November 2010. The Court found in the Commonwealth's favor with regard to certain of its claims under the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPL"), entered an injunction, and awarded $45 million in restitution and $6.5 million in civil penalties. The Court found in the J&J AWP Defendants' favor on the Commonwealth's claims of unjust enrichment, misrepresentation/fraud, civil conspiracy, and on certain of the Commonwealth's claims under the UTPL. The J&J AWP Defendants have appealed the Commonwealth Court's UTPL ruling to the Pennsylvania Supreme Court. The Company believes that the J&J AWP Defendants have strong arguments supporting their appeal. Because the Company believes that the potential for an unfavorable outcome is not probable, it has not established an accrual with respect to the verdict.

RISPERDAL®

In January 2004, Janssen Pharmaceutica Inc. (Janssen Pharmaceutica) (now Janssen Pharmaceuticals, Inc. (JPI)) received a subpoena from the Office of the Inspector General of the United States Office of Personnel Management seeking documents concerning sales and marketing of, any and all payments to physicians in connection with sales and marketing of, and clinical trials for, RISPERDAL® from 1997 to 2002. Documents subsequent to 2002 have also been requested by the Department of Justice. An additional subpoena seeking information about marketing of, and adverse reactions to, RISPERDAL® was received from the United States Attorney's Office for the Eastern District of Pennsylvania in November 2005. Numerous subpoenas seeking testimony from various witnesses before a grand jury were also received. JPI cooperated in responding to these requests for documents and witnesses. The United States Department of Justice and the United States Attorney's Office for the Eastern District of Pennsylvania (the Government) are continuing to actively pursue both criminal and civil actions. In February 2010, the Government served Civil Investigative Demands seeking additional information relating to sales and marketing of RISPERDAL® and sales and marketing of INVEGA®. The focus of these matters is the alleged promotion of RISPERDAL® and INVEGA® for off-label uses. The Government has notified JPI that there are also pending qui tam actions alleging off-label promotion of RISPERDAL®. The Government informed JPI that it will intervene in these qui tam actions and file a superseding complaint.

In 2011, discussions to resolve criminal penalties under the Food Drug and Cosmetic Act related to the promotion of RISPERDAL® resulted in an agreement in principle with the United States Attorney's Office for the Eastern District of Pennsylvania on key issues relevant to a disposition of criminal charges pursuant to a single misdemeanor violation of the Food Drug and Cosmetic Act, but certain issues remain open before a settlement can be finalized. During 2011, the Company accrued amounts to cover the financial component of the proposed criminal settlement.

In 2012, the Company also reached an agreement in principle with the United States Department of Justice to settle three pending civil False Claims Act matters that are pending in (1) the Eastern District of Pennsylvania concerning sales and marketing of RISPERDAL® and INVEGA®; (2) the Northern District of California regarding the sales and marketing of NATRECOR®, discussed separately below; and (3) the District of Massachusetts alleging that the defendants provided the Omnicare, Inc. (Omnicare) long-term care pharmacy with rebates and other payments regarding RISPERDAL® and other products, discussed separately below. Assuming these agreements are finalized, they will resolve the federal government's claims under the federal False Claims Act, resolve all pending state and federal government litigation regarding Omnicare and NATRECOR®, and settle the RISPERDAL® Medicaid-related claims for those states that opt into the settlement. With the tentative settlement agreements described above, issues remain open that must be resolved before the settlements can be finalized.

The Company has accrued amounts, including an additional accrual made in the second quarter of 2012, to cover these tentative settlement agreements. However, the settlements will not resolve all pending state litigation matters regarding RISPERDAL®, and some states may elect to opt out of the settlements. To the extent any state has a claim and has or will elect to opt out of these settlements, the Company has accrued an amount equal to what that state would receive if it was participating in the settlements. Among other states, Arkansas, Louisiana and South Carolina are not expected to participate in the settlements (as discussed below). Because the Company believes there are strong arguments on appeal in those cases, the Company has only accrued an amount equal to what these states would receive if they participated in the settlements.

In addition, the Attorneys General of multiple states, including Alaska, Arkansas, Louisiana, Massachusetts, Mississippi,

Montana, New Mexico, South Carolina, and Utah, have pending actions against Janssen Pharmaceutica (now JPI) seeking one or more of the following remedies: reimbursement of Medicaid or other public funds for RISPERDAL® prescriptions written for off-label use, compensation for treating their citizens for alleged adverse reactions to RISPERDAL®, civil fines or penalties, damages for "overpayments" by the state and others, violations of state consumer fraud statutes, punitive damages, or other relief relating to alleged unfair business practices. Certain of these actions also seek injunctive relief relating to the promotion of RISPERDAL®. In January 2012, JPI settled a lawsuit filed by the Attorney General of Texas. In April 2012, in the lawsuit brought by the Attorney General of Arkansas, the jury found against both JPI and Johnson & Johnson, and the Court imposed penalties in the amount of approximately $1.2 billion. JPI and Johnson & Johnson have filed an appeal and believe that they have strong arguments supporting the appeal. In January 2013, the same court awarded attorney fees of approximately $180 million. This judgment will also be appealed.

The Attorney General of West Virginia commenced suit in 2004 against Janssen Pharmaceutica (now JPI) based on claims of alleged consumer fraud as to DURAGESIC®, as well as RISPERDAL®. JPI was found liable and damages were assessed at $4.5 million. JPI filed an appeal, and in November 2010, the West Virginia Supreme Court reversed the trial court's decision. In December 2010, the Attorney General of West Virginia dismissed the case as it related to RISPERDAL® without any payment. Thereafter, JPI settled the case insofar as it related to DURAGESIC®.

In 2004, the Attorney General of Louisiana filed a multi-count Complaint against Janssen Pharmaceutica (now JPI). Johnson & Johnson was later added as a defendant. The case was tried in October 2010. The issue tried to the jury was whether Johnson & Johnson or JPI had violated the State's Medicaid Fraud Act (the Act) through misrepresentations allegedly made in the mailing of a November 2003 Dear Health Care Professional letter regarding RISPERDAL®. The jury returned a verdict that JPI and Johnson & Johnson had violated the Act and awarded $257.7 million in damages. The trial judge subsequently awarded the Attorney General counsel fees and expenses in the amount of $73 million. In August 2012, an interlocutory appellate court affirmed the judgment. In January 2013, the Louisiana Supreme Court accepted Johnson & Johnson and JPI's request for appeal. Oral argument on the appeal has been set for March 2013.

In 2007, the Office of General Counsel of the Commonwealth of Pennsylvania filed a lawsuit against Janssen Pharmaceutica (now JPI) on a multi-Count Complaint related to Janssen Pharmaceutica's sale of RISPERDAL® to the Commonwealth's Medicaid program. The trial occurred in June 2010. The trial judge dismissed the case after the close of the plaintiff's evidence. The Commonwealth filed an appeal in April 2011, and in July 2012, the Pennsylvania Appeals Court upheld the dismissal of the Commonwealth's case.

In 2007, the Attorney General of South Carolina filed a lawsuit against Johnson & Johnson and Janssen Pharmaceutica (now JPI) on several counts. In March 2011, the matter was tried on liability only, at which time the lawsuit was limited to claims of violation of the South Carolina Unfair Trade Practice Act, including, among others, questions of whether Johnson & Johnson or JPI engaged in unfair or deceptive acts or practices in the conduct of any trade or commerce by distributing the November 2003 Dear Health Care Professional letter regarding RISPERDAL® or in their use of the product's FDA-approved label. The jury found in favor of Johnson & Johnson and against JPI. In June 2011, the Court awarded civil penalties of approximately $327.1 million. JPI has appealed this judgment and the Company believes it has strong arguments supporting the appeal. Oral argument on the appeal has been set before the South Carolina Supreme Court for March 2013.

The Attorneys General of approximately 40 other states and the District of Columbia indicated an interest in pursuing similar litigation against JPI, and obtained a tolling agreement staying the running of the statute of limitations while they pursued an investigation of JPI regarding potential consumer fraud actions in connection with the marketing of RISPERDAL®. In September 2012, JPI settled with 36 of the states and the District of Columbia non-Medicaid claims in connection with the sales and marketing of RISPERDAL® and INVEGA® for a total of approximately $181 million, an amount which had been previously accrued.

In the Company's opinion, the ultimate resolution of any of the above RISPERDAL® matters is not expected to have a material adverse effect on the Company's financial position, although the resolution in any reporting period could have a material impact on the Company's results of operations and cash flows for that period.

OMNICARE

In September 2005, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts, seeking documents related to the sales and marketing of eight drugs to Omnicare, Inc. (Omnicare), a manager of pharmaceutical benefits for long-term care facilities. In April 2009, Johnson & Johnson and certain of its pharmaceutical subsidiaries were served in two civil qui tam cases asserting claims under the Federal False Claims Act and related state law claims alleging that the defendants provided Omnicare with rebates and other alleged kickbacks, causing Omnicare to file false claims with Medicaid and other government programs. In January 2010, the government intervened in both of these cases, naming Johnson & Johnson, Ortho-McNeil-Janssen Pharmaceuticals, Inc. (now Janssen Pharmaceuticals, Inc. (JPI)), and Johnson & Johnson Health Care Systems Inc. as defendants. Subsequently, the Commonwealth of Massachusetts, Virginia, and Kentucky, and the States of California and Indiana intervened in the action. In February 2011, the United States District Court for the District of Massachusetts dismissed one qui tam case entirely and dismissed the other case in part, rejecting allegations that the defendants had violated their obligation to report its "best price" to health care program officials. The claims of the

United States and individual states remain pending. In June 2012, the parties were granted their joint motion to stay the case pending resolution of the potential settlement discussed in the RISPERDAL® section above.

In November 2005, a lawsuit was filed by Scott Bartz, a former employee, in the United States District Court for the Eastern District of Pennsylvania against Johnson & Johnson and certain of its pharmaceutical subsidiaries (the J&J Defendants), along with co-defendants McKesson Corporation (McKesson) and Omnicare, Inc. In February 2011, the plaintiff filed an amended complaint. Thereafter, on the J&J Defendants' motion, the case was transferred to the United States District Court for the District of Massachusetts, where it is currently pending. The amended complaint alleges a variety of causes of action under the Federal False Claims Act and corresponding state and local statutes, including that the J&J Defendants engaged in various improper transactions that were allegedly designed to report false prescription drug prices to the federal government in order to reduce the J&J Defendants' Medicaid rebate obligations. The complaint further alleges that the J&J Defendants improperly retaliated against the plaintiff for having raised these allegations internally. Bartz seeks multiple forms of relief, including damages and reinstatement to a position with the same seniority status. The J&J Defendants subsequently moved to dismiss the complaint in May 2011. In March 2012, the District Court dismissed Bartz's claims under the Federal False Claims Act, and declined to exercise supplemental jurisdiction over numerous related claims under state false claims act statutes. The District Court, however, denied the dismissal motion with regard to Bartz's claims that he was retaliated against in violation of the Federal False Claims Act and in violation of New Jersey's Conscientious Employee Protection Act. In February 2013, the parties entered into a settlement agreement to resolve all of Bartz's claims and filed a joint motion to dismiss the lawsuit, with prejudice; the District Court granted the motion to dismiss all claims.

MCNEIL CONSUMER HEALTHCARE

Starting in June 2010, McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. (McNeil Consumer Healthcare) and certain affiliates, including Johnson & Johnson (the Companies), received grand jury subpoenas from the United States Attorney's Office for the Eastern District of Pennsylvania requesting documents broadly relating to recalls of various products of McNeil Consumer Healthcare, and the FDA inspections of the Fort Washington, Pennsylvania and Lancaster, Pennsylvania manufacturing facilities, as well as certain documents relating to recalls of a small number of products of other subsidiaries. In addition, in February 2011, the government served McNEIL-PPC, Inc. (McNEIL-PPC) with a Civil Investigative Demand seeking records relevant to its investigation to determine if there was a violation of the Federal False Claims Act. The Companies are cooperating with the United States Attorney's Office in responding to these subpoenas.

The Companies have also received Civil Investigative Demands from multiple State Attorneys General Offices broadly relating to the McNeil recall issues. The Companies continue to cooperate with these inquiries. In January 2011, the Oregon Attorney General filed a civil complaint against Johnson & Johnson, McNEIL-PPC and McNeil Healthcare LLC in state court alleging civil violations of the Oregon Unlawful Trade Practices Act relating to an earlier recall of a McNeil OTC product. In November 2012, the state court granted a motion by the Companies to dismiss Oregon's complaint in its entirety, with prejudice. In December 2012, Oregon filed a Notice of Appeal in the Court of Appeals of the State of Oregon.

In March 2011, the United States filed a complaint for injunctive relief in the United States District Court for the Eastern District of Pennsylvania against McNEIL-PPC and two of its employees, alleging that McNEIL-PPC is in violation of FDA regulations regarding the manufacture of drugs at the facilities it operates in Lancaster, Pennsylvania, Fort Washington, Pennsylvania, and Las Piedras, Puerto Rico. On the same day, the parties filed a consent decree of permanent injunction resolving the claims set forth in the complaint. The Court approved and entered the consent decree on March 16, 2011.

The consent decree, which is subject to ongoing enforcement by the Court, requires McNEIL-PPC to take enhanced measures to remediate the three facilities. The Fort Washington facility, which was voluntarily shut down in April 2010, will remain shut down until a third-party consultant certifies that its operations will be in compliance with applicable law, and the FDA concurs with the third-party certification. The Lancaster and Las Piedras facilities may continue to manufacture and distribute drugs, provided that a third party reviews manufacturing records for selected batches of drugs released from the facilities, and certifies that any deviations reviewed do not adversely affect the quality of the selected batches. McNEIL-PPC submitted a workplan to the FDA for remediation of the Lancaster and Las Piedras facilities, and that plan was approved by the FDA in October 2012. Third-party batch record review may cease if the FDA has stated that the facilities appear to be in compliance with applicable law. Each facility is subject to a five-year audit period by a third party after the facility has been deemed by the FDA to be in apparent compliance with applicable law.

OTHER

In July 2005, Scios Inc. (Scios) received a subpoena from the United States Attorney's Office for the District of Massachusetts, seeking documents related to the sales and marketing of NATRECOR®. In August 2005, Scios was advised that the investigation would be handled by the United States Attorney's Office for the Northern District of California in San Francisco. In February 2009, two qui tam complaints were unsealed in the United States District Court for the Northern District of California, alleging, among other things, improper activities in the promotion of NATRECOR®. In June 2009, the United States government intervened in one of the qui tam actions, and filed a complaint against Scios and Johnson & Johnson seeking relief

under the Federal False Claims Act and asserting a claim of unjust enrichment. In October 2011, the criminal matter was resolved. The civil case has been stayed pending resolution of the potential settlement discussed in the RISPERDAL® section above.

In June 2008, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts relating to the marketing of biliary stents by Cordis Corporation (Cordis). In February 2012, the government informed Cordis that it was closing its investigation. In addition, in January 2010, a complaint was unsealed in the United States District Court for the Northern District of Texas, filed by Kevin Colquitt, seeking damages against Cordis and other parties for alleged violations of the Federal False Claims Act and several similar state laws in connection with the marketing of biliary stents. The United States Department of Justice and several states declined to intervene. In January 2013, the Court granted Cordis's motion to dismiss the claims against Cordis, with prejudice. Plaintiff has appealed.

In September 2011, Synthes, Inc. (Synthes) received a Civil Investigative Demand issued pursuant to the False Claims Act from the United States Attorney's Office for the Eastern District of Pennsylvania. The Demand sought information regarding allegations that fellowships had been offered to hospitals in exchange for agreements to purchase products. Synthes has produced documents and information in response to the Demand and is cooperating with the inquiry.

In October 2011, the European Commission (EC) announced that it opened an investigation concerning an agreement between Janssen-Cilag B.V. (Janssen-Cilag) and Sandoz B.V. relating to the supply of fentanyl patches in The Netherlands and whether the agreement infringes European competition law. In January 2013, the EC issued a Statement of Objections setting out facts regarding a potential violation of EU antitrust laws. Janssen-Cilag is preparing a response to the Statement of Objections.

In April 2012, Janssen Pharmaceuticals, Inc. (JPI) received a letter requesting certain documents from the United States Department of Justice relating to the marketing and promotion of DORIBAX®. JPI has provided documents and continues to cooperate with this government inquiry.

In May 2012, Acclarent, Inc. (Acclarent) received a subpoena from the United States Attorney's Office for the District of Massachusetts requesting documents broadly relating to the sales, marketing and promotion by Acclarent of RELIEVA STRATUS™ MicroFlow Spacer products. Acclarent is cooperating with the United States Attorney's Office in responding to the subpoena.

In August 2012, DePuy Orthopaedics, Inc., DePuy, Inc. (now DePuy Synthes, Inc. (DePuy Synthes)), and Johnson & Johnson Services, Inc. received an informal request from the United States Attorney's Office for the District of Massachusetts and the Civil Division of the United States Department of Justice for the production of materials relating to the ASR™ XL Hip device. The government has since made additional informal requests for the production of documents as to the device. The government is investigating whether any person or entity submitted or caused to be submitted false claims or false statements affecting federal health care programs in connection with the marketing and use of the ASR™ XL Hip device. DePuy Orthopaedics, Inc., DePuy Synthes, and Johnson & Johnson Services, Inc. have voluntarily produced documents in response to the government's informal requests and are fully cooperating with the government's civil investigation.

In October 2012, Johnson & Johnson was contacted by the California Attorney General's office regarding a multi-state Attorney General investigation of the marketing of surgical mesh products for hernia and urogynecological purposes by Johnson & Johnson subsidiaries. Johnson & Johnson and its subsidiaries have since entered into a tolling agreement with the 42 states participating in the multi-state investigation.

In December 2012, Therakos, Inc. (Therakos), formerly a subsidiary of Johnson & Johnson and part of the Ortho-Clinical Diagnostics, Inc. (OCD) franchise, received a letter from the civil division of the United States Attorney's Office for the Eastern District of Pennsylvania informing Therakos that the United States Attorney's Office was investigating the sales and marketing of UVADEX® (methoxsalen) and the UVAR XTS® System during the period 2000 to the present. The United States Attorney's Office requested that OCD and Johnson & Johnson preserve documents that could relate to the investigation. Therakos was subsequently acquired by an affiliate of Gores Capital Partners III, L.P. OCD and Johnson & Johnson retain certain liabilities that may result from the investigation for activity that occurred prior to the sale of Therakos, and have taken appropriate steps to retain potentially relevant documents and will cooperate with the United States Attorney's Office's investigation with respect to such activity.

In recent years, Johnson & Johnson has received numerous requests from a variety of United States Congressional Committees to produce information relevant to ongoing congressional inquiries. It is the policy of Johnson & Johnson to cooperate with these inquiries by producing the requested information.

GENERAL LITIGATION

Starting in July 2006, five lawsuits were filed in United States District Court for the District of New Jersey by various employers and employee benefit plans and funds seeking to recover amounts they paid for RISPERDAL® for plan participants. In general, Plaintiffs allege that Johnson & Johnson and certain of its pharmaceutical subsidiaries engaged in off-label marketing of RISPERDAL® in violation of the federal and New Jersey RICO statutes. In addition, Plaintiffs asserted various state law claims. All of the cases were consolidated into one case seeking class action status, but shortly thereafter, one action was voluntarily dismissed. In December 2008, the Court dismissed the actions of the four remaining plaintiffs. In April 2010,

those plaintiffs filed a new consolidated class action against Johnson & Johnson and Janssen, L.P. (now Janssen Pharmaceuticals, Inc.); and in March 2013 that action was dismissed. In April 2011, one of those plaintiffs filed a notice of appeal with the United States Court of Appeals for the Third Circuit. That appeal was dismissed in July 2011.

In April 2009, Ortho-Clinical Diagnostics, Inc. (OCD) received a grand jury subpoena from the United States Department of Justice, Antitrust Division, requesting documents and information for the period beginning September 1, 2000 through the present, pertaining to an investigation of alleged violations of the antitrust laws in the blood reagents industry. OCD complied with the subpoena. In February 2011, OCD received a letter from the Antitrust Division indicating that it had closed its investigation in November 2010. In June 2009, following the public announcement that OCD had received a grand jury subpoena, multiple class action complaints were filed against OCD by direct purchasers seeking damages for alleged price fixing. The various cases were consolidated for pre-trial purposes in the United States District Court for the Eastern District of Pennsylvania as *In re Blood Reagent Antitrust Litigation*. In August 2012, the District Court granted a motion filed by Plaintiffs for class certification. OCD requested interlocutory review of the class certification decision, and in October 2012, the Appellate Court granted OCD's petition for interlocutory review.

In April 2010, a putative class action lawsuit was filed in the United States District Court for the Northern District of California by representatives of nursing home residents or their estates against Johnson & Johnson, Omnicare, Inc. (Omnicare), and other unidentified companies or individuals. In February 2011, Plaintiffs filed a second amended complaint asserting that certain rebate agreements between Johnson & Johnson and Omnicare increased the amount of money spent on pharmaceuticals by the nursing home residents and violated the Sherman Act and the California Business & Professions Code. The second amended complaint also asserted a claim of unjust enrichment. Plaintiffs sought multiple forms of monetary and injunctive relief. Johnson & Johnson moved to dismiss the second amended complaint in March 2011. The Court granted the motion in its entirety in August 2011, dismissing all claims asserted by Plaintiffs. In October 2011, the Court dismissed the action with prejudice. The plaintiffs filed a notice of appeal to the United States Court of Appeals for the Ninth Circuit in November 2011. In February 2012, Plaintiffs stipulated to a voluntary dismissal of the matter, with prejudice. Pursuant to the terms of the stipulation, the Ninth Circuit dismissed the case in its entirety in March 2012.

Starting in May 2010, multiple complaints seeking class action certification related to the McNeil recalls have been filed against McNeil Consumer Healthcare and certain affiliates, including Johnson & Johnson, in the United States District Court for the Eastern District of Pennsylvania, the Northern District of Illinois, the Central District of California, the Southern District of Ohio and the Eastern District of Missouri. These consumer complaints allege generally that purchasers of various McNeil medicines are owed monetary damages and penalties because they paid premium prices for defective medications rather than less expensive alternative medications. All but one complaint seeks certification of a nation-wide class of purchasers of these medicines, whereas one complaint, the Harvey case, seeks certification of a class of MOTRIN® IB purchasers in Missouri. In October 2010, the Judicial Panel on Multidistrict Litigation consolidated all of the consumer complaints, except for the Harvey case, which was consolidated in March 2011, into one lawsuit: *In re: McNeil Consumer Healthcare, et al., Marketing and Sales Practices Litigation,* for pretrial proceedings in the United States District Court for the Eastern District of Pennsylvania. In January 2011, the plaintiffs in all of the cases except the Harvey case filed a Consolidated Amended Civil Consumer Class Action Complaint (CAC) naming additional parties and claims. In July 2011, the Court granted a motion by Johnson & Johnson to dismiss the CAC without prejudice, but permitted the plaintiffs to file an amended complaint within thirty days of the dismissal order. In August 2011, the plaintiffs filed a Second Amended Civil Consumer Class Action Complaint (SAC). In July 2012, the Court granted Johnson & Johnson's motion to dismiss the SAC with prejudice.

Separately, in September 2011, Johnson & Johnson, Johnson & Johnson Inc. and McNeil Consumer Healthcare Division of Johnson & Johnson Inc. received a Notice of Civil Claim filed by Nick Field in the Supreme Court of British Columbia, Canada (the BC Civil Claim). The BC Civil Claim is a putative class action brought on behalf of persons who reside in British Columbia and who purchased during the period between September 20, 2001 and the present one or more various McNeil infants' or children's over-the-counter medicines that were manufactured at the Fort Washington facility. The BC Civil Claim alleges that the defendants violated the BC Business Practices and Consumer Protection Act, and other Canadian statutes and common laws, by selling medicines that were allegedly not safe and/or effective or did not comply with Canadian Good Manufacturing Practices. The BC plaintiff served their affidavits in support of class certification in April 2012. The defendants responding affidavits were served in June 2012. The date for hearing of the certification application has not yet been scheduled.

In September 2010, a shareholder, Ronald Monk, filed a lawsuit in the United States District Court for the District of New Jersey seeking class certification and alleging that Johnson & Johnson and certain individuals, including executive officers and employees of Johnson & Johnson, failed to disclose that a number of manufacturing facilities failed to maintain current good manufacturing practices, and that as a result, the price of the Company's stock declined significantly. Plaintiff seeks to pursue remedies under the Securities Exchange Act of 1934 to recover his alleged economic losses. In December 2011, a motion by Johnson & Johnson to dismiss was granted in part and denied in part. Plaintiff moved the Court to reconsider part of the December 2011 ruling. Defendants filed answers to the remaining claims of the Amended Complaint in February 2012 and the case is proceeding to discovery. In May 2012, the Court denied Plaintiff's motion for reconsideration. In September 2012, Plaintiff filed a Second Amended Complaint and Johnson & Johnson has moved to dismiss Plaintiff's Second Amended Complaint in part.

In April 2011, OMJ Pharmaceuticals, Inc. (OMJ PR) filed a lawsuit against the United States in United States District

Court for the District of Puerto Rico alleging overpayment of federal income taxes for the tax years ended November 30, 1999 and November 30, 2000. OMJ PR alleges that the Internal Revenue Service erroneously calculated OMJ PR's tax credits under Section 936 of the Tax Code. OMJ PR filed a motion for summary judgment, and the United States filed a cross motion for summary judgment. In October 2012, the Court granted the United States' motion for summary judgment and denied OMJ PR's motion for summary judgment. OMJ PR appealed this decision. If OMJ PR loses this lawsuit, it may face liability for subsequent tax years.

In August 2011, an arbitration panel ruled that Mitsubishi Tanabe Pharma Corporation (Tanabe), Janssen Biotech, Inc.'s (JBI's) distributor of REMICADE® in Japan, could seek to modify the proportion of net sales revenue that Tanabe must remit to JBI in exchange for distribution rights and commercial supply of REMICADE® (the Supply Price). Tanabe commenced the arbitration against Centocor Ortho Biotech, Inc. (now JBI) in 2009 pursuant to the parties' distribution agreement, which grants Tanabe the right to distribute REMICADE® in Japan and certain other parts of Asia. JBI has counterclaimed for an increase in the Supply Price. A hearing was held in November 2011 to determine the appropriate split of revenue and the parties are awaiting a decision.

Johnson & Johnson or its subsidiaries are also parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the cost of past and/or future remediation.

SHAREHOLDER DERIVATIVE ACTIONS

Starting in April 2010, a number of shareholder derivative lawsuits were filed in the United States District Court for the District of New Jersey against certain current and former directors and officers of Johnson & Johnson. Johnson & Johnson is named as a nominal defendant. These actions were consolidated in August 2010 into one lawsuit: *In re Johnson & Johnson Derivative Litigation*. Additionally, in September 2010, another shareholder derivative lawsuit was filed by Michael Wolin in New Jersey Superior Court against certain current and former directors and officers of Johnson & Johnson. Johnson & Johnson is named as a nominal defendant in this action as well. The parties to this action have stipulated that it shall be stayed until the *In re Johnson & Johnson Derivative Litigation* is completely resolved.

These shareholder derivative actions are similar in their claims and collectively they assert a variety of alleged breaches of fiduciary duties, including, among other things, that the defendants allegedly engaged in, approved of, or failed to remedy or prevent defective medical devices, improper pharmaceutical rebates, improper off-label marketing of pharmaceutical and medical device products, violations of current good manufacturing practice regulations that resulted in product recalls, and that they failed to disclose the aforementioned alleged misconduct in the Company's filings under the Securities Exchange Act of 1934. Each complaint seeks a variety of relief, including monetary damages and corporate governance reforms. Johnson & Johnson moved to dismiss these actions on the grounds, *inter alia*, that the plaintiffs failed to make a demand upon the Board of Directors. In September 2011, *In re Johnson & Johnson Derivative Litigation* was dismissed without prejudice and with leave to file an amended complaint.

Johnson & Johnson filed a report in the *In re Johnson & Johnson Derivative Litigation* matter in July 2011, prepared by a Special Committee of the Board of Directors, which investigated the allegations contained in the derivative actions and in a number of shareholder demand letters that the Board received in 2010 raising similar issues. The Special Committee was assisted in its investigation by independent counsel. The Special Committee's report recommended: i) that Johnson & Johnson reject the shareholder demands and take whatever steps are necessary or appropriate to secure dismissal of the derivative litigation and ii) that the Board of Directors create a new Regulatory and Compliance Committee charged with responsibility for monitoring and oversight of the Company's Health Care Compliance and Quality & Compliance systems and issues. The Board of Directors of Johnson & Johnson unanimously adopted the Special Committee's recommendations, and in April 2012, the Board of Directors created the Regulatory, Compliance & Government Affairs Committee.

In August 2011, two shareholders who had submitted shareholder demand letters in 2010 filed shareholder derivative lawsuits in the United States District Court for the District of New Jersey naming various current and former officers and directors as defendants and challenging the Board's rejection of their demands. In November 2011, the Court consolidated these two cases into *Copeland v. Prince*. Johnson & Johnson secured an extension of time to respond to the complaint.

Two additional shareholder derivative lawsuits were filed in May 2011 in the United States District Court for the District of New Jersey, and two other shareholder derivative lawsuits were filed in New Jersey Superior Court in May 2011 and August 2011, all naming current directors of Johnson & Johnson as defendants and Johnson & Johnson as the nominal defendant. The complaints allege breaches of fiduciary duties related to the Company's compliance with the Foreign Corrupt Practices Act and participation in the United Nations Iraq Oil For Food Program, that the Company has suffered damages as a result of those alleged breaches, and that the defendants failed to disclose the alleged misconduct in the Company's filings under the Securities Exchange Act of 1934. Plaintiffs seek monetary damages, and the state court plaintiffs also seek corporate governance reforms. The federal lawsuits were consolidated in July 2011 into *In re J&J FCPA Derivative Shareholder Litigation*, and an amended consolidated complaint was filed in August 2011. In October 2011, Johnson & Johnson moved to dismiss the consolidated federal lawsuit on the grounds that the plaintiffs failed to make a demand upon the Board of Directors. The plaintiffs secured an extension of time to respond to the motion. The state lawsuits were consolidated in November 2011 into *In re J&J Shareholder*

Derivative Litigation, and a consolidated complaint was filed in December 2011. In January 2012, Johnson & Johnson moved to dismiss or stay the state lawsuits pending resolution of the federal lawsuit and moved to dismiss on the ground that the plaintiffs failed to make a demand on the Board of Directors. In May 2012, the Court granted a motion by Johnson & Johnson to stay the state lawsuits pending resolution of *In re J&J FCPA Derivative Shareholder Litigation*.

In July 2012, the parties in each of the shareholder derivative cases pending in federal court discussed above (specifically, *In re Johnson & Johnson Derivative Litigation*, *Copeland v. Prince*, and *In re J&J FCPA Derivative Shareholder Litigation*) filed a Stipulation of Settlement to permanently resolve all of the actions in their entirety. In October 2012, the settlement was approved by the Court. In November 2012, a notice of appeal was filed in the United States Court of Appeals for the Third Circuit by a shareholder who objected to the approval of the settlement in the District Court on the grounds that the lawsuit and the settlement did not provide any benefit to the Company, and that plaintiffs' counsel had requested an excessive fee award.

In June 2012, two other shareholders who had submitted a shareholder demand letter in March 2010, the New Jersey Building Laborers Annuity and the New Jersey Building Laborers Pension Funds, filed an additional shareholder derivative lawsuit in New Jersey Superior Court naming various current and former officers and directors as defendants and also challenging the Board's rejection of their demands. This shareholder derivative lawsuit purports to allege the same claims that are the subject of the settlement described above. The parties to this action had entered into a consent order staying the action pending final approval of the settlement discussed above. In November 2012, the plaintiffs agreed to voluntarily dismiss the action.

In September 2011, two additional shareholder derivative lawsuits were filed in the United States District Court for the District of New Jersey by Donovan Spamer and The George Leon Family Trust naming current directors and one former director of Johnson & Johnson as defendants and Johnson & Johnson as the nominal defendant. These lawsuits allege that the defendants breached their fiduciary duties in their decisions with respect to the compensation of the Chief Executive Officer during the period from 2008 through 2011, and that the defendants made misleading statements in the Company's annual proxy statements. Both of these lawsuits have been voluntarily dismissed without prejudice, but a similar lawsuit on behalf of The George Leon Family Trust was refiled in July 2012. That lawsuit seeks a variety of relief, including monetary damages, injunctive relief, and corporate governance reforms. The above settlement does not resolve these potential claims. The Board of Directors' evaluation of these allegations is ongoing.

22. Restructuring

In 2011, Cordis Corporation, a subsidiary of Johnson & Johnson, announced the discontinuation of its clinical development program for the NEVO™ Sirolimus-Eluting Coronary Stent and cessation of the manufacture and marketing of CYPHER® and CYPHER SELECT® Plus Sirolimus-Eluting Coronary Stents by the end of 2011. The Company will focus on other cardiovascular therapies where significant patient needs exist.

As a result of the above mentioned restructuring plan announced by Cordis Corporation, the Company recorded $676 million in related pre-tax charges, of which approximately $164 million of the pre-tax restructuring charges require cash payments. The $676 million of restructuring charges consists of asset write-offs of $512 million and $164 million related to leasehold and contract obligations and other expenses. The $512 million of asset write-offs relate to property, plant and equipment of $265 million, intangible assets of $160 million and inventory of $87 million (recorded in cost of products sold). The Cordis restructuring program has been substantially completed. The restructuring charge was recorded in the Medical Devices and Diagnostics segment.

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of Johnson & Johnson:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of earnings, statements of comprehensive income, statements of equity, and statements of cash flows present fairly, in all material respects, the financial position of Johnson & Johnson and its subsidiaries at December 30, 2012 and January 1, 2012, and the results of their operations and their cash flows for each of the three years in the period ended December 30, 2012 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 30, 2012, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Management's Report on Internal Control over Financial Reporting." Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As described in “Management's Report on Internal Control over Financial Reporting,” management has excluded Synthes, Inc. from its assessment of internal control over financial reporting as of December 30, 2012, because it was acquired by the Company in a purchase business combination during 2012. We have also excluded Synthes, Inc. from our audit of internal control over financial reporting. Synthes, Inc. is a wholly-owned subsidiary whose total assets and total revenues represent approximately 17% and 3%, respectively, of the related consolidated financial statement amounts as of and for the year ended December 30, 2012.

PricewaterhouseCoopers LLP

New York, New York
February 21, 2013

Management's Report on Internal Control Over Financial Reporting

Under Section 404 of the Sarbanes-Oxley Act of 2002, management is required to assess the effectiveness of the Company's internal control over financial reporting as of the end of each fiscal year and report, based on that assessment, whether the Company's internal control over financial reporting is effective.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is designed to provide reasonable assurance as to the reliability of the Company's financial reporting and the preparation of external financial statements in accordance with generally accepted accounting principles.

Internal controls over financial reporting, no matter how well designed, have inherent limitations. Therefore, internal control over financial reporting determined to be effective can provide only reasonable assurance with respect to financial statement preparation and may not prevent or detect all misstatements. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management has assessed the effectiveness of the Company's internal control over financial reporting as of December 30, 2012. In making this assessment, the Company used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework." These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. The Company's assessment included extensive documenting, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

The Company acquired Synthes, Inc. and its consolidated subsidiaries (Synthes) in June 2012. Synthes total assets, which were primarily intangible assets and goodwill, and total revenues represented approximately 17% and 3%, respectively, of the related consolidated financial statements as of and for the period ended December 30, 2012. As the acquisition occurred in June 2012 and Synthes was previously not subject to the requirements under Section 404 of the Sarbanes-Oxley Act of 2002, the scope of the Company's assessment of the design and effectiveness of internal control over financial reporting for the fiscal year 2012 excluded Synthes. This exclusion is in accordance with the SEC's general guidance that an assessment of a recently acquired business may be omitted from the scope in the year of acquisition.

Based on the Company's processes and assessment, as described above, management has concluded that, as of December 30, 2012, the Company's internal control over financial reporting was effective.

The effectiveness of the Company's internal control over financial reporting as of December 30, 2012 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which appears herein.

Alex Gorsky
Chairman, Board of Directors
Chief Executive Officer

Dominic J. Caruso
Vice President, Finance
Chief Financial Officer

Summary of Operations and Statistical Data 2002-2012

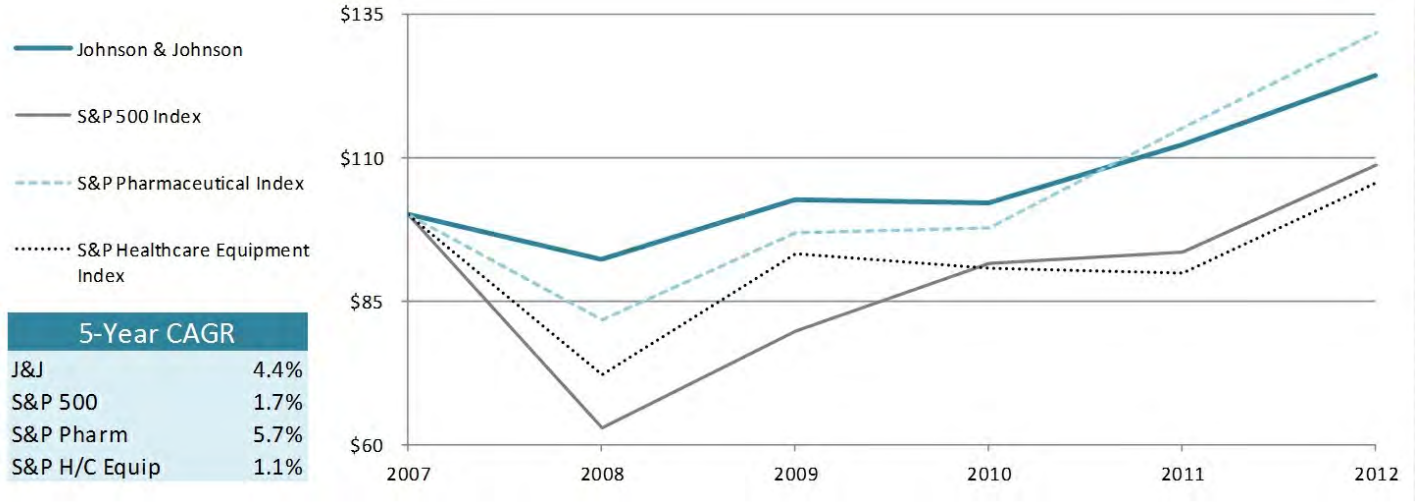
(Dollars in Millions Except Per Share Amounts)	2012	2011	2010	2009	2008	2007	2006	2005	2004	2003	2002
Sales to customers — U.S.	$ 29,830	28,908	29,450	30,889	32,309	32,444	29,775	28,377	27,770	25,274	22,455
Sales to customers — International	37,394	36,122	32,137	31,008	31,438	28,651	23,549	22,137	19,578	16,588	13,843
Total sales	67,224	65,030	61,587	61,897	63,747	61,095	53,324	50,514	47,348	41,862	36,298
Cost of products sold	21,658	20,360	18,792	18,447	18,511	17,751	15,057	14,010	13,474	12,231	10,498
Selling, marketing and administrative expenses	20,869	20,969	19,424	19,801	21,490	20,451	17,433	17,211	16,174	14,463	12,520
Research and development expense	7,665	7,548	6,844	6,986	7,577	7,680	7,125	6,462	5,344	4,834	4,094
In-process research and development	1,163	—	—	—	181	807	559	362	18	918	189
Interest income	(64)	(91)	(107)	(90)	(361)	(452)	(829)	(487)	(195)	(177)	(256)
Interest expense, net of portion capitalized	532	571	455	451	435	296	63	54	187	207	160
Other (income) expense, net	1,626	2,743	(768)	(526)	(1,015)	534	(671)	(214)	15	(385)	294
Restructuring	—	569	—	1,073	—	745	—	—	—	—	—
	53,449	52,669	44,640	46,142	46,818	47,812	38,737	37,398	35,017	32,091	27,499
Earnings before provision for taxes on income	$ 13,775	12,361	16,947	15,755	16,929	13,283	14,587	13,116	12,331	9,771	8,799
Provision for taxes on income	3,261	2,689	3,613	3,489	3,980	2,707	3,534	3,056	4,151	2,923	2,522
Net earnings	10,514	9,672	13,334	12,266	12,949	10,576	11,053	10,060	8,180	6,848	6,277
Add: Net loss attributable to noncontrolling interest	339	—	—	—	—	—	—	—	—	—	—
Net earnings attributable to Johnson & Johnson	10,853	9,672	13,334	12,266	12,949	10,576	11,053	10,060	8,180	6,848	6,277
Percent of sales to customers	16.1%	14.9	21.7	19.8	20.3	17.3	20.7	19.9	17.3	16.4	17.3
Diluted net earnings per share of common stock [1]	$ 3.86	3.49	4.78	4.40	4.57	3.63	3.73	3.35	2.74	2.29	2.06
Percent return on average shareholders' equity	17.8%	17.0	24.9	26.4	30.2	25.6	28.3	28.2	27.3	27.1	26.4
Percent increase (decrease) over previous year:											
Sales to customers	3.4%	5.6	(0.5)	(2.9)	4.3	14.6	5.6	6.7	13.1	15.3	12.3
Diluted net earnings per share	10.6%	(27.0)	8.6	(3.7)	25.9	(2.7)	11.3	22.3	19.7	11.2	17.7
Supplementary balance sheet data:											
Property, plant and equipment, net	16,097	14,739	14,553	14,759	14,365	14,185	13,044	10,830	10,436	9,846	8,710
Additions to property, plant and equipment	2,934	2,893	2,384	2,365	3,066	2,942	2,666	2,632	2,175	2,262	2,099
Total assets	121,347	113,644	102,908	94,682	84,912	80,954	70,556	58,864	54,039	48,858	40,984
Long-term debt	11,489	12,969	9,156	8,223	8,120	7,074	2,014	2,017	2,565	2,955	2,022
Operating cash flow	15,396	14,298	16,385	16,571	14,972	15,022	14,248	11,799	11,089	10,571	8,135
Common stock information											
Dividends paid per share	$ 2.400	2.250	2.110	1.930	1.795	1.620	1.455	1.275	1.095	0.925	0.795
Shareholders' equity per share	23.33	20.95	20.66	18.37	15.35	15.25	13.59	13.01	10.95	9.25	7.79
Market price per share (year-end close)	$ 69.48	65.58	61.85	64.41	58.56	67.38	66.02	60.10	63.42	50.62	53.11
Average shares outstanding (millions)											
— basic	2,753.3	2,736.0	2,751.4	2,759.5	2,802.5	2,882.9	2,936.4	2,973.9	2,968.4	2,968.1	2,998.3
— diluted	2,812.6	2,775.3	2,788.8	2,789.1	2,835.6	2,910.7	2,961.0	3,002.8	2,992.7	2,995.1	3,049.1
Employees (thousands)	127.6	117.9	114.0	115.5	118.7	119.2	122.2	115.6	109.9	110.6	108.3

[1] Attributable to Johnson & Johnson.

Shareholder Return Performance

Set forth below are line graphs comparing the cumulative total shareholder return on the Company's Common Stock for periods of five years and ten years ending December 31, 2012, against the cumulative total return of the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index. The graphs and tables assume that $100 was invested on December 31, 2007 and December 31, 2002 in each of the Company's Common Stock, the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index and that all dividends were reinvested.

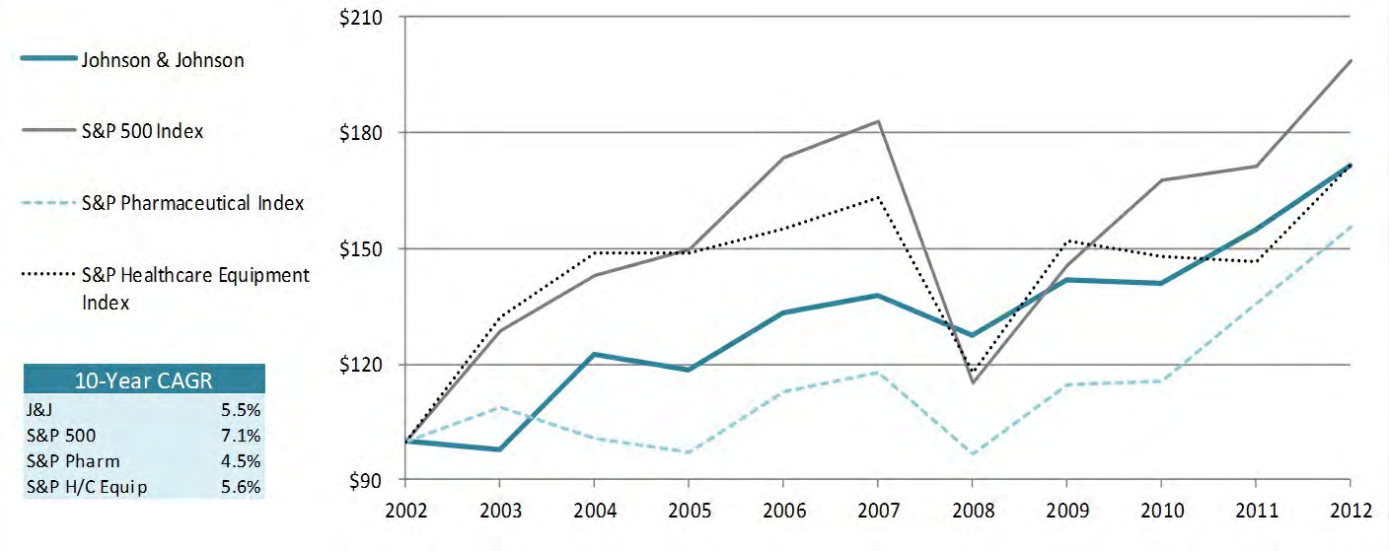
5-Year Cumulative Total Shareholder Return



5-Year CAGR	
J&J	4.4%
S&P 500	1.7%
S&P Pharm	5.7%
S&P H/C Equip	1.1%

	2007	2008	2009	2010	2011	2012
Johnson & Johnson	$ 100.00	$ 92.23	$ 102.63	$ 102.03	$ 112.13	$ 124.24
S&P 500 Index	$ 100.00	$ 63.00	$ 79.67	$ 91.68	$ 93.61	$ 108.59
S&P 500 Pharmaceutical Index	$ 100.00	$ 81.80	$ 97.03	$ 97.78	$ 115.14	$ 131.75
S&P 500 Healthcare Equipment Index	$ 100.00	$ 72.36	$ 93.18	$ 90.66	$ 89.93	$ 105.46

10-Year Cumulative Total Shareholder Return



10-Year CAGR	
J&J	5.5%
S&P 500	7.1%
S&P Pharm	4.5%
S&P H/C Equip	5.6%

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Johnson & Johnson	$ 100.00	$ 97.89	$ 122.52	$ 118.41	$ 133.14	$ 137.95	$ 127.23	$ 141.58	$ 140.75	$ 154.68	$ 171.38
S&P 500 Index	$ 100.00	$ 128.68	$ 142.68	$ 149.69	$ 173.33	$ 182.85	$ 115.20	$ 145.69	$ 167.63	$ 171.17	$ 198.57
S&P 500 Pharmaceutical Index	$ 100.00	$ 108.78	$ 100.70	$ 97.31	$ 112.74	$ 117.98	$ 96.51	$ 114.48	$ 115.36	$ 135.85	$ 155.45
S&P 500 Healthcare Equipment Index	$ 100.00	$ 132.04	$ 148.70	$ 148.78	$ 154.92	$ 162.86	$ 117.84	$ 151.76	$ 147.65	$ 146.47	$ 171.76

Exhibit “J11”

This is Exhibit “J11” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.
Arash Rouhi

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 29, 2013 **Commission file number 1-3215**

JOHNSON & JOHNSON

(Exact name of registrant as specified in its charter)

New Jersey	**22-1024240**
(State of incorporation)	(I.R.S. Employer Identification No.)
One Johnson & Johnson Plaza **New Brunswick, New Jersey**	**08933**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(732) 524-0400**

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT

Title of each class	Name of each exchange on which registered
Common Stock, Par Value $1.00	New York Stock Exchange
ALZA Corp Zero Coupon LYON Due July 2014	New York Stock Exchange
4.75% Notes Due November 2019	New York Stock Exchange
5.50% Notes Due November 2024	New York Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☑ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $242 billion.

On February 18, 2014, there were 2,828,901,694 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Parts I, II and III:	Portions of registrant's annual report to shareholders for fiscal year 2013 (the "Annual Report").
Parts I and III:	Portions of registrant's proxy statement for its 2014 annual meeting of shareholders filed within 120 days after the close of the registrant's fiscal year (the "Proxy Statement").

PART I

Item 1. BUSINESS

General

Johnson & Johnson and its subsidiaries (the "Company") have approximately 128,100 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. Johnson & Johnson is a holding company, which has more than 275 operating companies conducting business in virtually all countries of the world. The Company's primary focus has been on products related to human health and well-being. Johnson & Johnson was incorporated in the State of New Jersey in 1887.

The Company's structure is based on the principle of decentralized management. The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Consumer, Pharmaceutical and Medical Devices and Diagnostics business segments. Within the strategic parameters provided by the Committee, senior management groups at U.S. and international operating companies are each responsible for their own strategic plans, as well as the day-to-day operations of those companies, and each subsidiary within the business segments is, with some exceptions, managed by citizens of the country where it is located.

Segments of Business

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices and Diagnostics. Additional information required by this item is incorporated herein by reference to the narrative and tabular descriptions of segments and operating results under the caption "Management's Discussion and Analysis of Results of Operations and Financial Condition" and Note 18 "Segments of Business and Geographic Areas" under "Notes to Consolidated Financial Statements" of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K.

Consumer

The Consumer segment includes a broad range of products used in the baby care, skin care, oral care, wound care and women's health fields, as well as nutritionals, over-the-counter pharmaceutical products and wellness and prevention platforms. The Baby Care franchise includes the JOHNSON'S® Baby line of products. Major brands in the Skin Care franchise include the AVEENO®; CLEAN & CLEAR®; DABAO™; JOHNSON'S® Adult; LUBRIDERM®; NEUTROGENA®; RoC®; and VENDÔME® product lines. Brands in the Oral Care franchise include the LISTERINE® oral care lines. The Wound Care franchise includes BAND-AID® Brand Adhesive Bandages and NEOSPORIN® First Aid products. Major brands in the Women's Health franchise outside of North America are STAYFREE® and CAREFREE® sanitary pad and o.b.® tampon brands. The principal nutritional line is SPLENDA® No Calorie Sweetener. Over-the-counter medicines include the broad family of TYLENOL® acetaminophen products; SUDAFED® cold, flu and allergy products; ZYRTEC® allergy products; MOTRIN® IB ibuprofen products; and PEPCID® line of heartburn products. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world.

Pharmaceutical

The Pharmaceutical segment includes products in the following areas: anti-infective, antipsychotic, cardiovascular, contraceptive, gastrointestinal, hematology, immunology, infectious diseases, metabolic, neurology, oncology, pain management and vaccines. These products are distributed directly to retailers, wholesalers and health care professionals for prescription use. Key products in the Pharmaceutical segment include: REMICADE® (infliximab), a treatment for a number of immune-mediated inflammatory diseases; SIMPONI® (golimumab), a treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis and moderately active to severely active ulcerative colitis; STELARA® (ustekinumab), a treatment for adults with moderate to severe plaque psoriasis and active psoriatic arthritis; INCIVO® (telaprevir), for the treatment of hepatitis C; INTELENCE® (etravirine) and PREZISTA® (darunavir), treatments for HIV/AIDS; CONCERTA® (methylphenidate HCl) extended-release tablets CII, a treatment for attention deficit hyperactivity disorder; INVEGA® (paliperidone) extended-release tablets, for the treatment of schizophrenia and schizoaffective disorder; INVEGA® SUSTENNA®/XEPLION® (paliperidone palmitate), for the treatment of schizophrenia in adults; RISPERDAL® CONSTA® (risperidone), for the treatment of schizophrenia and for the maintenance treatment of Bipolar I Disorder; VELCADE® (bortezomib), a treatment for multiple myeloma; ZYTIGA® (abiraterone acetate), a treatment for metastatic castration-resistant prostate cancer; ACIPHEX®/PARIET®, a proton pump inhibitor co-marketed with Eisai Inc.; PROCRIT® (epoetin alfa, sold outside the U.S. as EPREX®), to stimulate red blood cell production; and XARELTO® (rivaroxaban), an oral anticoagulant for the prevention of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery, to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, for the treatment of DVT and PE, and for the reduction in the risk of recurrence of DVT and PE.

Medical Devices and Diagnostics

The Medical Devices and Diagnostics segment includes a broad range of products distributed to wholesalers, hospitals and retailers, used principally in the professional fields by physicians, nurses, hospitals, and clinics. These include products to treat cardiovascular disease; orthopaedic and neurological products; blood glucose monitoring and insulin delivery products; general surgery, biosurgical, and energy products; professional diagnostic products; infection prevention products; and disposable contact lenses.

Geographic Areas

The business of Johnson & Johnson is conducted by more than 275 operating companies located in 60 countries, including the United States, which sell products in virtually all countries throughout the world. The products made and sold in the international business include many of those described above under "— Segments of Business — Consumer," "— Pharmaceutical" and "— Medical Devices and Diagnostics." However, the principal markets, products and methods of distribution in the international business vary with the country and the culture. The products sold in international business include not only those developed in the United States, but also those developed by subsidiaries abroad.

Investments and activities in some countries outside the United States are subject to higher risks than comparable U.S. activities because the investment and commercial climate may be influenced by restrictive economic policies and political uncertainties.

Raw Materials

Raw materials essential to the Company's business are generally readily available from multiple sources. Where there are exceptions, the temporary unavailability of those raw materials would not likely have a material adverse effect on the financial results of the Company.

Patents and Trademarks

The Company's subsidiaries have made a practice of obtaining patent protection on their products and processes where possible. They own or are licensed under a number of patents relating to their products and manufacturing processes, which in the aggregate are believed to be of material importance to the Company in the operation of its businesses. Sales of the Company's largest product, REMICADE® (infliximab), accounted for approximately 9.4% of the Company's total revenues for fiscal 2013. Accordingly, the patents related to this product are believed to be material to the Company.

There are two sets of patents related to REMICADE® (infliximab). The first set of patents is co-owned by Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson, and New York University Medical Center (NYU). Janssen Biotech, Inc. has an exclusive license to NYU's interests in the patents. Patents have been granted in the United States, certain countries in the European Union (certain of these patents have been extended by Supplementary Patent Certificates), and Australia. In the United States, the patent expires in September 2018. These patents expired in Canada in March 2012. In certain countries in Europe the patent has been extended to February 2015 (Germany, Spain, United Kingdom, Sweden, Austria, Belgium, Switzerland, Denmark, France, Greece, Italy, Luxembourg and the Netherlands). In Australia, the patent expires in March 2017.

The second set of patents related to REMICADE® was granted to the Kennedy Institute of Rheumatology in the United Kingdom in Europe, Canada, Australia and the United States. Janssen Biotech, Inc. has an exclusive license to these patents which expire in 2017 outside of the United States and 2018 in the United States. The validity of these patents has been
challenged and is currently in litigation.

Loss of exclusivity for REMICADE® in the above-mentioned markets may result in a reduction in sales. Johnson & Johnson does not expect that any additional extensions will be available for the patents related to REMICADE®.

In addition to competing in the immunology market with REMICADE®, the Company is currently marketing STELARA® (ustekinumab), SIMPONI® (golimumab) and SIMPONI® ARIA™ (golimumab), next generation immunology products with remaining patent lives of 10 years.

The Company's subsidiaries have made a practice of selling their products under trademarks and of obtaining protection for these trademarks by all available means. These trademarks are protected by registration in the United States and other countries where such products are marketed. The Company considers these trademarks in the aggregate to be of material importance in the operation of its businesses.

Seasonality

Worldwide sales do not reflect any significant degree of seasonality; however, spending has been heavier in the fourth quarter of each year than in other quarters. This reflects increased spending decisions, principally for advertising and research and development activity.

Competition

In all of their product lines, the Company's subsidiaries compete with companies both locally and globally, throughout the world. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products is important to the Company's success in all areas of its business. This also includes protecting the Company's portfolio of intellectual property. The competitive environment requires substantial investments in continuing research. In addition, the development and maintenance of customer demand for the Company's consumer products involves significant expenditures for advertising and promotion.

Research and Development

Research activities represent a significant part of the Company's businesses. Research and development expenditures relate to the processes of discovering, testing and developing new products, improving existing products, as well as demonstrating product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products. Worldwide costs of research and development activities amounted to $8.2 billion, $7.7 billion and $7.5 billion for fiscal years 2013, 2012 and 2011, respectively. Major research facilities are located not only in the United States, but also in Belgium, Brazil, Canada, China, France, Germany, India, Israel, Japan, the Netherlands, Singapore, Switzerland and the United Kingdom.

Environment

The Company is subject to a variety of U.S. and international environmental protection measures. The Company believes that its operations comply in all material respects with applicable environmental laws and regulations. The Company's compliance with these requirements did not during the past year, and is not expected to, have a material effect upon its capital expenditures, cash flows, earnings or competitive position.

Regulation

Most of the Company's businesses are subject to varying degrees of governmental regulation in the countries in which operations are conducted, and the general trend is toward increasingly stringent regulation. In the United States, the drug, device, diagnostics and cosmetic industries have long been subject to regulation by various federal and state agencies, primarily as to product safety, efficacy, manufacturing, advertising, labeling and safety reporting. The exercise of broad regulatory powers by the U.S. Food and Drug Administration (the "FDA") continues to result in increases in the amounts of testing and documentation required for FDA clearance of new drugs and devices and a corresponding increase in the expense of product introduction. Similar trends are also evident in major markets outside of the United States.

The costs of human health care have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. In the United States, attention has been focused on drug prices and profits and programs that encourage doctors to write prescriptions for particular drugs or recommend, use or purchase particular medical devices. Payers have become a more potent force in the market place and increased attention is being paid to drug and medical device pricing, appropriate drug and medical device utilization and the quality and costs of health care generally.

Following the U.S. Supreme Court decision in June 2012 upholding the Patient Protection and Affordable Care Act (the "ACA"), there has been an increase in the pace of regulatory issuances by those U.S. government agencies designated to carry out the extensive requirements of the ACA. These have both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of the ACA will ultimately affect the industry.

The regulatory agencies under whose purview the Company operates have administrative powers that may subject it to actions such as product withdrawals, recalls, seizure of products and other civil and criminal sanctions. In some cases, the Company's subsidiaries may deem it advisable to initiate product recalls.

In addition, business practices in the health care industry have come under increased scrutiny, particularly in the United States, by government agencies and state attorneys general, and resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Available Information

The Company's main corporate website address is *www.jnj.com*. Copies of the Company's Quarterly Reports on Form 10-Q, Annual Report on Form 10-K and Current Reports on Form 8-K filed or furnished to the U.S. Securities and Exchange Commission (the "SEC"), and any amendments to the foregoing, will be provided without charge to any shareholder submitting a written request to the Secretary at the principal executive offices of the Company or by calling 1-800-950-5089. All of the Company's SEC filings are also available on the Company's website at *www.investor.jnj.com/governance/sec-filings.cfm*, as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*. In addition, the written charters of the Audit Committee, the Compensation & Benefits Committee, the Nominating & Corporate Governance Committee, the Regulatory, Compliance & Government Affairs Committee and the Science, Technology & Sustainability Committee of the Board of Directors and the Company's Principles of Corporate Governance, Policy on Business Conduct for employees, Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers, and other corporate governance materials, are available at *www.investor.jnj.com/governance/materials.cfm* on the Company's website and will be provided without charge to any shareholder submitting a written request, as provided above. The information on the Company's website is not, and will not be deemed, a part of this Report on Form 10-K or incorporated into any other filings the Company makes with the SEC.

Item 1A. RISK FACTORS

Some important factors that could cause the Company's actual results to differ from the Company's expectations in any forward-looking statements in this Report are set forth in Exhibit 99 to this Report on Form 10-K.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

The Company's subsidiaries operate 144 manufacturing facilities occupying approximately 21.7 million square feet of floor space. The manufacturing facilities are used by the industry segments of the Company's business approximately as follows:

Segment	Square Feet (in thousands)
Consumer	7,104
Pharmaceutical	7,069
Medical Devices and Diagnostics	7,500
Worldwide Total	21,673

Within the United States, eight facilities are used by the Consumer segment, eight by the Pharmaceutical segment and 34 by the Medical Devices and Diagnostics segment. The Company's manufacturing operations outside the United States are often conducted in facilities that serve more than one business segment. The locations of the manufacturing facilities by major geographic areas of the world are as follows:

Geographic Area	Number of Facilities	Square Feet (in thousands)
United States	50	6,510
Europe	43	7,979
Western Hemisphere, excluding U.S.	15	2,886
Africa, Asia and Pacific	36	4,298
Worldwide Total	144	21,673

In addition to the manufacturing facilities discussed above, Johnson & Johnson and its subsidiaries maintain numerous office and warehouse facilities throughout the world. Research facilities are also discussed in Item 1 under "Business — Research and Development."

The Company's subsidiaries generally seek to own their manufacturing facilities, although some, principally in locations abroad, are leased. Office and warehouse facilities are often leased.

The Company is committed to maintaining all of its properties in good operating condition and repair, and the facilities are well utilized.

McNEIL-PPC, Inc. continues to operate under a consent decree, signed in 2011 with the U.S. Food and Drug Administration (FDA), which governs certain McNeil Consumer Healthcare manufacturing operations. McNeil continues to operate the manufacturing facilities in Las Piedras, Puerto Rico and Lancaster, Pennsylvania and has made significant progress, having met the remediation commitments at those facilities. The Company also successfully reintroduced many products previously made in Fort Washington, Pennsylvania, from other sites. Plants operating under the consent decree will continue to produce a simplified portfolio focused on key brands. The Fort Washington manufacturing site is not in operation at this time and the Company recently made the decision to make further investments in that facility prior to certification. A discussion of this matter can be found under the heading “Government Proceedings - McNeil Consumer Healthcare” in Note 21 “Legal Proceedings” under “Notes to the Consolidated Financial Statements” of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K.

For information regarding lease obligations, see Note 16 “Rental Expense and Lease Commitments” under “Notes to Consolidated Financial Statements” of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K. Segment information on additions to property, plant and equipment is contained in Note 18 “Segments of Business and Geographic Areas” under “Notes to Consolidated Financial Statements” of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K.

Item 3. LEGAL PROCEEDINGS

The following information is incorporated by reference: the information set forth in Note 21 “Legal Proceedings” under “Notes to Consolidated Financial Statements” of the Annual Report filed as Exhibit 13 to this Report on Form 10-K.

In addition, Johnson & Johnson and its subsidiaries are from time to time party to government investigations, inspections or other proceedings relating to environmental matters, including their compliance with applicable environmental laws. In connection with a routine inspection of a subsidiary's manufacturing facility, the California Department of Toxic Substances Control (the "Department") has alleged violation of regulations dealing with the handling of certain wastes. The Company believes that adequate defenses to those allegations exist and has reached an agreement in principal with the Department to resolve this matter. The Company does not expect the resolution of this matter to have a material adverse impact on the Company.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

EXECUTIVE OFFICERS OF THE REGISTRANT

Listed below are the executive officers of the Company as of February 21, 2014. There are no family relationships between any of the executive officers, and there is no arrangement or understanding between any executive officer and any other person pursuant to which the executive officer was selected. At the annual meeting of the Board of Directors, the executive officers are elected by the Board to hold office for one year and until their respective successors are elected and qualified, or until earlier resignation or removal.

Information with regard to the Directors of the Company, including information for Alex Gorsky, is incorporated herein by reference to the material captioned “Election of Directors” in the Proxy Statement.

Name	Age	Position
Dominic J. Caruso	56	Member, Executive Committee; Vice President, Finance; Chief Financial Officer(a)
Peter M. Fasolo	51	Member, Executive Committee; Vice President, Global Human Resources(b)
Alex Gorsky	53	Chairman, Board of Directors; Chairman, Executive Committee; Chief Executive Officer
Sandra E. Peterson	55	Member, Executive Committee; Group Worldwide Chairman(c)
Paulus Stoffels	52	Member, Executive Committee; Chief Scientific Officer; Worldwide Chairman, Pharmaceuticals Group(d)
Michael H. Ullmann	55	Member, Executive Committee; Vice President, General Counsel(e)

(a) Mr. D. J. Caruso joined the Company in 1999 when the Company acquired Centocor, Inc. At the time of that acquisition, he had been Senior Vice President, Finance of Centocor. Mr. Caruso was named Vice President, Finance of Ortho-McNeil Pharmaceutical, Inc., a subsidiary of the Company, in 2001 and Vice President, Group Finance of the Company's Medical Devices and Diagnostics Group in 2003. In 2005, Mr. Caruso was named Vice President of the Company's Group Finance organization. Mr. Caruso became a Member of the Executive Committee and Vice President, Finance and Chief Financial Officer in 2007.

(b) Dr. P. M. Fasolo joined the Company in 2004 as Vice President, Worldwide Human Resources for Cordis Corporation, a subsidiary of the Company. He was then named Vice President, Global Talent Management for the Company. He left Johnson & Johnson in 2007 to join Kohlberg Kravis Roberts & Co. as Chief Talent Officer. Dr. Fasolo returned to the Company in 2010 as the Vice President, Global Human Resources, and in 2011, he became a Member of the Executive Committee.

(c) Ms. S. E. Peterson joined the Company in 2012 as Group Worldwide Chairman and a Member of the Executive Committee, with responsibility for the Consumer Group of Companies, consumer-directed medical device businesses, Johnson & Johnson Vision Care and Johnson & Johnson Diabetes Care franchises, and functions such as Johnson & Johnson Supply Chain, Information Technology, Wellness and Prevention and Global Strategic Design. Prior to joining Johnson & Johnson, Ms. Peterson had an extensive global career in healthcare, consumer goods and consulting. Most recently, she was Chairman and Chief Executive Officer of Bayer CropScience AG in Germany, previously serving as President and Chief Executive Officer of Bayer Medical Care and President of Bayer HealthCare AG's Diabetes Care Division. Before joining Bayer in 2005, Ms. Peterson held a number of leadership roles at Medco Health Solutions (previously known as Merck-Medco). Among her responsibilities was the application of information technology to healthcare systems.

(d) Dr. P. Stoffels joined the Company in 2002 with the acquisition of Virco and Tibotec, where he was Chief Executive Officer of Virco and Chairman of Tibotec. In 2005, he was appointed Company Group Chairman, Global Virology where he led the development of PREZISTA® and INTELENCE®, leading products for the treatment of HIV. In 2006, he assumed the role of Company Group Chairman, Pharmaceuticals, with responsibility for worldwide research and development for the Central Nervous System and Internal Medicine Franchises. Dr. Stoffels was appointed Global Head, Research & Development, Pharmaceuticals, in 2009, and in 2011 became Worldwide Chairman, Pharmaceuticals Group, with responsibility for the Company's therapeutic pipeline through global research and development and strategic business development. In 2012, Dr. Stoffels was also appointed Chief Scientific Officer, with responsibility for enterprise-wide innovation and product safety, and a Member of the Executive Committee.

(e) Mr. M. H. Ullmann joined the Company in 1989 as a corporate attorney in the Law Department. He was appointed Corporate Secretary in 1999 and served in that role until 2006. During that time, he also held various management positions in the Law Department. In 2006, he was named General Counsel of the Medical Devices and Diagnostics Group. Mr. Ullmann was appointed Vice President, General Counsel and a Member of the Executive Committee in 2012.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

As of February 18, 2013, there were 165,304 record holders of Common Stock of the Company. Additional information called for by this item is incorporated herein by reference to: the material under the captions "Management's Discussion and Analysis of Results of Operations and Financial Condition — Liquidity and Capital Resources — Dividends"; "— Other Information — Common Stock Market Prices"; Note 17 "Common Stock, Stock Option Plans and Stock Compensation Agreements" under "Notes to Consolidated Financial Statements"; and "Shareholder Return Performance Graphs" under "Supporting Schedules" of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K; and Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters — Equity Compensation Plan Information" of this Report on Form 10-K.

Issuer Purchases of Equity Securities

The following table provides information with respect to Common Stock purchases by the Company during the fiscal fourth quarter of 2013. Common Stock purchases on the open market are made as part of a systematic plan to meet the needs of the Company's compensation programs. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal fourth quarter.

Period	Total Number of Shares Purchased	Avg. Price Paid Per Share	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
September 30, 2013 through October 27, 2013	693,733	$ 88.12	-	-
October 28, 2013 through November 24, 2013	1,929,925	92.95	-	-
November 25, 2013 through December 29, 2013	2,728,307	94.07	-	-
Total	5,351,965			

Item 6. SELECTED FINANCIAL DATA

The information called for by this item is incorporated herein by reference to the "Summary of Operations and Statistical Data 2003-2013" under "Supporting Schedules" of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K.

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The information called for by this item is incorporated herein by reference to the narrative and tabular material under the caption "Management's Discussion and Analysis of Results of Operations and Financial Condition" of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The information called for by this item is incorporated herein by reference to the material under the caption "Management's Discussion and Analysis of Results of Operations and Financial Condition — Liquidity and Capital Resources — Financing and Market Risk" and Note 1 "Summary of Significant Accounting Policies — Financial Instruments" under "Notes to Consolidated Financial Statements" of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information called for by this item is incorporated herein by reference to the Audited Consolidated Financial Statements and Notes thereto and the material under the caption "Report of Independent Registered Public Accounting Firm" of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures. At the end of the period covered by this report, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Alex Gorsky, Chairman and Chief Executive Officer, and Dominic J. Caruso, Chief Financial Officer, reviewed and participated in

this evaluation. Based on this evaluation, Messrs. Gorsky and Caruso concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures were effective.

Management's Report on Internal Control Over Financial Reporting. The information called for by this item is incorporated herein by reference to the material under the caption "Management's Report on Internal Control Over Financial Reporting" of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K.

Changes in Internal Control Over Financial Reporting. During the fiscal quarter ended December 29, 2013, there were no changes in the Company's internal control over financial reporting identified in connection with the evaluation required under Rules 13a-15 and 15d-15 under the Exchange Act that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1: Election of Directors" and "Stock Ownership and Section 16 Compliance — Section 16(a) Beneficial Ownership Reporting Compliance" and the discussion of the Audit Committee under the caption "Corporate Governance — Standing Board Committees" in the Proxy Statement; and the material under the caption "Executive Officers of the Registrant" in Part I of this Report on Form 10-K.

The Company's Policy on Business Conduct, which covers all employees (including the Chief Executive Officer, Chief Financial Officer and Controller), meets the requirements of the SEC rules promulgated under Section 406 of the Sarbanes-Oxley Act of 2002. The Policy on Business Conduct is available on the Company's website at *www.investor.jnj.com/governance/policies.cfm*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Policy on Business Conduct or any waiver of the Policy granted to the Chief Executive Officer, the Chief Financial Officer or the Controller will be posted on the Company's website at *www.investor.jnj.com/governance.cfm* within five business days (and retained on the website for at least one year).

In addition, the Company has adopted a Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers. The Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers is available on the Company's website at *www.investor.jnj.com/governance/policies.cfm*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code or any waiver of the Code granted to any member of the Board of Directors or any executive officer will be posted on the Company's website at *www.investor.jnj.com/governance.cfm* within five business days (and retained on the website for at least one year).

Item 11. EXECUTIVE COMPENSATION

The information called for by this item is incorporated herein by reference to the material under the captions Corporate Governance — Item 1: Election of Directors — Director Compensation - 2013," "Compensation Committee Report," "Compensation Discussion and Analysis" and "Executive Compensation" in the Proxy Statement.

The material incorporated herein by reference to the material under the caption "Compensation Committee Report" in the Proxy Statement shall be deemed furnished, and not filed, in this Report on Form 10-K and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, as a result of this furnishing, except to the extent that the Registrant specifically incorporates it by reference.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Additional information called for by this item is incorporated herein by reference to the material under the captions "Stock Ownership and Section 16 Compliance" in the Proxy Statement and Note 17 "Common Stock, Stock Option Plans and Stock Compensation Agreements" under "Notes to Consolidated Financial Statements" of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K.

Equity Compensation Plan Information

The following table provides certain information as of December 29, 2013 concerning the shares of the Company's Common Stock that may be issued under existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights	Weighted Average Exercise Price of Outstanding Options and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans[2][3]
Equity Compensation Plans Approved by Security Holders[1]	151,707,900	$50.99	583,022,234
Equity Compensation Plans Not Approved by Security Holders	-	-	-
Total	151,707,900	$50.99	583,022,234

(1) Included in this category are the following equity compensation plans, which have been approved by the Company's shareholders: 2000 Stock Option Plan, 2005 Long-Term Incentive Plan and 2012 Long-Term Incentive Plan.

(2) This column excludes shares reflected under the column "Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights."

(3) The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information called for by this item is incorporated herein by reference to the material under the captions "Transactions with Related Persons" and "Corporate Governance — Director Independence" in the Proxy Statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information called for by this item is incorporated herein by reference to the material under the caption "Ratification of Appointment of Independent Registered Public Accounting Firm" in the Proxy Statement.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

1. *Financial Statements*

The following Audited Consolidated Financial Statements and Notes thereto and the material under the caption "Report of Independent Registered Public Accounting Firm" of the Annual Report are incorporated herein by reference and filed as Exhibit 13 to this Report on Form 10-K:

Consolidated Balance Sheets at end of Fiscal Years 2013 and 2012

Consolidated Statements of Earnings for Fiscal Years 2013, 2012 and 2011

Consolidated Statements of Comprehensive Income for Fiscal Years 2013, 2012 and 2011

Consolidated Statements of Equity for Fiscal Years 2013, 2012 and 2011

Consolidated Statements of Cash Flows for Fiscal Years 2013, 2012 and 2011

Notes to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

2. *Financial Statement Schedules*

Schedule II — Valuation and Qualifying Accounts

Schedules other than those listed above are omitted because they are not required or are not applicable.

3. *Exhibits Required to be Filed by Item 601 of Regulation S-K*

The information called for by this item is incorporated herein by reference to the Exhibit Index in this report.

JOHNSON & JOHNSON AND SUBSIDIARIES

SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

Fiscal Years Ended December 29, 2013, December 30, 2012 and January 1, 2012
(Dollars in Millions)

	Balance at Beginning of Period	Accruals	Payments/Other	Balance at End of Period
2013				
Accrued Rebates[1]	$ 2,466	10,559	(10,102)	2,923
Accrued Returns	710	480	(558)	632
Accrued Promotions	435	1,619	(1,571)	483
Subtotal	$ 3,611	12,658	(12,231)	4,038
Reserve for doubtful accounts	466	53	(186)	333
Reserve for cash discounts	105	1,097	(1,099)	103
Total	$ 4,182	13,808	(13,516)	4,474
2012				
Accrued Rebates[1]	$ 2,215	8,973	(8,722)	2,466
Accrued Returns	682	549	(521)	710
Accrued Promotions	396	1,583	(1,544)	435
Subtotal	$ 3,293	11,105	(10,787)	3,611
Reserve for doubtful accounts	361	127	(22)	466
Reserve for cash discounts	99	1,010	(1,004)	105
Total	$ 3,753	12,242	(11,813)	4,182
2011				
Accrued Rebates[1]	$ 2,146	8,331	(8,262)	2,215
Accrued Returns	640	560	(518)	682
Accrued Promotions	427	1,774	(1,805)	396
Subtotal	$ 3,213	10,665	(10,585)	3,293
Reserve for doubtful accounts	340	77	(56)	361
Reserve for cash discounts	110	960	(971)	99
Total	$ 3,663	11,702	(11,612)	3,753

(1) Includes reserve for customer rebates of $730 million, $642 million and $656 million at December 29, 2013, December 30, 2012 and January 1, 2012, respectively, recorded as a contra asset.

SIGNATURES

Pursuant to the requirements of Section 13 of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 21, 2014

JOHNSON & JOHNSON

(Registrant)

By /s/ A. Gorsky

A. Gorsky, Chairman, Board of Directors,
and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

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Signature	Title	Date
/s/ A. Gorsky A. Gorsky	Chairman, Board of Directors, Chief Executive Officer, and Director (Principal Executive Officer)	February 21, 2014
/s/ D. J. Caruso D. J. Caruso	Chief Financial Officer (Principal Financial Officer)	February 21, 2014
/s/ S. J. Cosgrove S. J. Cosgrove	Controller (Principal Accounting Officer)	February 21, 2014
/s/ M. S. Coleman M. S. Coleman	Director	February 21, 2014
/s/ J. G. Cullen J. G. Cullen	Director	February 21, 2014
/s/ I. E. L. Davis I. E. L. Davis	Director	February 21, 2014
/s/ M. M. E. Johns M. M. E. Johns	Director	February 21, 2014

Signature	Title	Date
/s/ S. L. Lindquist S. L. Lindquist	Director	February 21, 2014
/s/ M. B. McClellan M. B. McClellan	Director	February 21, 2014
/s/ A. M. Mulcahy A. M. Mulcahy	Director	February 21, 2014
/s/ L. F. Mullin L. F. Mullin	Director	February 21, 2014
/s/ W. D. Perez W. D. Perez	Director	February 21, 2014
/s/ C. Prince C. Prince	Director	February 21, 2014
/s/ A. E. Washington A. E. Washington	Director	February 21, 2014
/s/ R. A. Williams R. A. Williams	Director	February 21, 2014

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON FINANCIAL STATEMENT SCHEDULE

To the Board of Directors of
Johnson & Johnson:

Our audits of the consolidated financial statements and of the effectiveness of internal control over financial reporting referred to in our report dated February 21, 2014 appearing in the 2013 Annual Report to Shareholders of Johnson & Johnson (which report and consolidated financial statements are incorporated by reference in this Annual Report on Form 10-K) also included an audit of the financial statement schedule listed in Item 15(a)(2) of this Form 10-K. In our opinion, this financial statement schedule presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements.

/s/ PricewaterhouseCoopers LLP
PricewaterhouseCoopers LLP

New York, New York
February 21, 2014

EXHIBIT INDEX

Reg. S-K Exhibit Table Item No.	Description of Exhibit
3(i)(a)	Restated Certificate of Incorporation effective April 26, 1990 — Incorporated herein by reference to Exhibit 3(a) of the Registrant's Form 10-K Annual Report for the year ended December 30, 1990.
3(i)(b)	Certificate of Amendment to the Restated Certificate of Incorporation of the Company effective May 20, 1992 — Incorporated herein by reference to Exhibit 3(a) of the Registrant's Form 10-K Annual Report for the year ended January 3, 1993.
3(i)(c)	Certificate of Amendment to the Restated Certificate of Incorporation of the Company effective May 21, 1996 — Incorporated herein by reference to Exhibit 3(a)(iii) of the Registrant's Form 10-K Annual Report for the year ended December 29, 1996.
3(i)(d)	Certificate of Amendment to the Restated Certificate of Incorporation of the Company effective May 22, 2001 — Incorporated herein by reference to Exhibit 3 of the Registrant's Form 10-Q Quarterly Report for the quarter ended July 1, 2001.
3(i)(e)	Certificate of Amendment to the Restated Certificate of Incorporation of the Company effective April 27, 2006 — Incorporated herein by reference to Exhibit 3(i) of the Registrant's Form 10-Q Quarterly Report for the quarter ended April 2, 2006.
3(ii)	By-Laws of the Company, as amended effective April 17, 2012 — Incorporated herein by reference to Exhibit 3.1 the Registrant's Form 8-K Current Report filed April 19, 2012.
4(a)	Upon the request of the Securities and Exchange Commission, the Registrant will furnish a copy of all instruments defining the rights of holders of long-term debt of the Registrant.
10(a)	Stock Option Plan for Non-Employee Directors — Incorporated herein by reference to Exhibit 10(a) of the Registrant's Form 10-K Annual Report for the year ended December 29, 1996.*
10(b)	2000 Stock Option Plan (as amended) — Incorporated herein by reference to Exhibit 10(b) of the Registrant's Form 10-K Annual Report for the year ended January 1, 2012.*
10(c)	2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 4 of the Registrant's S-8 Registration Statement filed with the Commission on May 10, 2005 (file no. 333-124785).*
10(d)	Form of Restricted Shares to Non-Employee Directors under the 2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 8-K Current Report filed August 25, 2005.*
10(e)	Form of Stock Option Certificate, Restricted Share Unit Certificate and Performance Share Unit Certificate under the 2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.1, 10.2 and 10.3 of the Registrant's Form 8-K Current Report filed January 13, 2012.*
10(f)	2012 Long-Term Incentive Plan — Incorporated herein by reference to Appendix A of the Registrant's Proxy Statement filed with the Commission on March 14, 2012 .*
10(g)	Form of Stock Option Certificate, Restricted Share Unit Certificate and Performance Share Unit Certificate under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.2, 10.3 and 10.4 of the Registrant's Form 10-Q Quarterly Report filed May 7, 2012.*
10(h)	Executive Incentive Plan (as amended) — Incorporated herein by reference to Exhibit 10(f) of the Registrant's Form 10-K Annual Report for the year ended December 31, 2000.*
10(i)	Domestic Deferred Compensation (Certificate of Extra Compensation) Plan — Incorporated herein by reference to Exhibit 10(g) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2003.*
10(j)	Amendments to the Certificate of Extra Compensation Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(k)	2009 Certificates of Long-Term Performance Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 27, 2009.*
10(l)	Amended and Restated Deferred Fee Plan for Directors — Incorporated herein by reference to Exhibit 10(k) of the Registrant's Form 10-K Annual Report for the year ended January 1, 2012.*
10(m)	Executive Income Deferral Plan (Amended and Restated) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*

Reg. S-K Exhibit Table Item No.	Description of Exhibit
10(n)	Excess Savings Plan — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the year ended December 29, 1996.*
10(o)	Amendments to the Johnson & Johnson Excess Savings Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(p) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(p)	Excess Benefit Plan (Supplemental Retirement Plan) — Incorporated herein by reference to Exhibit 10(h) of the Registrant's Form 10-K Annual Report for the year ended January 3, 1993.*
10(q)	Amendments to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(r) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(r)	Executive Life Plan Agreement — Incorporated herein by reference to Exhibit 10(i) of the Registrant's Form 10-K Annual Report for the year ended January 3, 1993.*
10(s)	Johnson & Johnson Retirement Savings Plan, Johnson & Johnson Savings Plan for Union Represented Employees, and Johnson & Johnson Savings Plan - Incorporated herein by reference to Exhibits 99.1, 99.2 and 99.3 of the Registrant's Form S-8 filed with the Commission on May 6, 2013.*
10(t)	Employment Agreement for Dr. Paulus Stoffels - Incorporated herein by reference to Exhibit 10.2 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*
10(u)	Summary of Employment Arrangements for Sandra E. Peterson — Incorporated herein by reference to Exhibit 10(t) of the Registrant's Form 10-K Annual Report for the year ended December 30, 2012.*
12	Statement of Computation of Ratio of Earnings to Fixed Charges — Filed with this document.
13	The following sections of the Annual Report to Shareholders for fiscal year 2013, which are incorporated by reference in this report, are deemed "filed": "Management's Discussion and Analysis of Results of Operations and Financial Condition"; "Audited Consolidated Financial Statements"; "Supporting Schedules - Summary of Operations and Statistical Data 2003 - 2013"; and "Supporting Schedules - Shareholder Return Performance Graphs" - Filed with this document.
21	Subsidiaries — Filed with this document.
23	Consent of Independent Registered Public Accounting Firm — Filed with this document.
31(a)	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
31(b)	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
32(a)	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
32(b)	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
99	Cautionary Statement Pursuant to Private Securities Litigation Reform Act of 1995 — "Safe Harbor" for Forward-Looking Statements — Filed with this document.
101	XBRL (Extensible Business Reporting Language) The following materials from Johnson & Johnson's Annual Report on Form 10-K for the fiscal year-ended December 29, 2013, formatted in Extensive Business Reporting Language (XBRL): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Earnings, (iii) Consolidated Statements of Comprehensive Income, (iv) Consolidated Statements of Equity, (v) Consolidated Statements of Cash Flows, (vi) Notes to the Consolidated Financial Statements, and (vii) Schedule II — Valuation and Qualifying Accounts.

* Management contract or compensatory plan.

A copy of any of the Exhibits listed above will be provided without charge to any shareholder submitting a written request specifying the desired exhibit(s) to the Secretary at the principal executive offices of the Company.

Exhibit “J12”

This is Exhibit “J12” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OF
THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 28, 2014 **Commission file number 1-3215**

JOHNSON & JOHNSON

(Exact name of registrant as specified in its charter)

New Jersey	**22-1024240**
(State of incorporation)	(I.R.S. Employer Identification No.)
One Johnson & Johnson Plaza **New Brunswick, New Jersey**	**08933**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(732) 524-0400**

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT

Title of each class	Name of each exchange on which registered
Common Stock, Par Value $1.00	New York Stock Exchange
4.75% Notes Due November 2019	New York Stock Exchange
5.50% Notes Due November 2024	New York Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☑ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $296 billion.

On February 17, 2015, there were 2,780,488,708 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Parts I, II and III:	Portions of registrant's annual report to shareholders for fiscal year 2014 (the "Annual Report").
Parts I and III:	Portions of registrant's proxy statement for its 2015 annual meeting of shareholders filed within 120 days after the close of the registrant's fiscal year (the "Proxy Statement").

PART I

Item 1. BUSINESS

General

Johnson & Johnson and its subsidiaries (the "Company") have approximately 126,500 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. Johnson & Johnson is a holding company, which has more than 265 operating companies conducting business in virtually all countries of the world. The Company's primary focus is products related to human health and well-being. Johnson & Johnson was incorporated in the State of New Jersey in 1887.

The Company's structure is based on the principle of decentralized management. The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Consumer, Pharmaceutical and Medical Devices (previously referred to as Medical Devices and Diagnostics) business segments. Within the strategic parameters provided by the Committee, senior management groups at U.S. and international operating companies are each responsible for their own strategic plans, as well as the day-to-day operations of those companies, and each subsidiary within the business segments is, with some exceptions, managed by citizens of the country where it is located.

Segments of Business

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. Additional information required by this item is incorporated herein by reference to the narrative and tabular descriptions of segments and operating results under the caption "Management's Discussion and Analysis of Results of Operations and Financial Condition" and Note 18 "Segments of Business and Geographic Areas" under "Notes to Consolidated Financial Statements" of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K.

Consumer

The Consumer segment includes a broad range of products used in the baby care, oral care, skin care, over-the-counter pharmaceutical, women's health and wound care markets. Baby Care includes the JOHNSON'S® Baby line of products. Oral Care includes the LISTERINE® product line. Major brands in Skin Care include the AVEENO®; CLEAN & CLEAR®; DABAO™; JOHNSON'S® Adult; LE PETITE MARSEILLAIS®; LUBRIDERM®; NEUTROGENA®; and RoC® product lines. Over-the-counter medicines include the broad family of TYLENOL® acetaminophen products; SUDAFED® cold, flu and allergy products; BENADRYL® and ZYRTEC® allergy products; MOTRIN® IB ibuprofen products; and the PEPCID® line of heartburn products. Major brands in Women's Health outside of North America are STAYFREE® and CAREFREE® sanitary pad and o.b.® tampon brands. Wound Care brands include the BAND-AID® Brand Adhesive Bandages and NEOSPORIN® First Aid product lines. The principal nutritional line is SPLENDA® No Calorie Sweetener. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world.

Pharmaceutical

The Pharmaceutical segment is focused on five therapeutic areas, including immunology (e.g., rheumatoid arthritis, inflammatory bowel disease, psoriasis and pulmonary diseases), infectious diseases (e.g., HIV, hepatitis, respiratory infections, tuberculosis and vaccines), neuroscience (e.g., Alzheimer's disease, mood disorders, schizophrenia and pain), oncology (e.g., prostate cancer, multiple myeloma, hematologic malignancies and lung cancer), and cardiovascular and metabolic diseases (e.g., thrombosis and diabetes). Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. Key products in the Pharmaceutical segment include: REMICADE® (infliximab), a treatment for a number of immune-mediated inflammatory diseases; SIMPONI® (golimumab), a subcutaneous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis and moderately active to severely active ulcerative colitis; SIMPONI ARIA® (golimumab) an intravenous treatment for adults with moderate to severe rheumatoid arthritis; STELARA® (ustekinumab), a treatment for adults with moderate to severe plaque psoriasis and active psoriatic arthritis; INCIVO® (telaprevir), for the treatment of hepatitis C; OLYSIO®/SOVRIAD®(simeprevir), for combination treatment of chronic hepatitis C in adult patients; PREZISTA® (darunavir), a treatment for HIV/AIDS; EDURANT® (rilpivirine), for the treatment of HIV; CONCERTA® (methylphenidate HCl) extended-release tablets CII, a treatment for attention deficit hyperactivity disorder; INVEGA® (paliperidone) extended-release tablets, for the treatment of schizophrenia and schizoaffective disorder; INVEGA SUSTENNA®/XEPLION® (paliperidone palmitate), for the treatment of schizophrenia and schizoaffective disorder in adults; RISPERDAL CONSTA® (risperidone long-acting injection), for the treatment of schizophrenia and the maintenance treatment of Bipolar I Disorder in adults; VELCADE® (bortezomib), a treatment for multiple myeloma; ZYTIGA® (abiraterone acetate), a treatment for metastatic castration-resistant prostate cancer; IMBRUVICA® (ibrutinib), an oral, once-daily therapy approved for use in treating certain B-cell malignancies, or blood

cancers; PROCRIT® (epoetin alfa, sold outside the U.S. as EPREX®), to stimulate red blood cell production; XARELTO® (rivaroxaban), an oral anticoagulant for the prevention of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery, to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, for the treatment of DVT and PE, and for the reduction in the risk of recurrence of DVT and PE; and INVOKANA® (canagliflozin), for the treatment of adults with type 2 diabetes. Many of these products were developed in collaboration with strategic partners or are licensed from other companies.

Medical Devices

The Medical Devices (previously referred to as Medical Devices and Diagnostics) segment includes a broad range of products used in the orthopaedic, surgical care, specialty surgery, cardiovascular care, diagnostics, diabetes care, and vision care markets, which are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, and clinics. These include orthopaedic, trauma and neurological products; general surgery, biosurgical and energy products; products to treat cardiovascular disease; infection prevention products; diagnostics products; blood glucose monitoring and insulin delivery products; and disposable contact lenses. The Company completed the divestiture of its Ortho-Clinical Diagnostics business in June 2014.

Geographic Areas

The business of Johnson & Johnson is conducted by more than 265 operating companies located in 60 countries, including the U.S., which conduct business in virtually all countries throughout the world. The products made and sold in the international business include many of those described above under "- Segments of Business - Consumer," "- Pharmaceutical" and "- Medical Devices." However, the principal markets, products and methods of distribution in the international business vary with the country and the culture. The products sold in international business include not only those developed in the United States, but also those developed by subsidiaries abroad.

Investments and activities in some countries outside the U.S. are subject to higher risks than comparable U.S. activities because the investment and commercial climate may be influenced by financial instability in international economies, restrictive economic policies and political and legal system uncertainties.

Raw Materials

Raw materials essential to the Company's business are generally readily available from multiple sources. Where there are exceptions, the temporary unavailability of those raw materials would not likely have a material adverse effect on the financial results of the Company.

Patents

The Company's subsidiaries have made a practice of obtaining patent protection on their products and processes where possible. They own or are licensed under a number of patents relating to their products and manufacturing processes, which in the aggregate are believed to be of material importance to the Company in the operation of its businesses. Sales of the Company's largest product, REMICADE® (infliximab), accounted for approximately 9.2% of the Company's total revenues for fiscal 2014. Accordingly, the patents related to this product are believed to be material to the Company.

There are two sets of patents related to REMICADE® (infliximab). The first set of patents is co-owned by Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson, and NYU Langone Medical Center (NYU). Janssen Biotech, Inc. has an exclusive license to NYU's interests in the patents. Patents have been granted in the United States, certain countries in the European Union (certain of these patents have been extended by Supplementary Patent Certificates), and Australia. In the United States, the latest patent expires in September 2018. The patent expired in Canada in March 2012. In certain countries in Europe the patent was extended to February 2015 (Germany, Spain, United Kingdom, Sweden, Austria, Belgium, Switzerland, Denmark, France, Greece, Italy, Luxembourg and the Netherlands). In Australia, the patent expires in August 2015. In the United States, the patent expiring in 2018 is subject to reexamination proceedings instituted by a third party. Those proceedings are on-going.

The second set of patents related to REMICADE® was granted to the Kennedy Institute of Rheumatology in the United Kingdom in Europe, Canada, Australia and the United States. Janssen Biotech, Inc. has licenses (exclusive for human anti-TNF antibodies and semi-exclusive for non-human anti-TNF antibodies) to these patents that expire in 2017 outside of the United States and 2018 in the United States. The validity of these patents has been challenged. Certain claims have been invalidated and others are under review in various patent offices around the world and are also subject to litigation in Canada.

The Company does not expect that any additional extensions will be available for the patents related to REMICADE®. Loss of exclusivity will likely result in a reduction in sales as biosimilar versions of REMICADE® are introduced to the market.

For legal matters regarding the patents related to REMICADE®, see Note 21 "Legal Proceedings" under "Notes to Consolidated Financial Statements" of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K, under the heading "Intellectual Property - Pharmaceutical - REMICADE® Related Cases".

In addition to competing in the immunology market with REMICADE®, the Company is currently marketing STELARA® (ustekinumab), SIMPONI® (golimumab) and SIMPONI ARIA® (golimumab), next generation immunology products with remaining patent lives of up to nine years.

Trademarks

The Company's subsidiaries have made a practice of selling their products under trademarks and of obtaining protection for these trademarks by all available means. These trademarks are protected by registration in the United States and other countries where such products are marketed. The Company considers these trademarks in the aggregate to be of material importance in the operation of its businesses.

Seasonality

Worldwide sales do not reflect any significant degree of seasonality; however, spending has been heavier in the fourth quarter of each year than in other quarters. This reflects increased spending decisions, principally for advertising and research and development activity.

Competition

In all of their product lines, the Company's subsidiaries compete with companies both locally and globally, throughout the world. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, both internally and externally sourced, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products is important to the Company's success in all areas of its business. This also includes protecting the Company's portfolio of intellectual property. The competitive environment requires substantial investments in continuing research. In addition, the development and maintenance of customer demand for the Company's consumer products involves significant expenditures for advertising and promotion.

Research and Development

Research activities represent a significant part of the Company's businesses. Research and development expenditures relate to the processes of discovering, testing and developing new products, improving existing products, as well as demonstrating product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products. Worldwide costs of research and development activities amounted to $8.5 billion, $8.2 billion and $7.7 billion for fiscal years 2014, 2013 and 2012, respectively. Major research facilities are located not only in the United States, but also in Belgium, Brazil, Canada, China, France, Germany, India, Israel, Japan, the Netherlands, Singapore, Switzerland and the United Kingdom.

Environment

The Company is subject to a variety of U.S. and international environmental protection measures. The Company believes that its operations comply in all material respects with applicable environmental laws and regulations. The Company's compliance with these requirements did not during the past year, and is not expected to, have a material effect upon its capital expenditures, cash flows, earnings or competitive position.

Regulation

Most of the Company's businesses are subject to varying degrees of governmental regulation in the countries in which operations are conducted, and the general trend is toward increasingly stringent regulation. In the U.S., the drug, device, diagnostics and cosmetic industries have long been subject to regulation by various federal and state agencies, primarily as to product safety, efficacy, manufacturing, advertising, labeling and safety reporting. The exercise of broad regulatory powers by the U.S. Food and Drug Administration (the "FDA") continues to result in increases in the amounts of testing and documentation required for FDA clearance of new drugs and devices and a corresponding increase in the expense of product introduction. Similar trends are also evident in major markets outside of the U.S.

The costs of human health care have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. In the U.S., attention has been focused on drug prices and profits and programs that encourage doctors to write prescriptions for particular drugs or recommend, use or purchase particular medical devices. Payers have become a more potent force in the market place and increased attention is being paid to

drug and medical device pricing, appropriate drug and medical device utilization and the quality and costs of health care generally.

Following the U.S. Supreme Court decision in June 2012 upholding the Patient Protection and Affordable Care Act (the "ACA"), there has been an increase in the pace of regulatory issuances by those U.S. government agencies designated to carry out the extensive requirements of the ACA. These have both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of the ACA will ultimately affect the industry.

The regulatory agencies under whose purview the Company operates have administrative powers that may subject it to actions such as product withdrawals, recalls, seizure of products and other civil and criminal sanctions. In some cases, the Company's subsidiaries may deem it advisable to initiate product recalls.

In addition, business practices in the health care industry have come under increased scrutiny, particularly in the United States, by government agencies and state attorneys general, and resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Further, the Company relies on global supply chains, and production and distribution processes, that are complex, are subject to increasing regulatory requirements that may affect sourcing, supply and pricing of materials used in the Company's products, and which are subject to lengthy regulatory approvals.

Available Information

The Company's main corporate website address is *www.jnj.com*. Copies of the Company's Quarterly Reports on Form 10-Q, Annual Report on Form 10-K and Current Reports on Form 8-K filed or furnished to the U.S. Securities and Exchange Commission (the "SEC"), and any amendments to the foregoing, will be provided without charge to any shareholder submitting a written request to the Secretary at the principal executive offices of the Company or by calling 1-800-950-5089. All of the Company's SEC filings are also available on the Company's website at *www.investor.jnj.com/governance/sec-filings.cfm*, as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*. In addition, the written charters of the Audit Committee, the Compensation & Benefits Committee, the Nominating & Corporate Governance Committee, the Regulatory, Compliance & Government Affairs Committee and the Science, Technology & Sustainability Committee of the Board of Directors and the Company's Principles of Corporate Governance, Policy on Business Conduct for employees, Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers, and other corporate governance materials, are available at *www.investor.jnj.com/governance/materials.cfm* on the Company's website and will be provided without charge to any shareholder submitting a written request, as provided above. The information on the Company's website is not, and will not be deemed, a part of this Report on Form 10-K or incorporated into any other filings the Company makes with the SEC.

Item 1A. RISK FACTORS

The Company faces a number of uncertainties and risks that are difficult to predict and many of which are outside of the Company's control. In addition to the other information in this Report and the Company's other filings with the SEC, investors should consider carefully the factors set forth in Exhibit 99 to this Report on Form 10-K. Investors should realize that if known or unknown risks or uncertainties materialize, the Company's business, results of operations or financial condition could be adversely affected.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

The Company's subsidiaries operate 134 manufacturing facilities occupying approximately 21.5 million square feet of floor space. The manufacturing facilities are used by the industry segments of the Company's business approximately as follows:

Segment	Square Feet (in thousands)
Consumer	7,213
Pharmaceutical	7,404
Medical Devices	6,850
Worldwide Total	21,467

Within the United States, eight facilities are used by the Consumer segment, eight by the Pharmaceutical segment and 26 by the Medical Devices segment. The Company's manufacturing operations outside the United States are often conducted in facilities that serve more than one business segment.

In 2014, the divestiture of the Ortho-Clinical Diagnostics business resulted in the sale of eight manufacturing facilities, seven in the United States and one in Europe.

The locations of the manufacturing facilities by major geographic areas of the world are as follows:

Geographic Area	Number of Facilities	Square Feet (in thousands)
United States	42	5,892
Europe	41	7,673
Western Hemisphere, excluding U.S.	15	3,005
Africa, Asia and Pacific	36	4,897
Worldwide Total	134	21,467

In addition to the manufacturing facilities discussed above, the Company maintains numerous office and warehouse facilities throughout the world. Research facilities are also discussed in Item 1 under "Business — Research and Development."

The Company's subsidiaries generally seek to own their manufacturing facilities, although some, principally in non-U.S. locations, are leased. Office and warehouse facilities are often leased.

The Company is committed to maintaining all of its properties in good operating condition and repair, and the facilities are well utilized.

McNEIL-PPC, Inc. continues to operate under a consent decree, signed in 2011 with the FDA, which governs certain McNeil Consumer Healthcare manufacturing operations (the "Consent Decree"). The Consent Decree requires McNEIL-PPC to remediate the facilities it operates in Lancaster, Pennsylvania, Fort Washington, Pennsylvania, and Las Piedras, Puerto Rico. The Fort Washington facility, which was voluntarily shut down in April 2010, will remain shut down until a third-party current Good Manufacturing Practices (cGMP) expert certifies that its operations are in compliance with applicable law, and the FDA concurs with the third-party certification. Many products previously made in Fort Washington have been transferred to other manufacturing sites and successfully reintroduced to the market. The Lancaster and Las Piedras facilities continue to manufacture and distribute drugs with third-party oversight. Third-party oversight will cease once the FDA has determined that the facilities appear to be in compliance with applicable law. Each facility operating under the Consent Decree is subject to a five-year audit period by a third-party cGMP expert after the facility has been deemed by the FDA to be in apparent compliance with applicable law. McNeil has successfully completed all requirements contained in the Consent Decree Workplan for the Lancaster and Las Piedras manufacturing sites and has completed the steps required for third-party certification of the Fort Washington plant. In February 2015, the third-party cGMP expert submitted written certification to the FDA for all three manufacturing sites. The timeline for completion of any FDA inspection is within the FDA's discretion. A discussion of legal proceedings related to this matter can be found under the heading "Government Proceedings - McNeil Consumer Healthcare" in Note 21 "Legal Proceedings" under "Notes to Consolidated Financial Statements" of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K.

For information regarding lease obligations, see Note 16 "Rental Expense and Lease Commitments" under "Notes to Consolidated Financial Statements" of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K. Segment information on additions to property, plant and equipment is contained in Note 18 "Segments of Business and Geographic Areas" under "Notes to Consolidated Financial Statements" of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K.

Item 3. LEGAL PROCEEDINGS

The following information is incorporated herein by reference: the information set forth in Note 21 "Legal Proceedings" under "Notes to Consolidated Financial Statements" of the Annual Report filed as Exhibit 13 to this Report on Form 10-K.

In addition, Johnson & Johnson and its subsidiaries are from time to time party to government investigations, inspections or other proceedings relating to environmental matters, including their compliance with applicable environmental laws. In connection with a routine inspection of a subsidiary's manufacturing facility, the California Department of Toxic Substances Control alleged violation of regulations dealing with the handling of certain wastes. In the fourth quarter of 2014, the subsidiary entered into a settlement agreement with the State of California and agreed to perform certain remedial actions and pay approximately $400,000 to settle the claim.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

EXECUTIVE OFFICERS OF THE REGISTRANT

Listed below are the executive officers of the Company as of February 23, 2015. There are no family relationships between any of the executive officers, and there is no arrangement or understanding between any executive officer and any other person pursuant to which the executive officer was selected. At the annual meeting of the Board of Directors, the executive officers are elected by the Board to hold office for one year and until their respective successors are elected and qualified, or until earlier resignation or removal.

Information with regard to the Directors of the Company, including information for Alex Gorsky, is incorporated herein by reference to the material captioned "Item 1: Election of Directors" in the Proxy Statement.

Name	Age	Position
Dominic J. Caruso	57	Member, Executive Committee; Vice President, Finance; Chief Financial Officer(a)
Peter M. Fasolo	52	Member, Executive Committee; Vice President, Global Human Resources(b)
Alex Gorsky	54	Chairman, Board of Directors; Chairman, Executive Committee; Chief Executive Officer
Sandra E. Peterson	56	Member, Executive Committee; Group Worldwide Chairman(c)
Paulus Stoffels	53	Member, Executive Committee; Chief Scientific Officer; Worldwide Chairman, Pharmaceuticals(d)
Michael H. Ullmann	56	Member, Executive Committee; Vice President, General Counsel(e)

(a) Mr. D. J. Caruso joined the Company in 1999 when the Company acquired Centocor, Inc. At the time of that acquisition, he had been Senior Vice President, Finance of Centocor. Mr. Caruso was named Vice President, Finance of Ortho-McNeil Pharmaceutical, Inc., a subsidiary of the Company, in 2001 and Vice President, Group Finance of the Company's Medical Devices and Diagnostics Group in 2003. In 2005, Mr. Caruso was named Vice President of the Company's Group Finance organization. Mr. Caruso became a Member of the Executive Committee and Vice President, Finance and Chief Financial Officer in 2007.

(b) Dr. P. M. Fasolo joined the Company in 2004 as Vice President, Worldwide Human Resources for Cordis Corporation, a subsidiary of the Company. He was then named Vice President, Global Talent Management for the Company. He left Johnson & Johnson in 2007 to join Kohlberg Kravis Roberts & Co. as Chief Talent Officer. Dr. Fasolo returned to the Company in 2010 as the Vice President, Global Human Resources, and in 2011, he became a Member of the Executive Committee.

(c) Ms. S. E. Peterson joined the Company in 2012 as Group Worldwide Chairman and a Member of the Executive Committee, with responsibility for the Consumer Group of Companies, consumer medical device businesses in the Vision Care and Diabetes Care franchises, and functions such as Johnson & Johnson Supply Chain, Information

Technology, Wellness and Prevention and Global Strategic Design. Prior to joining Johnson & Johnson, Ms. Peterson had an extensive global career in healthcare, consumer goods and consulting. Most recently, she was Chairman and Chief Executive Officer of Bayer CropScience AG in Germany, previously serving as President and Chief Executive Officer of Bayer Medical Care and President of Bayer HealthCare AG's Diabetes Care Division. Before joining Bayer in 2005, Ms. Peterson held a number of leadership roles at Medco Health Solutions (previously known as Merck-Medco). Among her responsibilities was the application of information technology to healthcare systems.

(d) Dr. P. Stoffels joined the Company in 2002 with the acquisition of Virco and Tibotec, where he was Chief Executive Officer of Virco and Chairman of Tibotec. In 2005, he was appointed Company Group Chairman, Global Virology where he led the development of PREZISTA® and INTELENCE®, leading products for the treatment of HIV. In 2006, he assumed the role of Company Group Chairman, Pharmaceuticals, with responsibility for worldwide research and development for the Central Nervous System and Internal Medicine Franchises. Dr. Stoffels was appointed Global Head, Research & Development, Pharmaceuticals, in 2009, and in 2011 became Worldwide Chairman, Pharmaceuticals, with responsibility for the Company's therapeutic pipeline through global research and development and strategic business development. In 2012, Dr. Stoffels was also appointed Chief Scientific Officer, with responsibility for enterprise-wide innovation and product safety, and a Member of the Executive Committee.

(e) Mr. M. H. Ullmann joined the Company in 1989 as a corporate attorney in the Law Department. He was appointed Corporate Secretary in 1999 and served in that role until 2006. During that time, he also held various management positions in the Law Department. In 2006, he was named General Counsel, Medical Devices and Diagnostics. Mr. Ullmann was appointed Vice President, General Counsel and a Member of the Executive Committee in 2012.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

As of February 17, 2015, there were 162,062 record holders of common stock of the Company. Additional information called for by this item is incorporated herein by reference to: the material under the captions "Management's Discussion and Analysis of Results of Operations and Financial Condition - Liquidity and Capital Resources - Dividends"; "- Other Information - Common Stock Market Prices"; Note 17 "Common Stock, Stock Option Plans and Stock Compensation Agreements" under "Notes to Consolidated Financial Statements"; and "Shareholder Return Performance Graphs" under "Supporting Schedules" of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K; and Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters - Equity Compensation Plan Information" of this Report on Form 10-K.

Issuer Purchases of Equity Securities

On July 21, 2014, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's Common Stock. Share repurchases will take place on the open market from time to time based on market conditions. The repurchase program has no time limit and may be suspended for periods or discontinued at any time.

The following table provides information with respect to common stock purchases by the Company during the fiscal fourth quarter of 2014. Common stock purchases on the open market are made as part of a systematic plan to meet the needs of the Company's compensation programs. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal fourth quarter.

Period	Total Number of Shares Purchased[1]	Avg. Price Paid Per Share	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs[2]	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs[3]
September 29, 2014 through October 26, 2014	5,431,384	$ 100.16	4,610,000	-
October 27, 2014 through November 23, 2014	8,154,338	106.65	6,567,056	-
November 24, 2014 through December 28, 2014	12,593,034	106.63	5,423,816	-
Total	26,178,756		16,600,872	14,275,927

[1] During the fiscal fourth quarter of 2014, the Company repurchased an aggregate of 26,178,756 shares of Johnson & Johnson Common Stock in open-market transactions, of which 16,600,872 shares were purchased pursuant to the repurchase program that was publicly announced on July 21, 2014, and of which 9,577,884 shares were purchased in open-market transactions as part of a systematic plan to meet the needs of the Company's compensation programs.

(2) As of December 28, 2014, an aggregate of 33,683,058 shares were purchased for a total of $3.5 billion since the inception of the repurchase program announced on July 21, 2014.

(3) As of December 28, 2014, the maximum number of shares that may yet be purchased under the plan is 14,275,927 based on the closing price of Johnson & Johnson Common Stock on the New York Stock Exchange on December 26, 2014 of $105.06 per share.

Item 6. SELECTED FINANCIAL DATA

The information called for by this item is incorporated herein by reference to the "Summary of Operations and Statistical Data 2004-2014" under "Supporting Schedules" of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K.

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The information called for by this item is incorporated herein by reference to the narrative and tabular material under the caption "Management's Discussion and Analysis of Results of Operations and Financial Condition" of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The information called for by this item is incorporated herein by reference to the material under the caption "Management's Discussion and Analysis of Results of Operations and Financial Condition — Liquidity and Capital Resources — Financing and Market Risk" and Note 1 "Summary of Significant Accounting Policies — Financial Instruments" under "Notes to Consolidated Financial Statements" of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information called for by this item is incorporated herein by reference to the Audited Consolidated Financial Statements and Notes thereto and the material under the caption "Report of Independent Registered Public Accounting Firm" of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures. At the end of the period covered by this report, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Alex Gorsky, Chairman and Chief Executive Officer, and Dominic J. Caruso, Vice President, Finance and Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Gorsky and Caruso concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures were effective.

Management's Report on Internal Control Over Financial Reporting. The information called for by this item is incorporated herein by reference to the material under the caption "Management's Report on Internal Control Over Financial Reporting" of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K.

Changes in Internal Control Over Financial Reporting. During the fiscal quarter ended December 28, 2014, there were no changes in the Company's internal control over financial reporting identified in connection with the evaluation required under Rules 13a-15 and 15d-15 under the Exchange Act that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

The Company is implementing a multi-year, enterprise-wide initiative to integrate, simplify and standardize processes and systems for the human resources, information technology, procurement and finance functions. These are enhancements to support the growth of the Company's financial shared service capabilities and standardize financial systems. This initiative is not in response to any identified deficiency or weakness in the Company's internal control over financial reporting. In response

to this initiative, the Company has and will continue to align and streamline the design and operation of its financial control environment.

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information called for by this item is incorporated herein by reference to the material under the captions “Item 1: Election of Directors” and “Stock Ownership and Section 16 Compliance - Section 16(a) Beneficial Ownership Reporting Compliance” and the discussion of the Audit Committee under the caption “Corporate Governance - Standing Board Committees” in the Proxy Statement; and the material under the caption “Executive Officers of the Registrant” in Part I of this Report on
Form 10-K.

The Company’s Policy on Business Conduct, which covers all employees (including the Chief Executive Officer, Chief Financial Officer and Controller), meets the requirements of the SEC rules promulgated under Section 406 of the Sarbanes-Oxley Act of 2002. The Policy on Business Conduct is available on the Company’s website at *www.investor.jnj.com/governance/policies.cfm*, and copies are available to shareholders without charge upon written request to the Secretary at the Company’s principal executive offices. Any substantive amendment to the Policy on Business Conduct or any waiver of the Policy granted to the Chief Executive Officer, the Chief Financial Officer or the Controller will be posted on the Company’s website at *www.investor.jnj.com/governance.cfm* within five business days (and retained on the website for at least one year).

In addition, the Company has adopted a Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers. The Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers is available on the Company’s website at *www.investor.jnj.com/governance/policies.cfm*, and copies are available to shareholders without charge upon written request to the Secretary at the Company’s principal executive offices. Any substantive amendment to the Code or any waiver of the Code granted to any member of the Board of Directors or any executive officer will be posted on the Company’s website at *www.investor.jnj.com/governance.cfm* within five business days (and retained on the website for at least one year).

Item 11. EXECUTIVE COMPENSATION

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1: Election of Directors — Director Compensation - 2014," "Compensation Committee Report," “Compensation Discussion and Analysis” and "Executive Compensation Tables" in the Proxy Statement.

The material incorporated herein by reference to the material under the caption “Compensation Committee Report” in the Proxy Statement shall be deemed furnished, and not filed, in this Report on Form 10-K and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, as a result of this furnishing, except to the extent that the Registrant specifically incorporates it by reference.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Additional information called for by this item is incorporated herein by reference to the material under the captions “Stock Ownership and Section 16 Compliance” in the Proxy Statement and Note 17 “Common Stock, Stock Option Plans and Stock Compensation Agreements” under “Notes to Consolidated Financial Statements” of the Annual Report, filed as Exhibit 13 to this Report on Form 10-K.

Equity Compensation Plan Information

The following table provides certain information as of December 28, 2014 concerning the shares of the Company's Common Stock that may be issued under existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights	Weighted Average Exercise Price of Outstanding Options and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans[2][3]
Equity Compensation Plans Approved by Security Holders[1]	145,936,341	$55.80	529,841,040
Equity Compensation Plans Not Approved by Security Holders	-	-	-
Total	145,936,341	$55.80	529,841,040

(1) Included in this category are the following equity compensation plans which have been approved by the Company's shareholders: 2000 Stock Option Plan, 2005 Long-Term Incentive Plan and 2012 Long-Term Incentive Plan.

(2) This column excludes shares reflected under the column "Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights."

(3) The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information called for by this item is incorporated herein by reference to the material under the captions "Transactions with Related Persons" and "Corporate Governance - Director Independence" in the Proxy Statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information called for by this item is incorporated herein by reference to the material under the caption "Ratification of Appointment of Independent Registered Public Accounting Firm" in the Proxy Statement.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

1. *Financial Statements*

The following Audited Consolidated Financial Statements and Notes thereto and the material under the caption "Report of Independent Registered Public Accounting Firm" of the Annual Report are incorporated herein by reference and filed as Exhibit 13 to this Report on Form 10-K:

Consolidated Balance Sheets at end of Fiscal Years 2014 and 2013

Consolidated Statements of Earnings for Fiscal Years 2014, 2013 and 2012

Consolidated Statements of Comprehensive Income for Fiscal Years 2014, 2013 and 2012

Consolidated Statements of Equity for Fiscal Years 2014, 2013 and 2012

Consolidated Statements of Cash Flows for Fiscal Years 2014, 2013 and 2012

Notes to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

Schedules other than those listed above are omitted because they are not required or are not applicable.

2. *Exhibits Required to be Filed by Item 601 of Regulation S-K*

The information called for by this item is incorporated herein by reference to the Exhibit Index in this report.

SIGNATURES

Pursuant to the requirements of Section 13 of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 23, 2015

JOHNSON & JOHNSON

(Registrant)

By /s/ A. Gorsky

A. Gorsky, Chairman, Board of Directors,
and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

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Signature	Title	Date
/s/ A. Gorsky A. Gorsky	Chairman, Board of Directors, Chief Executive Officer, and Director (Principal Executive Officer)	February 23, 2015
/s/ D. J. Caruso D. J. Caruso	Chief Financial Officer (Principal Financial Officer)	February 23, 2015
/s/ S. J. Cosgrove S. J. Cosgrove	Controller (Principal Accounting Officer)	February 23, 2015
/s/ M. S. Coleman M. S. Coleman	Director	February 23, 2015
/s/ J. G. Cullen J. G. Cullen	Director	February 23, 2015
/s/ D. S. Davis D. S. Davis	Director	February 23, 2015
/s/ I. E. L. Davis I. E. L. Davis	Director	February 23, 2015

Signature	Title	Date
/s/ S. L. Lindquist S. L. Lindquist	Director	February 23, 2015
/s/ M. B. McClellan M. B. McClellan	Director	February 23, 2015
/s/ A. M. Mulcahy A. M. Mulcahy	Director	February 23, 2015
/s/ L. F. Mullin L. F. Mullin	Director	February 23, 2015
/s/ W. D. Perez W. D. Perez	Director	February 23, 2015
/s/ C. Prince C. Prince	Director	February 23, 2015
/s/ A. E. Washington A. E. Washington	Director	February 23, 2015
/s/ R. A. Williams R. A. Williams	Director	February 23, 2015

EXHIBIT INDEX

Reg. S-K Exhibit Table Item No.	Description of Exhibit
3(i)(a)	Restated Certificate of Incorporation effective April 26, 1990 — Incorporated herein by reference to Exhibit 3(a) of the Registrant's Form 10-K Annual Report for the year ended December 30, 1990.
3(i)(b)	Certificate of Amendment to the Restated Certificate of Incorporation of the Company effective May 20, 1992 — Incorporated herein by reference to Exhibit 3(a) of the Registrant's Form 10-K Annual Report for the year ended January 3, 1993.
3(i)(c)	Certificate of Amendment to the Restated Certificate of Incorporation of the Company effective May 21, 1996 — Incorporated herein by reference to Exhibit 3(a)(iii) of the Registrant's Form 10-K Annual Report for the year ended December 29, 1996.
3(i)(d)	Certificate of Amendment to the Restated Certificate of Incorporation of the Company effective May 22, 2001 — Incorporated herein by reference to Exhibit 3 of the Registrant's Form 10-Q Quarterly Report for the quarter ended July 1, 2001.
3(i)(e)	Certificate of Amendment to the Restated Certificate of Incorporation of the Company effective April 27, 2006 — Incorporated herein by reference to Exhibit 3(i) of the Registrant's Form 10-Q Quarterly Report for the quarter ended April 2, 2006.
3(ii)	By-Laws of the Company, as amended effective April 17, 2012 — Incorporated herein by reference to Exhibit 3.1 the Registrant's Form 8-K Current Report filed April 19, 2012.
4(a)	Upon the request of the Securities and Exchange Commission, the Registrant will furnish a copy of all instruments defining the rights of holders of long-term debt of the Registrant.
10(a)	2000 Stock Option Plan (as amended) — Incorporated herein by reference to Exhibit 10(b) of the Registrant's Form 10-K Annual Report for the year ended January 1, 2012.*
10(b)	2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 4 of the Registrant's S-8 Registration Statement filed with the Commission on May 10, 2005 (file no. 333-124785).*
10(c)	Form of Restricted Shares to Non-Employee Directors under the 2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 8-K Current Report filed August 25, 2005.*
10(d)	Form of Stock Option Certificate, Restricted Share Unit Certificate and Performance Share Unit Certificate under the 2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.1, 10.2 and 10.3 of the Registrant's Form 8-K Current Report filed January 13, 2012.*
10(e)	2012 Long-Term Incentive Plan — Incorporated herein by reference to Appendix A of the Registrant's Proxy Statement filed with the Commission on March 14, 2012 .*
10(f)	Form of Stock Option Certificate, Restricted Share Unit Certificate and Performance Share Unit Certificate under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.2, 10.3 and 10.4 of the Registrant's Form 10-Q Quarterly Report filed May 7, 2012.*
10(g)	Executive Incentive Plan (as amended) — Incorporated herein by reference to Exhibit 10(f) of the Registrant's Form 10-K Annual Report for the year ended December 31, 2000.*
10(h)	Domestic Deferred Compensation (Certificate of Extra Compensation) Plan — Incorporated herein by reference to Exhibit 10(g) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2003.*
10(i)	Amendments to the Certificate of Extra Compensation Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(j)	2009 Certificates of Long-Term Performance Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 27, 2009.*
10(k)	Amended and Restated Deferred Fee Plan for Directors — Incorporated herein by reference to Exhibit 10(k) of the Registrant's Form 10-K Annual Report for the year ended January 1, 2012.*
10(l)	Executive Income Deferral Plan (Amended and Restated) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*

Reg. S-K Exhibit Table Item No.	Description of Exhibit
10(m)	Excess Savings Plan — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the year ended December 29, 1996.*
10(n)	Amendments to the Johnson & Johnson Excess Savings Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(p) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(o)	Excess Benefit Plan (Supplemental Retirement Plan) — Incorporated herein by reference to Exhibit 10(h) of the Registrant's Form 10-K Annual Report for the year ended January 3, 1993.*
10(p)	Amendments to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(r) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(q)	Amendment to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies, effective as of January 1, 2015 — Filed with this document.*
10(r)	Executive Life Plan Agreement — Incorporated herein by reference to Exhibit 10(i) of the Registrant's Form 10-K Annual Report for the year ended January 3, 1993.*
10(s)	Johnson & Johnson Retirement Savings Plan, Johnson & Johnson Savings Plan for Union Represented Employees, and Johnson & Johnson Savings Plan - Incorporated herein by reference to Exhibits 99.1, 99.2 and 99.3 of the Registrant's Form S-8 filed with the Commission on May 6, 2013.*
10(t)	Employment Agreement for Dr. Paulus Stoffels - Incorporated herein by reference to Exhibit 10.2 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*
10(u)	Summary of Employment Arrangements for Sandra E. Peterson — Incorporated herein by reference to Exhibit 10(t) of the Registrant's Form 10-K Annual Report for the year ended December 30, 2012.*
10(v)	Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies, Amended and Restated as of October 1, 2014 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 28, 2014.*
12	Statement of Computation of Ratio of Earnings to Fixed Charges — Filed with this document.
13	The following sections of the Annual Report to Shareholders for fiscal year 2014, which are incorporated by reference in this report, are deemed "filed": "Management's Discussion and Analysis of Results of Operations and Financial Condition"; "Audited Consolidated Financial Statements"; "Supporting Schedules - Summary of Operations and Statistical Data 2004 - 2014"; and "Supporting Schedules - Shareholder Return Performance Graphs" - Filed with this document.
21	Subsidiaries - Filed with this document.
23	Consent of Independent Registered Public Accounting Firm — Filed with this document.
31(a)	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
31(b)	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
32(a)	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
32(b)	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
99	Cautionary Statement Pursuant to Private Securities Litigation Reform Act of 1995 — "Safe Harbor" for Forward-Looking Statements — Filed with this document.
101	XBRL (Extensible Business Reporting Language) The following materials from Johnson & Johnson's Annual Report on Form 10-K for the fiscal year-ended December 28, 2014, formatted in Extensive Business Reporting Language (XBRL): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Earnings, (iii) Consolidated Statements of Comprehensive Income, (iv) Consolidated Statements of Equity, (v) Consolidated Statements of Cash Flows, and (vi) Notes to the Consolidated Financial Statements.

* Management contract or compensatory plan.

A copy of any of the Exhibits listed above will be provided without charge to any shareholder submitting a written request specifying the desired exhibit(s) to the Secretary at the principal executive offices of the Company.

Exhibit “J13”

This is Exhibit “J13” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.
Arash Rouhi

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended January 3, 2016 **Commission file number 1-3215**

JOHNSON & JOHNSON

(Exact name of registrant as specified in its charter)

New Jersey	**22-1024240**
(State of incorporation)	(I.R.S. Employer Identification No.)
One Johnson & Johnson Plaza **New Brunswick, New Jersey**	**08933**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(732) 524-0400**

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT

Title of each class	Name of each exchange on which registered
Common Stock, Par Value $1.00	New York Stock Exchange
4.75% Notes Due November 2019	New York Stock Exchange
5.50% Notes Due November 2024	New York Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☑ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $276 billion.

On February 19, 2016, there were 2,759,359,192 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Parts I and III: Portions of registrant's proxy statement for its 2016 annual meeting of shareholders filed within 120 days after the close of the registrant's fiscal year (the "Proxy Statement"), are incorporated by reference to this report on Form 10-K (this "Report").

PART I

Item 1. BUSINESS

General

Johnson & Johnson and its subsidiaries (the "Company") have approximately 127,100 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. Johnson & Johnson is a holding company, which has more than 250 operating companies conducting business in virtually all countries of the world. The Company's primary focus is products related to human health and well-being. Johnson & Johnson was incorporated in the State of New Jersey in 1887.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Company's three business segments: Consumer, Pharmaceutical and Medical Devices. Within the strategic parameters provided by the Committee, senior management groups at U.S. and international operating companies are each responsible for their own strategic plans and the day-to-day operations of those companies. Each subsidiary within the business segments is, with limited exceptions, managed by residents of the country where located.

Segments of Business

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. Additional information required by this item is incorporated herein by reference to the narrative and tabular descriptions of segments and operating results under: Item 7 "Management's Discussion and Analysis of Results of Operations and Financial Condition" of this Report; and Note 18 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Consumer

The Consumer segment includes a broad range of products used in the baby care, oral care, skin care, over-the-counter pharmaceutical, women's health and wound care markets. Baby Care includes the JOHNSON'S® line of products. Oral Care includes the LISTERINE® product line. Major brands in Skin Care include the AVEENO®; CLEAN & CLEAR®; DABAO™; JOHNSON'S® Adult; LE PETITE MARSEILLAIS®; LUBRIDERM®; NEUTROGENA®; and RoC® product lines. Over-the-counter medicines include the broad family of TYLENOL® acetaminophen products; SUDAFED® cold, flu and allergy products; BENADRYL® and ZYRTEC® allergy products; MOTRIN® IB ibuprofen products; and the PEPCID® line of heartburn products. Major brands in Women's Health outside of North America are STAYFREE® and CAREFREE® sanitary pads and o.b.® tampon brands. Wound Care brands include the BAND-AID® Brand Adhesive Bandages and NEOSPORIN® First Aid product lines. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world.

Pharmaceutical

The Pharmaceutical segment is focused on five therapeutic areas: immunology (e.g., rheumatoid arthritis, inflammatory bowel disease and psoriasis), infectious diseases and vaccines (e.g., HIV, hepatitis, respiratory infections and tuberculosis), neuroscience (e.g., Alzheimer's disease, mood disorders and schizophrenia), oncology (e.g., prostate cancer, hematologic malignancies and lung cancer), and cardiovascular and metabolic diseases (e.g., thrombosis and diabetes). Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. Key products in the Pharmaceutical segment include: REMICADE® (infliximab), a treatment for a number of immune-mediated inflammatory diseases; SIMPONI® (golimumab), a subcutaneous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis and moderately active to severely active ulcerative colitis; SIMPONI ARIA® (golimumab), an intravenous treatment for adults with moderate to severe rheumatoid arthritis; STELARA® (ustekinumab), a treatment for adults with moderate to severe plaque psoriasis and active psoriatic arthritis, and for adolescents with moderate to severe psoriasis; OLYSIO®/SOVRIAD® (simeprevir), for combination treatment of chronic hepatitis C in adult patients; PREZISTA® (darunavir), EDURANT® (rilpivirine), and PREZCOBIX®/REZOLSTA® (darunavir/cobicistat), antiretroviral medicines for the treatment of human immunodeficiency virus (HIV-1) in combination with other antiretroviral products; SIRTURO® (bedaquiline), a diarylquinoline antimycobacterial drug indicated as part of combination therapy in adults (>18 years) with pulmonary multi-drug resistant tuberculosis (MDR-TB); CONCERTA® (methylphenidate HCl) extended-release tablets CII, a treatment for attention deficit hyperactivity disorder; INVEGA® (paliperidone) extended-release tablets, for the treatment of schizophrenia and schizoaffective disorder; INVEGA SUSTENNA®/XEPLION® (paliperidone palmitate), for the treatment of schizophrenia and schizoaffective disorder in adults; INVEGA TRINZA® (paliperidone palmitate), for the treatment of schizophrenia in patients after they have been adequately treated with INVEGA SUSTENNA® for at least four months; RISPERDAL CONSTA® (risperidone long-acting injection), for the treatment of

schizophrenia and the maintenance treatment of Bipolar 1 Disorder in adults; VELCADE® (bortezomib), a treatment for multiple myeloma and for use in combination with rituximab, cyclophosphamide, doxorubicin and prednisone for the treatment of adult patients with previously untreated mantle cell lymphoma; ZYTIGA® (abiraterone acetate), used in combination with prednisone as a treatment for metastatic castration-resistant prostate cancer; IMBRUVICA® (ibrutinib), an oral, once-daily therapy approved for use in treating certain B-cell malignancies, or blood cancers, and Waldenström's Macroglobulinemia; DARZALEX™ (daratumumab), for the treatment of double refractory multiple myeloma; YONDELIS® (trabectedin), for the treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen; PROCRIT® (epoetin alfa, sold outside the U.S. as EPREX®), to stimulate red blood cell production; XARELTO® (rivaroxaban), an oral anticoagulant for the prevention of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery, to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, for the treatment and reduction of risk of recurrence of DVT and PE; INVOKANA® (canagliflozin), for the treatment of adults with type 2 diabetes; and INVOKAMET®/VOKANAMET® (canagliflozin/metformin HCl), a combination therapy of fixed doses of canagliflozin and metformin hydrochloride for the treatment of adults with type 2 diabetes. Many of these medicines were developed in collaboration with strategic partners or are licensed from other companies and maintain active lifecycle development programs.

Medical Devices

The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, cardiovascular, diabetes care and vision care fields. These products are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics. They include orthopaedic products; general surgery, biosurgical, endomechanical and energy products; electrophysiology products to treat cardiovascular disease; sterilization and disinfection products to reduce surgical infection; diabetes care products, such as blood glucose monitoring and insulin delivery products; and disposable contact lenses.

Geographic Areas

The business of Johnson & Johnson is conducted by more than 250 operating companies located in 60 countries, including the U.S., in virtually all countries throughout the world. The products made and sold in the international business include many of those described above under "– Segments of Business – Consumer," "– Pharmaceutical" and "– Medical Devices." However, the principal markets, products and methods of distribution in the international business vary with the country and the culture. The products sold in international business include those developed in the United States and by subsidiaries abroad.

Investments and activities in some countries outside the U.S. are subject to higher risks than comparable U.S. activities because the investment and commercial climate may be influenced by financial instability in international economies, restrictive economic policies and political and legal system uncertainties.

Raw Materials

Raw materials essential to the Company's business are generally readily available from multiple sources. Where there are exceptions, the temporary unavailability of those raw materials would not likely have a material adverse effect on the financial results of the Company.

Patents

The Company's subsidiaries have made a practice of obtaining patent protection on their products and processes where possible. They own or are licensed under a number of patents relating to their products and manufacturing processes, which in the aggregate are believed to be of material importance to the Company in the operation of its businesses. Sales of the Company's largest product, REMICADE® (infliximab), accounted for approximately 9.4% of the Company's total revenues for fiscal 2015. Accordingly, the patents related to this product are believed to be material to the Company.

There are two sets of patents related specifically to REMICADE® (infliximab). The first set of patents is co-owned by Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson, and NYU Langone Medical Center (NYU). Janssen Biotech, Inc. has an exclusive license to NYU's interests in the patents. These patents have expired in all countries outside the United States. In the United States, the latest of these patents expires in September 2018 and this patent stands rejected and is subject to reexamination proceedings instituted by a third party in the United States Patent and Trademark Office. Those proceedings are on going.

The second set of patents specifically related to REMICADE® was granted to The Kennedy Institute of Rheumatology in Europe, Canada, Australia and the United States. Janssen Biotech, Inc. has licenses (exclusive for human anti-TNF antibodies and semi-exclusive for non-human anti-TNF antibodies) to these patents that expire in 2017 outside of the United

States and 2018 in the United States. The validity of these patents has been challenged. Certain claims have been invalidated and others are under review in various patent offices around the world and are also subject to litigation in Canada.

The Company does not expect that any additional extensions will be available for the above described patents specifically related to REMICADE®. If any of the REMICADE® related patents discussed above is found to be invalid, any such patent could not be relied upon to prevent the introduction of biosimilar versions of REMICADE®. For a more extensive description of legal matters regarding the patents related to REMICADE®, see Note 21 "Legal Proceedings – Intellectual Property – Pharmaceutical – REMICADE® Related Cases" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

In addition to competing in the immunology market with REMICADE®, the Company is currently marketing STELARA® (ustekinumab), SIMPONI® (golimumab) and SIMPONI ARIA® (golimumab), next generation immunology products with remaining patent lives of up to eight years.

Trademarks

The Company's subsidiaries have made a practice of selling their products under trademarks and of obtaining protection for these trademarks by all available means. These trademarks are protected by registration in the United States and other countries where such products are marketed. The Company considers these trademarks in the aggregate to be of material importance in the operation of its businesses.

Seasonality

Worldwide sales do not reflect any significant degree of seasonality; however, spending has been heavier in the fourth quarter of each year than in other quarters. This reflects increased spending decisions, principally for advertising and research and development activity.

Competition

In all of their product lines, the Company's subsidiaries compete with companies both locally and globally. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, both internally and externally sourced, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products, as well as protecting the underlying intellectual property of the Company's product portfolio, is important to the Company's success in all areas of its business. The competitive environment requires substantial investments in continuing research. In addition, the development and maintenance of customer demand for the Company's consumer products involve significant expenditures for advertising and promotion.

Research and Development

Research activities represent a significant part of the Company's businesses. Research and development expenditures relate to the processes of discovering, testing and developing new products, improving existing products, as well as demonstrating product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products. Worldwide costs of research and development activities amounted to $9.0 billion, $8.5 billion and $8.2 billion for fiscal years 2015, 2014 and 2013, respectively. Research facilities are located in the United States, Belgium, Brazil, Canada, China, France, Germany, India, Israel, Japan, the Netherlands, Singapore, Switzerland and the United Kingdom.

Environment

The Company is subject to a variety of U.S. and international environmental protection measures. The Company believes that its operations comply in all material respects with applicable environmental laws and regulations. The Company's compliance with these requirements did not change during the past year, and is not expected to have a material effect upon its capital expenditures, cash flows, earnings or competitive position.

Regulation

The Company's businesses are subject to varying degrees of governmental regulation in the countries in which operations are conducted, and the general trend is toward increasingly stringent regulation. In the U.S., the drug, device and cosmetic industries have long been subject to regulation by various federal and state agencies, primarily as to product safety, efficacy, manufacturing, advertising, labeling and safety reporting. The exercise of broad regulatory powers by the U.S. Food and Drug Administration (the "FDA") continues to result in increases in the amounts of testing and documentation required for

FDA approval of new drugs and devices and a corresponding increase in the expense of product introduction. Similar trends are also evident in major markets outside of the U.S.

The costs of human health care have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. In the U.S., attention has been focused on drug prices and profits and programs that encourage doctors to write prescriptions for particular drugs, or to recommend, use or purchase particular medical devices. Payers have become a more potent force in the market place and increased attention is being paid to drug and medical device pricing, appropriate drug and medical device utilization and the quality and costs of health care generally.

U.S. government agencies continue to implement the extensive requirements of the Patient Protection and Affordable Care Act (the "ACA"). These have both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of the ACA will ultimately affect the industry.

The regulatory agencies under whose purview the Company operates have administrative powers that may subject it to actions such as product withdrawals, recalls, seizure of products and other civil and criminal sanctions. In some cases, the Company's subsidiaries may deem it advisable to initiate product recalls.

In addition, business practices in the health care industry have come under increased scrutiny, particularly in the United States, by government agencies and state attorneys general, and resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Further, the Company relies on global supply chains, and production and distribution processes, that are complex, are subject to increasing regulatory requirements that may affect sourcing, supply and pricing of materials used in the Company's products. These processes also are subject to lengthy regulatory approvals.

Available Information

The Company's main corporate website address is *www.jnj.com*. Copies of the Company's Quarterly Reports on Form 10-Q, Annual Report on Form 10-K and Current Reports on Form 8-K filed or furnished to the U.S. Securities and Exchange Commission (the "SEC"), and any amendments to the foregoing, will be provided without charge to any shareholder submitting a written request to the Secretary at the principal executive offices of the Company or by calling 1-800-950-5089. All of the Company's SEC filings are also available on the Company's website at *www.investor.jnj.com/gov/sec-filings.cfm*, as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*. In addition, the written charters of the Audit Committee, the Compensation & Benefits Committee, the Nominating & Corporate Governance Committee, the Regulatory, Compliance & Government Affairs Committee and the Science, Technology & Sustainability Committee of the Board of Directors and the Company's Principles of Corporate Governance, Code of Business Conduct (for employees), Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers, and other corporate governance materials, are available at *www.investor.jnj.com/gov/materials.cfm* on the Company's website and will be provided without charge to any shareholder submitting a written request, as provided above. The information on the Company's website is not, and will not be deemed, a part of this Report or incorporated into any other filings the Company makes with the SEC.

Item 1A. RISK FACTORS

The Company faces a number of uncertainties and risks that are difficult to predict and many of which are outside of the Company's control. In addition to the other information in this Report and the Company's other filings with the SEC, investors should consider carefully the factors set forth in Exhibit 99 to this Report. Investors should realize that if known or unknown risks or uncertainties materialize, the Company's business, results of operations or financial condition could be adversely affected.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES 590

The Company's subsidiaries operate 121 manufacturing facilities occupying approximately 21.3 million square feet of floor space. The manufacturing facilities are used by the industry segments of the Company's business approximately as follows:

Segment	Square Feet (in thousands)
Consumer	6,942
Pharmaceutical	7,435
Medical Devices	6,919
Worldwide Total	21,296

Within the United States, eight facilities are used by the Consumer segment, eight by the Pharmaceutical segment and 20 by the Medical Devices segment. Outside of the United States, 30 facilities are used by the Consumer segment, 18 by the Pharmaceutical segment and 37 by the Medical Devices segment.

The locations of the manufacturing facilities by major geographic areas of the world are as follows:

Geographic Area	Number of Facilities	Square Feet (in thousands)
United States	36	5,808
Europe	38	7,917
Western Hemisphere, excluding U.S.	14	2,815
Africa, Asia and Pacific	33	4,756
Worldwide Total	121	21,296

In addition to the manufacturing facilities discussed above, the Company maintains numerous office and warehouse facilities throughout the world. Research facilities are also discussed in Item 1 of this Report under "Business – Research and Development."

The Company's subsidiaries generally seek to own their manufacturing facilities, although some, principally in non-U.S. locations, are leased. Office and warehouse facilities are often leased. The Company also engages contract manufacturers.

The Company is committed to maintaining all of its properties in good operating condition and repair, and the facilities are well utilized.

McNEIL-PPC, Inc. (now Johnson & Johnson Consumer Inc.) (McNEIL-PPC) continues to operate under a consent decree, signed in 2011 with the FDA, which governs certain McNeil Consumer Healthcare manufacturing operations, and requires McNEIL-PPC to remediate the facilities it operates in Lancaster, Pennsylvania, Fort Washington, Pennsylvania, and Las Piedras, Puerto Rico (the "Consent Decree"). The Fort Washington facility was voluntarily shut down in April 2010, and subsequently many products were transferred to other manufacturing sites and successfully reintroduced to the market. After McNEIL-PPC successfully completed all requirements contained in the Consent Decree Workplans for the Lancaster and Las Piedras manufacturing sites and completed the steps required for third-party certification of the Fort Washington plant, a third-party cGMP expert submitted written certifications to the FDA for all three manufacturing sites. Following FDA inspections in 2015, McNEIL-PPC received notifications from the FDA that all three manufacturing facilities are in conformity with applicable laws and regulations. Commercial production in Fort Washington started as of September 2015.

Under the Consent Decree, after receiving notice from the FDA of being in compliance with applicable laws and regulations, each of the three facilities is subject to a five-year audit period by a third-party cGMP expert. Thus, a third-party expert will continue to reassess the sites at various times for at least five years. A discussion of legal proceedings related to this matter can be found in Note 21 "Legal Proceedings – Government Proceedings – McNeil Consumer Healthcare" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

For information regarding lease obligations, see Note 16 "Rental Expense and Lease Commitments" of the Notes to Consolidated Financial Statements included in Item 8 of this Report. Segment information on additions to property, plant and equipment is contained in Note 18 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 3. LEGAL PROCEEDINGS

The information called for by this item is incorporated herein by reference to the information set forth in Note 21 "Legal Proceedings" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

In addition, Johnson & Johnson and its subsidiaries are from time to time party to government investigations, inspections or other proceedings relating to environmental matters, including their compliance with applicable environmental laws.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

EXECUTIVE OFFICERS OF THE REGISTRANT

Listed below are the executive officers of the Company as of February 23, 2016. There are no family relationships between any of the executive officers, and there is no arrangement or understanding between any executive officer and any other person pursuant to which the executive officer was selected. At the annual meeting of the Board of Directors, the executive officers are elected by the Board to hold office for one year and until their respective successors are elected and qualified, or until earlier resignation or removal.

Information with regard to the Directors of the Company, including information for Alex Gorsky, is incorporated herein by reference to the material captioned "Item 1: Election of Directors" in the Proxy Statement.

Name	Age	Position
Dominic J. Caruso	58	Member, Executive Committee; Vice President, Finance; Chief Financial Officer(a)
Peter M. Fasolo	53	Member, Executive Committee; Vice President, Global Human Resources(b)
Alex Gorsky	55	Chairman, Board of Directors; Chairman, Executive Committee; Chief Executive Officer
Sandra E. Peterson	57	Member, Executive Committee; Group Worldwide Chairman(c)
Paulus Stoffels	54	Member, Executive Committee; Chief Scientific Officer; Worldwide Chairman, Pharmaceuticals(d)
Michael H. Ullmann	57	Member, Executive Committee; Vice President, General Counsel(e)

(a) Mr. D. J. Caruso joined the Company in 1999 when the Company acquired Centocor, Inc. At the time of that acquisition, he had been Senior Vice President, Finance of Centocor. Mr. Caruso was named Vice President, Finance of Ortho-McNeil Pharmaceutical, Inc., a subsidiary of the Company, in 2001 and Vice President, Group Finance of the Company's Medical Devices and Diagnostics Group in 2003. In 2005, Mr. Caruso was named Vice President of the Company's Group Finance organization. Mr. Caruso became a Member of the Executive Committee and Vice President, Finance and Chief Financial Officer in 2007.

(b) Dr. P. M. Fasolo joined the Company in 2004 as Vice President, Worldwide Human Resources for Cordis Corporation, a subsidiary of the Company. He was then named Vice President, Global Talent Management for the Company. He left Johnson & Johnson in 2007 to join Kohlberg Kravis Roberts & Co. as Chief Talent Officer. Dr. Fasolo returned to the Company in 2010 as the Vice President, Global Human Resources, and in 2011, he became a Member of the Executive Committee.

(c) Ms. S. E. Peterson joined the Company in 2012 as Group Worldwide Chairman and a Member of the Executive Committee, with responsibility for the Consumer Group of Companies, consumer medical device businesses in the Vision Care and Diabetes Care franchises, and functions such as Johnson & Johnson Supply Chain, Information Technology, Wellness and Prevention and Global Strategic Design. Prior to joining Johnson & Johnson, Ms. Peterson had an extensive global career in healthcare, consumer goods and consulting. Most recently, she was Chairman and Chief Executive Officer of Bayer CropScience AG in Germany, previously serving as President and Chief Executive Officer of Bayer Medical Care and President of Bayer HealthCare AG's Diabetes Care Division. Before joining Bayer in 2005, Ms. Peterson held a number of leadership roles at Medco Health Solutions (previously known as Merck-Medco). Among her responsibilities was the application of information technology to healthcare systems.

(d) Dr. P. Stoffels joined the Company in 2002 with the acquisition of Virco and Tibotec, where he was Chief Executive Officer of Virco and Chairman of Tibotec. In 2005, he was appointed Company Group Chairman, Global Virology where he led the development of PREZISTA® and INTELENCE®, leading products for the treatment of HIV. In 2006, he assumed the role of Company Group Chairman, Pharmaceuticals, with responsibility for worldwide research and development for the Central Nervous System and Internal Medicine Franchises. Dr. Stoffels was appointed Global Head, Research & Development, Pharmaceuticals, in 2009, and in 2011 became Worldwide Chairman, Pharmaceuticals, with responsibility for the Company's therapeutic pipeline through global research and development and strategic business development. In 2012, Dr. Stoffels was also appointed Chief Scientific Officer, with responsibility for enterprise-wide innovation and product safety, and a Member of the Executive Committee.

(e) Mr. M. H. Ullmann joined the Company in 1989 as a corporate attorney in the Law Department. He was appointed Corporate Secretary in 1999 and served in that role until 2006. During that time, he also held various management positions in the Law Department. In 2006, he was named General Counsel, Medical Devices and Diagnostics. Mr. Ullmann was appointed Vice President, General Counsel and a Member of the Executive Committee in 2012.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

As of February 19, 2016, there were 158,749 record holders of common stock of the Company. Additional information called for by this item is incorporated herein by reference to the following sections of this Report: Item 7 "Management's Discussion and Analysis of Results of Operations and Financial Condition – Liquidity and Capital Resources – Dividends" and "— Other Information Common Stock Market Prices"; Note 17 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements included in Item 8; and Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters – Equity Compensation Plan Information".

Issuer Purchases of Equity Securities

On October 13, 2015, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $10.0 billion of the Company's Common Stock. Share repurchases take place on the open market from time to time based on market conditions. The repurchase program has no time limit and may be suspended for periods or discontinued at any time.

The following table provides information with respect to common stock purchases by the Company during the fiscal fourth quarter of 2015. Common stock purchases on the open market are made as part of a systematic plan to meet the needs of the Company's compensation programs. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal fourth quarter.

Period	Total Number of Shares Purchased[1]	Avg. Price Paid Per Share	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs[2]	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs[3]
September 28, 2015 through October 25, 2015	1,134,367	$ 96.45	-	-
October 26, 2015 through November 22, 2015	6,298,421	100.21	5,408,965	-
November 23, 2015 through January 3, 2016	11,330,068	102.30	4,462,352	-
Total	18,762,856		9,871,317	87,618,945

(1) During the fiscal fourth quarter of 2015, the Company repurchased an aggregate of 18,762,856 shares of Johnson & Johnson Common Stock in open-market transactions, of which 9,871,317 shares were purchased pursuant to the repurchase program that was publicly announced on October 13, 2015, and of which 8,891,539 shares were purchased in open-market transactions as part of a systematic plan to meet the needs of the Company's compensation programs.

(2) As of January 3, 2016, an aggregate of 9,871,317 shares were purchased for a total of $1.0 billion since the inception of the repurchase program announced on October 13, 2015.

(3) As of January 3, 2016, the maximum number of shares that may yet be purchased under the plan is 87,618,945 based on the closing price of Johnson & Johnson Common Stock on the New York Stock Exchange on December 31, 2015 of $102.72 per share.

Item 6. SELECTED FINANCIAL DATA

Summary of Operations and Statistical Data 2005-2015

(Dollars in Millions Except Per Share Amounts)	2015	2014	2013	2012	2011	2010	2009	2008	2007	2006	2005
Sales to customers — U.S.	$35,687	34,782	31,910	29,830	28,908	29,450	30,889	32,309	32,444	29,775	28,377
Sales to customers — International	34,387	39,549	39,402	37,394	36,122	32,137	31,008	31,438	28,651	23,549	22,137
Total sales	70,074	74,331	71,312	67,224	65,030	61,587	61,897	63,747	61,095	53,324	50,514
Cost of products sold	21,536	22,746	22,342	21,658	20,360	18,792	18,447	18,511	17,751	15,057	14,010
Selling, marketing and administrative expenses	21,203	21,954	21,830	20,869	20,969	19,424	19,801	21,490	20,451	17,433	17,211
Research and development expense	9,046	8,494	8,183	7,665	7,548	6,844	6,986	7,577	7,680	7,125	6,462
In-process research and development	224	178	580	1,163	—	—	—	181	807	559	362
Interest income	(128)	(67)	(74)	(64)	(91)	(107)	(90)	(361)	(452)	(829)	(487)
Interest expense, net of portion capitalized	552	533	482	532	571	455	451	435	296	63	54
Other (income) expense, net	(2,064)	(70)	2,498	1,626	2,743	(768)	(526)	(1,015)	534	(671)	(214)
Restructuring	509	—	—	—	569	—	1,073	—	745	—	—
	50,878	53,768	55,841	53,449	52,669	44,640	46,142	46,818	47,812	38,737	37,398
Earnings before provision for taxes on income	$19,196	20,563	15,471	13,775	12,361	16,947	15,755	16,929	13,283	14,587	13,116
Provision for taxes on income	3,787	4,240	1,640	3,261	2,689	3,613	3,489	3,980	2,707	3,534	3,056
Net earnings	15,409	16,323	13,831	10,514	9,672	13,334	12,266	12,949	10,576	11,053	10,060
Add: Net loss attributable to noncontrolling interest	—	—	—	339	—	—	—	—	—	—	—
Net earnings attributable to Johnson & Johnson	15,409	16,323	13,831	10,853	9,672	13,334	12,266	12,949	10,576	11,053	10,060
Percent of sales to customers	22.0%	22.0	19.4	16.1	14.9	21.7	19.8	20.3	17.3	20.7	19.9
Diluted net earnings per share of common stock [1]	$5.48	5.70	4.81	3.86	3.49	4.78	4.40	4.57	3.63	3.73	3.35
Percent return on average shareholders' equity	21.9%	22.7	19.9	17.8	17.0	24.9	26.4	30.2	25.6	28.3	28.2
Percent increase (decrease) over previous year:											
Sales to customers	(5.7)%	4.2	6.1	3.4	5.6	(0.5)	(2.9)	4.3	14.6	5.6	6.7
Diluted net earnings per share	(3.9)%	18.5	24.6	10.6	(27.0)	8.6	(3.7)	25.9	(2.7)	11.3	22.3
Supplementary balance sheet data:											
Property, plant and equipment, net	15,905	16,126	16,710	16,097	14,739	14,553	14,759	14,365	14,185	13,044	10,830
Additions to property, plant and equipment	3,463	3,714	3,595	2,934	2,893	2,384	2,365	3,066	2,942	2,666	2,632
Total assets[2]	133,411	130,358	131,754	121,347	113,644	102,908	94,682	84,912	80,954	70,556	58,864
Long-term debt	12,857	15,122	13,328	11,489	12,969	9,156	8,223	8,120	7,074	2,014	2,017
Operating cash flow	19,279	18,471	17,414	15,396	14,298	16,385	16,571	14,972	15,022	14,248	11,799
Common stock information											
Dividends paid per share	$2.95	2.76	2.59	2.40	2.25	2.11	1.93	1.795	1.62	1.455	1.275
Shareholders' equity per share	25.82	25.06	26.25	23.33	20.95	20.66	18.37	15.35	15.25	13.59	13.01
Market price per share (year-end close)	$102.72	105.06	92.35	69.48	65.58	61.85	64.41	58.56	67.38	66.02	60.10
Average shares outstanding (millions)											
— basic	2,771.8	2,815.2	2,809.2	2,753.3	2,736.0	2,751.4	2,759.5	2,802.5	2,882.9	2,936.4	2,973.9
— diluted	2,812.9	2,863.9	2,877.0	2,812.6	2,775.3	2,788.8	2,789.1	2,835.6	2,910.7	2,961.0	3,002.8
Employees (thousands)	127.1	126.5	128.1	127.6	117.9	114.0	115.5	118.7	119.2	122.2	115.6

[1] Attributable to Johnson & Johnson. [2] Amounts have been reclassified to conform to current year presentation.

Organization and Business Segments

Description of the Company and Business Segments

Johnson & Johnson and its subsidiaries (the Company) have approximately 127,100 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. The Consumer segment includes a broad range of products used in the baby care, oral care, skin care, over-the-counter pharmaceutical, women's health and wound care markets. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on five therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, and cardiovascular and metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, cardiovascular, diabetes care and vision care fields which are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Consumer, Pharmaceutical and Medical Devices business segments.

In all of its product lines, the Company competes with companies both locally and globally, throughout the world. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products, as well as protecting the underlying intellectual property of the Company's product portfolio, is important to the Company's success in all areas of its business. The competitive environment requires substantial investments in continuing research. In addition, the development and maintenance of customer demand for the Company's consumer products involves significant expenditures for advertising and promotion.

Management's Objectives

The Company manages within a strategic framework with Our Credo as the foundation. The Company believes that our strategic operating principles: being broadly based in human health care, managing the business for the long term, having a decentralized management approach, and being committed to our people and values, are crucial to successfully meeting the demands of the rapidly evolving markets in which we compete. To this end, management is focused on our long-term strategic growth drivers: creating value through innovation, expanding our global reach with a local focus, excellence in execution and leading with purpose.

The Company is broadly based in human health care, and is committed to creating value by developing accessible, high quality, innovative products and services. New products introduced within the past five years accounted for approximately 25% of 2015 sales. In 2015, $9.0 billion, or 12.9% of sales, was invested in research and development, reflecting management's commitment to delivering new and differentiated products and services to meet evolving health care needs and sustain the Company's long-term growth.

Our diverse businesses with more than 250 operating companies located in 60 countries are the key drivers of the Company's success. Maintaining the Company's decentralized management approach, while at the same time leveraging the extensive resources of the enterprise, positions the Company well to innovate, execute strategic plans and reach markets globally, as well as address the needs and challenges of the local markets.

In order to remain a leader in health care, the Company strives to maintain a purpose-driven organization and is committed to developing global business leaders who can achieve these growth objectives. Businesses are managed for the long-term in order to sustain market leadership positions and enable growth, which provides an enduring source of value to our shareholders.

Our Credo unifies all Johnson & Johnson employees in achieving these objectives, and provides a common set of values that serve as the foundation of the Company's responsibilities to patients, consumers and health care professionals, employees, communities and shareholders. The Company believes that these foundational values, its strategic framework and long-term growth drivers, along with its overall mission of improving the quality of life for people around the world, will enable Johnson & Johnson to continue to be a leader in the health care industry.

Results of Operations

Analysis of Consolidated Sales

In 2015, worldwide sales decreased 5.7% to $70.1 billion, compared to increases of 4.2% in 2014 and 6.1% in 2013. These sales changes consisted of the following:

Sales increase/(decrease) due to:	2015	2014	2013
Volume	1.2 %	6.3	7.6
Price	0.6	(0.2)	0.1
Currency	(7.5)	(1.9)	(1.6)
Total	**(5.7)%**	**4.2**	**6.1**

In 2015, the introduction of competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a negative impact of 2.7% on the worldwide operational sales growth. In 2015, the impact of acquisitions and divestitures on the worldwide operational sales growth was negative 2.0%.

In 2014, sales of the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a positive impact of 2.8%, and the divestiture of the Ortho-Clinical Diagnostics business had a negative impact of 1.4% on the worldwide operational growth. In 2013, the acquisition of Synthes, Inc., net of the related divestiture, increased worldwide operational growth by 2.5%.

Sales by U.S. companies were $35.7 billion in 2015, $34.8 billion in 2014 and $31.9 billion in 2013. This represents increases of 2.6% in 2015, 9.0% in 2014 and 7.0% in 2013. Sales by international companies were $34.4 billion in 2015, $39.5 billion in 2014 and $39.4 billion in 2013. This represents a decrease of 13.1% in 2015, and increases of 0.4% in 2014 and 5.4% in 2013.

The five-year compound annual growth rates for worldwide, U.S. and international sales were 2.6%, 3.9% and 1.4%, respectively. The ten-year compound annual growth rates for worldwide, U.S. and international sales were 3.3%, 2.3% and 4.5%, respectively.

Sales by companies in Europe experienced a decline of 15.6% as compared to the prior year, including operational growth of 1.1%, offset by a negative currency impact of 16.7%. Sales by companies in the Western Hemisphere (excluding the U.S.) experienced a decline of 15.6% as compared to the prior year, including operational growth of 2.6% offset by a negative currency impact of 18.2%. Sales by companies in the Asia-Pacific, Africa region experienced a decline of 8.1% as compared to the prior year, including operational growth of 0.3% and a negative currency impact of 8.4%.

2015 results benefited from the inclusion of a 53rd week. (See Note 1 to the Consolidated Financial Statements for Annual Closing Date details). The Company estimated that the fiscal year 2015 growth rate was enhanced by approximately 1.0%. While the additional week added a few days to sales, it also added a full week's worth of operating costs; therefore, the net earnings impact was negligible.

In 2015 and 2014, the Company had one wholesaler distributing products for all three segments that represented approximately 12.5% and 11.0%, respectively, of the total consolidated revenues. In 2013, the Company did not have a customer that represented 10% or more of total consolidated revenues.

U.S. Health Care Reform

On July 28, 2014, the Internal Revenue Service issued final regulations for the Branded Prescription Drug Fee, an annual non-tax deductible fee imposed on entities engaged in the business of manufacturing or importing branded prescription drugs (covered entities), enacted by Section 9008 of the Patient Protection and Affordable Care Act. The final regulations accelerated the expense recognition criteria for the fee obligation by one year, from the year in which the fee is paid to the year in which the sales used to calculate the fee occur. This change impacted covered entities and resulted in the need for all entities to record an additional expense in 2014 for the fee that would have otherwise been expensed when paid in 2015. The Company accrued an additional $220 million in the fiscal third quarter of 2014 due to this change. The fee associated with this accelerated expense was paid, as scheduled, in 2015 and had no cash impact in 2014.

Analysis of Sales by Business Segments
Consumer Segment
Consumer segment sales in 2015 were $13.5 billion, a decrease of 6.8% from 2014, which included 2.7% operational growth offset by a negative currency impact of 9.5%. U.S. Consumer segment sales were $5.2 billion, an increase of 2.5%. International sales were $8.3 billion, a decrease of 11.9%, which included 2.7% operational growth offset by a negative currency impact of 14.6%. In 2015, divestitures had a negative impact of 1.4% on the worldwide Consumer segment operational growth.

Major Consumer Franchise Sales:

				% Change	
(Dollars in Millions)	**2015**	**2014**	**2013**	**'15 vs. '14**	**'14 vs. '13**
OTC	$ 3,975	4,106	4,028	(3.2)%	1.9
Skin Care	3,531	3,758	3,704	(6.0)	1.5
Baby Care	2,044	2,239	2,295	(8.7)	(2.4)
Oral Care	1,580	1,647	1,622	(4.1)	1.5
Women's Health	1,200	1,302	1,568	(7.8)	(17.0)
Wound Care/Other	1,177	1,444	1,480	(18.5)	(2.4)
Total Consumer Sales	**$ 13,507**	**14,496**	**14,697**	**(6.8)%**	**(1.4)**

The Over-the-Counter (OTC) franchise sales of $4.0 billion decreased 3.2% as compared to the prior year, which included 8.1% operational growth and a negative currency impact of 11.3%. Operational growth was primarily driven by analgesics, upper respiratory, including ZYRTEC®, and digestive health products.

McNEIL-PPC, Inc. (now Johnson & Johnson Consumer Inc.) (McNEIL-PPC) continues to operate under a consent decree, signed in 2011 with the U.S. Food and Drug Administration (FDA), which governs certain McNeil Consumer Healthcare manufacturing operations and requires McNEIL-PPC to remediate the facilities it operates in Lancaster, Pennsylvania; Fort Washington, Pennsylvania; and Las Piedras, Puerto Rico (the Consent Decree). In February 2015, a third-party expert submitted written certification to the FDA for all three manufacturing sites. Following FDA inspections in 2015, McNEIL-PPC received notifications from the FDA that all three manufacturing facilities are in conformity with applicable laws and regulations. Under the Consent Decree, after receiving notice from the FDA of being in compliance with applicable laws and regulations, each of the three facilities is subject to a five-year audit period by a third-party cGMP expert. Thus, a third-party expert will continue to reassess the sites at various times for at least five years.

The Skin Care franchise sales of $3.5 billion decreased 6.0% as compared to the prior year, which included 1.3% operational growth and a negative currency impact of 7.3%. Operational growth was primarily due to sales growth of NEUTROGENA® and AVEENO® products partially offset by lower sales in China.

The Baby Care franchise sales were $2.0 billion in 2015, a decrease of 8.7% compared to the prior year, which included 1.2% operational growth and a negative currency impact of 9.9%. Operational growth was primarily due to new product launches partially offset by competition in China.

The Oral Care franchise sales were $1.6 billion in 2015, a decrease of 4.1% as compared to the prior year, which included 5.2% operational growth and a negative currency impact of 9.3%. Operational growth was driven by increased sales of LISTERINE® products, attributable to geographical expansion of new products and successful marketing campaigns.

The Women's Health franchise sales were $1.2 billion in 2015, a decrease of 7.8% as compared to the prior year, which included 7.6% operational growth and a negative currency impact of 15.4%. Operational growth outside the U.S. was driven by new product launches and successful marketing campaigns.

The Wound Care/Other franchise sales were $1.2 billion in 2015, a decrease of 18.5% from 2014, primarily due to the SPLENDA® and BENECOL® divestitures.

Consumer segment sales in 2014 were $14.5 billion, a decrease of 1.4% from 2013, which included 1.0% operational growth offset by a negative currency impact of 2.4%. U.S. Consumer segment sales were $5.1 billion, a decrease of 1.3%. International sales were $9.4 billion, a decrease of 1.4%, which included 2.3% operational growth offset by a negative currency impact of 3.7%.

Pharmaceutical Segment

Pharmaceutical segment sales in 2015 were $31.4 billion, a decrease of 2.7% from 2014, which included operational growth of 4.2% offset by a negative currency impact of 6.9%. U.S. sales were $18.3 billion, an increase of 5.2%. International sales were $13.1 billion, a decrease of 12.0%, which included 3.0% operational growth offset by a negative currency impact of 15.0%. The Pharmaceutical segment operational growth was negatively impacted by 6.5% due to the introduction of competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), and positively impacted by 1.4% due to an adjustment to previous reserve estimates, including Managed Medicaid rebates primarily in the Cardiovascular/Metabolism/Other therapeutic area. In 2015, divestitures had a negative impact of 0.3% on the worldwide Pharmaceutical segment operational growth.

Major Pharmaceutical Therapeutic Area Sales:*

(Dollars in Millions)	2015	2014	2013	% Change '15 vs. '14	% Change '14 vs. '13
Total Immunology	**$ 10,402**	**10,193**	**9,190**	**2.1 %**	**10.9**
REMICADE®	6,561	6,868	6,673	(4.5)	2.9
SIMPONI®/SIMPONI ARIA®	1,328	1,187	932	11.9	27.4
STELARA®	2,474	2,072	1,504	19.4	37.8
Other Immunology	39	66	81	(40.9)	(18.5)
Total Infectious Diseases	**3,656**	**5,599**	**3,550**	**(34.7)**	**57.7**
EDURANT®	410	365	236	12.3	54.7
OLYSIO®/SOVRIAD®	621	2,302	23	(73.0)	**
PREZISTA®/ PREZCOBIX®/REZOLSTA®	1,810	1,831	1,673	(1.1)	9.4
Other Infectious Diseases	815	1,101	1,618	(26.0)	(32.0)
Total Neuroscience	**6,259**	**6,487**	**6,667**	**(3.5)**	**(2.7)**
CONCERTA®/methylphenidate	821	599	782	37.1	(23.4)
INVEGA®/paliperidone	573	640	583	(10.5)	9.8
INVEGA SUSTENNA®/XEPLION®/INVEGA TRINZA®	1,830	1,588	1,248	15.2	27.2
RISPERDAL® CONSTA®	970	1,190	1,318	(18.5)	(9.7)
Other Neuroscience	2,065	2,470	2,736	(16.4)	(9.7)
Total Oncology	**4,695**	**4,457**	**3,773**	**5.3**	**18.1**
IMBRUVICA®	689	200	—	**	—
VELCADE®	1,333	1,618	1,660	(17.6)	(2.5)
ZYTIGA®	2,231	2,237	1,698	(0.3)	31.7
Other Oncology	442	402	415	10.0	(3.1)
Cardiovascular / Metabolism / Other* **	**6,418**	**5,577**	**4,945**	**15.1**	**12.8**
XARELTO®	1,868	1,522	864	22.7	76.2
INVOKANA®/ INVOKAMET®	1,308	586	123	**	**
PROCRIT®/EPREX®	1,068	1,238	1,364	(13.7)	(9.2)
Other	2,174	2,231	2,594	(2.6)	(14.0)
Total Pharmaceutical Sales	**$ 31,430**	**32,313**	**28,125**	**(2.7)%**	**14.9**

* Prior year amounts have been reclassified to conform to current year presentation.
** Percentage greater than 100%
***Previously referred to as Other

Immunology products achieved sales of $10.4 billion in 2015, representing an increase of 2.1% as compared to the prior year. Immunology products growth of 2.1% included operational growth of 6.9% and a negative currency impact of 4.8%. The increased sales of STELARA® (ustekinumab) and SIMPONI®/SIMPONI ARIA® (golimumab) were due to market growth and increased penetration of SIMPONI ARIA®. Growth was partially offset by lower REMICADE® (infliximab) sales to the Company's distributor primarily due to the weakening of the euro and biosimilar competition in Europe. The patents for REMICADE® in certain countries in Europe expired in February 2015. Biosimilar versions of REMICADE® have been introduced in certain markets outside the United States, resulting in a reduction in sales of REMICADE® in those markets.

Additional biosimilar competition will likely result in a further reduction in REMICADE® sales in markets outside the United States. The timing of the possible introduction of a biosimilar version of REMICADE® in the United States is subject to enforcement of patent rights, approval by the FDA and compliance with the 180-day notice provisions of the Biologics Price Competition and Innovation Act (the BPCIA). On February 9, 2016, the Arthritis Advisory Committee of the FDA recommended by a vote of 21-3 to approve the first investigational biosimilar infliximab across all eligible indications in the United States. There is a risk that a competitor could launch a biosimilar version of REMICADE® following FDA approval (subject to compliance with the 180-day notice provisions of the BPCIA), even though one or more valid patents are in place. Introduction to the U.S. market of a biosimilar version of REMICADE® will result in a reduction in U.S. sales of REMICADE®. In 2015, U.S. sales of REMICADE® were $4.5 billion. The launch of a biosimilar version of REMICADE® in the U.S. is not expected to have a material adverse effect on the Company's results of operations and cash flows in 2016. See Note 21 to the Consolidated Financial Statements for legal matters regarding the REMICADE® patents.

Infectious disease products sales were $3.7 billion, a decline of 34.7% from 2014, which included an operational decrease of 27.6% and a negative currency impact of 7.1%. Competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a significant negative impact on U.S. sales and will continue to have a negative impact on future sales. The decline of Hepatitis C sales was partially offset by sales growth of EDURANT®(rilpivirine) and sales of PREZISTA®/ PREZCOBIX®/REZOLSTA® (darunavir/cobicistat).

Neuroscience products sales were $6.3 billion, a decrease of 3.5% from 2014, which included an operational growth of 5.0% and a negative currency impact of 8.5%. The U.S. sales growth of CONCERTA®/methylphenidate was primarily due to a therapeutic equivalence reclassification of generic competitors by the FDA in November 2014. Strong sales of INVEGA SUSTENNA®/XEPLION®/INVEGA TRINZA® (paliperidone palmitate) were primarily due to increased market share and the launch of INVEGA TRINZA®. Neuroscience products sales were negatively impacted by the U.S. divestiture of NUCYNTA® (tapentadol) and lower sales of RISPERDAL® CONSTA® (risperidone).

Oncology products achieved sales of $4.7 billion in 2015, representing an increase of 5.3% as compared to the prior year. Oncology products growth of 5.3% included operational growth of 17.7% and a negative currency impact of 12.4%. Contributors to the growth were strong sales of IMBRUVICA® (ibrutinib) due to the approval of new indications, additional country launches and strong patient uptake. Additionally, sales of ZYTIGA® (abiraterone acetate) grew in the U.S. due to market growth partially offset by share decline, and strong growth in Asia and Latin America was partially offset by lower sales in Europe due to competition.

Cardiovascular/Metabolism/Other products achieved sales of $6.4 billion in 2015, representing an increase of 15.1% as compared to the prior year due to strong sales of XARELTO®(rivaroxaban) and INVOKANA®/INVOKAMET® (canagliflozin). PROCRIT®/EPREX® (Epoetin alfa) sales were impacted by competition.

During 2015, the Company advanced its pipeline with several regulatory submissions and approvals for new drugs and additional indications for existing drugs as follows:

Product Name (Chemical Name)	Indication	US Approv	EU Approv	US Filing	EU Filing
DARZALEX™ (daratumumab)	For the treatment of double refractory multiple myeloma	✓			✓
EDURANT® (rilpiravine)	For use in combination with other anti-retroviral agents, for the treatment-naïve adolescent patients aged 12 to 18 years with HIV-1 infection	✓	✓		
IMBRUVICA® (ibrutinib)	Treatment of Waldenström's Macroglobulinemia	✓	✓		
	Treatment for patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma in combination with bendamustine and rituximab			✓	✓
	For use in treatment-naïve patients with chronic lymphocytic leukemia			✓	✓
INVEGA TRINZA® (paliperidone palmitate)	An atypical antipsychotic injection administered four times a year for the treatment of schizophrenia	✓			✓
INVOKAMET® XR (canagliflozin)	A once-daily therapy combining fixed doses of canagliflozin and metformin hydrochloride extended release for the treatment of adults with type 2 diabetes			✓	
PREZCOBIX® (darunavir/cobicistat)	For use in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1)	✓			
SIMPONI® (golimumab)	Treatment of non-radiographic axial spondyloarthritis		✓		
STELARA® (ustekinumab)	For the treatment of adolescents with moderate-to-severe psoriasis		✓		
	For the treatment of adult patients with moderately to severely active Crohn's disease			✓	✓
VELCADE® (bortezomib)	For use in combination with rituximab, cyclophosphamide, doxorubicin and prednisone for the treatment of adult patients with previously untreated mantle cell lymphoma		✓		
YONDELIS® (trabectedin)	For the treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma	✓			

The Pharmaceutical segment achieved sales of $32.3 billion in 2014, representing an increase of 14.9% over the prior year, with strong operational growth of 16.5% and a negative currency impact of 1.6%. U.S. sales were $17.4 billion, an increase of 25.0%. International sales were $14.9 billion, an increase of 5.0%, which included 8.3% operational growth and a negative currency impact of 3.3%. In 2013, Pharmaceutical segment sales included a positive adjustment to previous estimates for Managed Medicaid rebates. This negatively impacted 2014 Pharmaceutical operational sales growth by 0.8% as compared to the prior year. In 2014, sales of the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a positive impact of 6.9% on the operational growth of the Pharmaceutical segment.

Medical Devices Segment
The Medical Devices segment sales in 2015 were $25.1 billion, a decrease of 8.7% from 2014, which included an operational decline of 1.4% and a negative currency impact of 7.3%. U.S. sales were $12.1 billion, a decrease of 1.0% as compared to the prior year. International sales were $13.0 billion, a decrease of 14.8% as compared to the prior year, with an operational decrease of 1.7% and a negative currency impact of 13.1%. The divestitures of the Ortho-Clinical Diagnostics and the Cordis Businesses had a negative impact of 3.2% and 0.6%, respectively, on the worldwide operational growth of the Medical Devices segment as compared to 2014.

Major Medical Devices Franchise Sales:*

				% Change	
(Dollars in Millions)	2015	2014	2013	'15 vs. '14	'14 vs. '13
Orthopaedics	**$ 9,262**	**9,675**	**9,509**	(4.3)%	1.7
Hips	1,332	1,368	1,333	(2.6)	2.6
Knees	1,496	1,533	1,496	(2.4)	2.5
Trauma	2,528	2,640	2,555	(4.2)	3.3
Spine & Other	3,906	4,134	4,125	(5.5)	0.2
Surgery	**9,217**	**9,717**	**9,773**	(5.1)	(0.6)
Advanced	3,275	3,237	3,088	1.2	4.8
General	4,482	4,970	5,136	(9.8)	(3.2)
Specialty	1,460	1,510	1,549	(3.3)	(2.5)
Vision Care	**2,608**	**2,818**	**2,937**	(7.5)	(4.1)
Cardiovascular	**2,036**	**2,208**	**2,077**	(7.8)	6.3
Diabetes Care	**1,928**	**2,142**	**2,309**	(10.0)	(7.2)
Diagnostics	**86**	**962**	**1,885**	(91.1)	(49.0)
Total Medical Devices Sales	**$ 25,137**	**27,522**	**28,490**	**(8.7)%**	**(3.4)**

* Prior year amounts have been reclassified to conform to current year presentation.

The Orthopaedics franchise sales were $9.3 billion in 2015, a decrease of 4.3% from 2014, which included operational growth of 1.7% and a negative currency impact of 6.0%. Operational growth in the U.S. and Europe regions was primarily driven by sales of the hip primary stem platform, the ATTUNE® Knee System, trauma TFNA nailing system and sports medicine ORTHOVISC®/MONOVISC® products. Growth was negatively impacted by softer demand and a reduction in customer inventory levels primarily in China and continued pricing pressures.

The Surgery franchise sales were $9.2 billion in 2015, a decrease of 5.1% from 2014, which included operational growth of 2.7% and a negative currency impact of 7.8%. Operational growth in Advanced Surgery was driven by endocutter, biosurgical and energy products, primarily attributable to market growth, increased penetration in certain markets and new product launches. Operational growth in Specialty Surgery was primarily driven by Mentor products. Growth was partially offset by lower sales of women's health and urology products in General Surgery.

The Vision Care franchise sales were $2.6 billion in 2015, a decrease of 7.5% from 2014, which included operational growth of 1.7% and a negative currency impact of 9.2%. Operational growth in all the major regions was primarily driven by new product launches partially offset by lower price.

The Cardiovascular franchise sales were $2.0 billion, a decrease of 7.8% from 2014, which represented an operational decline of 0.1% and a negative currency impact of 7.7%. Strong operational growth in the electrophysiology business was driven by market growth and the success of the THERMOCOOL® SMARTTOUCH® Catheter and was offset by the impact of divesting the Cordis business. The Company completed the divestiture of the Cordis business to Cardinal Health on October 4, 2015. The Cordis business generated annual net revenues of approximately $535 million and $780 million in 2015 and 2014, respectively. For additional details see Note 20 to the Consolidated Financial Statements.

The Diabetes Care franchise sales were $1.9 billion, a decrease of 10.0% from 2014, which represented an operational decline of 0.7% and a negative currency impact of 9.3%. The operational decline was primarily due to lower price partially offset by the success of the ANIMAS® VIBE® products.

On June 30, 2014, the Company divested the Ortho-Clinical Diagnostics business (the Diagnostics Franchise) to The Carlyle Group. For additional details see Note 20 to the Consolidated Financial Statements.

The Medical Devices segment sales in 2014 were $27.5 billion, a decrease of 3.4% from 2013, which included an operational decline of 1.6% and a negative currency impact of 1.8%. U.S. sales were $12.3 billion, a decrease of 4.3% as compared to the prior year. International sales were $15.3 billion, a decline of 2.7% as compared to the prior year, with operational growth of 0.5% offset by a negative currency impact of 3.2%. In 2014, the divestiture of the Ortho-Clinical Diagnostics business had a negative impact of 3.2% on the operational growth of the Medical Devices segment.

Analysis of Consolidated Earnings Before Provision for Taxes on Income

Consolidated earnings before provision for taxes on income decreased to $19.2 billion as compared to $20.6 billion in 2014, a decrease of 6.6%. The decrease was primarily attributable to significantly lower sales of OLYSIO®/SOVRIAD® (simeprevir), negative currency impacts, a restructuring charge of $0.6 billion and higher intangible asset write-downs of $0.1 billion in 2015 as compared to 2014. The decrease was partially offset by lower net litigation expense of $1.1 billion, lower Synthes integration costs of $0.6 billion, a positive adjustment of $0.4 billion to previous reserve estimates including Managed Medicaid rebates, and higher gains of $0.3 billion from divestitures as compared to the prior year. The fiscal year 2015 included higher gains of $0.3 billion primarily from the divestitures of the Cordis business, the SPLENDA® brand and the U.S. divestiture of NUCYNTA® versus the gains recorded in 2014 from the divestitures of the Ortho-Clinical Diagnostics business and the K-Y® brand. Additionally, 2014 included an additional year of the Branded Prescription Drug Fee of $0.2 billion.

Consolidated earnings before provision for taxes on income increased to $20.6 billion in 2014 as compared to $15.5 billion in 2013, an increase of 32.9%. Earnings before provision for taxes on income were favorable due to strong sales volume growth, particularly sales of OLYSIO®/SOVRIAD® (simeprevir), positive mix from higher sales of higher margin products in the Pharmaceutical business, divestitures of lower margin businesses and cost reduction efforts across many of the businesses. Additionally, 2014 included higher net gains on divestitures of $2.3 billion, primarily the divestiture of the Ortho-Clinical Diagnostics business, lower litigation expense of $1.0 billion, lower in-process research and development costs of $0.4 billion and lower expenses of $0.1 billion related to the DePuy ASR™ Hip program as compared to the fiscal year 2013. This was partially offset by the inclusion of an additional year of the Branded Prescription Drug Fee of $0.2 billion and $0.1 billion of higher Synthes integration/transaction costs in 2014. The fiscal year 2013 included a net gain of $0.4 billion on equity investment transactions, primarily the sale of Elan American Depositary Shares.

As a percent to sales, consolidated earnings before provision for taxes on income in 2015 was 27.4% versus 27.7% in 2014.

Cost of Products Sold and Selling, Marketing and Administrative Expenses: Cost of products sold and selling, marketing and administrative expenses as a percent to sales were as follows:

% of Sales	2015	2014	2013
Cost of products sold	30.7%	30.6	31.3
Percent point increase/(decrease) over the prior year	0.1	(0.7)	(0.9)
Selling, marketing and administrative expenses	30.3%	29.5	30.6
Percent point increase/(decrease) over the prior year	0.8	(1.1)	(0.4)

In 2015, cost of products sold as a percent to sales increased slightly as compared to the prior year. Favorable mix between the segments was offset by $81 million associated with the restructuring activity in the Medical Devices segment, negative transactional currency and lower sales of OLYSIO®/SOVRIAD® (simeprevir) in 2015. Intangible asset amortization expense included in cost of products sold for 2015 and 2014 was $1.2 billion and $1.4 billion, respectively. There was an increase in the percent to sales of selling, marketing and administrative expenses in 2015 compared to the prior year, primarily due to incremental investment spending in all the segments and the impact from lower sales of OLYSIO®/SOVRIAD® (simeprevir), partially offset by favorable mix and the inclusion of an additional year of the Branded Prescription Drug Fee of $0.2 billion in 2014.

In 2014, cost of products sold as a percent to sales decreased compared to the prior year. This was primarily the result of positive mix from higher sales of higher margin products in the Pharmaceutical business, divestitures of lower margin businesses and cost improvements across many of the businesses. This was partially offset by pricing and the impact of negative transactional currency. In addition, 2013 included an inventory step-up charge of $0.1 billion related to the Synthes acquisition. Intangible asset amortization expense included in cost of products sold for both 2014 and 2013 was $1.4 billion. There was a decrease in the percent to sales of selling, marketing and administrative expenses in 2014 compared to the prior year primarily due to leveraged costs resulting from growth in the Pharmaceutical business, particularly sales of OLYSIO®/SOVRIAD® (simeprevir), and cost containment initiatives across many of the businesses. This was partially offset by the inclusion of an additional year of the Branded Prescription Drug Fee of $220 million in the fiscal third quarter of 2014.

Research and Development Expense: Research and development expense by segment of business was as follows:

	2015		2014		2013	
(Dollars in Millions)	**Amount**	**% of Sales***	**Amount**	**% of Sales***	**Amount**	**% of Sales***
Consumer	$ 625	4.6%	629	4.3	590	4.0
Pharmaceutical	6,821	21.7	6,213	19.2	5,810	20.7
Medical Devices	1,600	6.4	1,652	6.0	1,783	6.3
Total research and development expense	$ 9,046	12.9%	8,494	11.4	8,183	11.5
Percent increase/(decrease) over the prior year	6.5%		3.8		6.8	

* As a percent to segment sales

Research and development activities represent a significant part of the Company's business. These expenditures relate to the processes of discovering, testing and developing new products, upfront payments and milestones, improving existing products, as well as ensuring product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products. In 2015, worldwide costs of research and development activities increased by 6.5% compared to 2014. The increase as a percent to sales was attributable to increased investment spending primarily in the Pharmaceutical segment, lower overall sales and business mix. In 2014, worldwide costs of research and development activities increased by 3.8% compared to 2013. The reduction as a percent to sales was primarily due to strong sales growth in the Pharmaceutical business. Research spending in the Pharmaceutical segment increased in absolute dollars to $6.2 billion as compared to $5.8 billion primarily due to higher levels of spending to advance the Company's Pharmaceutical pipeline.

In-Process Research and Development (IPR&D): In 2015, the Company recorded an IPR&D charge of $0.2 billion primarily for the discontinuation of certain development projects related to Covagen. In 2014, the Company recorded an IPR&D charge of $0.2 billion for the impairment of various IPR&D projects related to RespiVert, Crucell, Mentor and Synthes for the delay or discontinuation of certain development projects. In 2013, the Company recorded an IPR&D charge of $0.6 billion primarily for the impairment of various IPR&D projects related to Crucell, CorImmun and Acclarent for the delay or discontinuation of certain development projects.

Other (Income) Expense, Net: Other (income) expense, net is the account where the Company records gains and losses related to the sale and write-down of certain investments in equity securities held by Johnson & Johnson Innovation - JJDC, Inc. (formerly Johnson & Johnson Development Corporation), gains and losses on divestitures, transactional currency gains and losses, acquisition-related costs, litigation accruals and settlements, as well as royalty income. The change in other (income) expense, net for the fiscal year 2015 was a favorable change of $2.0 billion as compared to the prior year primarily due to lower litigation expense of $1.1 billion, lower Synthes integration costs of $0.6 billion and higher JJDC portfolio gains of $0.2 billion as compared to the prior year. Additionally, the fiscal year 2015 included higher gains of $0.3 billion primarily from the divestitures of the Cordis business, the SPLENDA® brand and the U.S. divestiture of NUCYNTA®versus the gains recorded in 2014 from the divestitures of the Ortho-Clinical Diagnostics business and the K-Y® brand. This was partially offset by higher intangible asset write-downs of $0.1 billion in 2015.

The change in other (income) expense, net for the fiscal year 2014 was a favorable change of $2.6 billion as compared to the prior year. The fiscal year 2014 included higher net gains on divestitures of $2.3 billion, primarily the divestiture of the Ortho-Clinical Diagnostics business, lower litigation expense of $1.0 billion and lower costs of $0.1 billion related to the DePuy ASR™ Hip program as compared to 2013. This was partially offset by higher Synthes integration/transaction costs of $0.2 billion and higher intangible asset write-downs of $0.1 billion primarily related to INCIVO® (telaprevir) in 2014. Additionally, the fiscal year 2013 included a higher net gain of $0.5 billion as compared to 2014 on equity investment transactions, primarily the sale of Elan American Depositary Shares.

Interest (Income) Expense: Interest income in 2015 increased by $61 million as compared to 2014 due to a higher average balance of cash, cash equivalents and marketable securities and higher interest rates. Cash, cash equivalents and marketable securities totaled $38.4 billion at the end of 2015, and averaged $35.7 billion as compared to the $31.1 billion average cash balance in 2014. The increase in the year-end cash balance was primarily due to cash generated from operating activities.

Interest expense in 2015 increased slightly as compared to 2014. The average debt balance was $19.3 billion in 2015 versus $18.5 billion in 2014. The total debt balance at the end of 2015 was $19.9 billion as compared to $18.8 billion at the end of 2014. The higher debt balance of approximately $1.1 billion was an increase in commercial paper for general corporate purposes, primarily the stock repurchase program.

Interest income in 2014 was comparable to the prior year. A higher balance in cash, cash equivalents and marketable securities was offset by lower interest rates. Cash, cash equivalents and marketable securities totaled $33.1 billion at the end of

2014, and averaged $31.1 billion as compared to the $25.2 billion average cash balance in 2013. The increase in the year-end cash balance was primarily due to cash generated from operating activities.

Interest expense in 2014 increased by $51 million as compared to 2013 due to a higher average debt balance. The average debt balance was $18.5 billion in 2014 versus $17.2 billion in 2013. The total debt balance at the end of 2014 was $18.8 billion as compared to $18.2 billion at the end of 2013. The higher debt balance of approximately $0.6 billion was due to increased borrowings in November 2014. The Company increased borrowings, capitalizing on favorable terms in the capital markets. The proceeds of the borrowings were used for general corporate purposes.

Income Before Tax by Segment

Income before tax by segment of business were as follows:

			Percent of Segment Sales	
(Dollars in Millions)	**2015**	**2014**	**2015**	**2014**
Consumer	$ 1,787	1,941	13.2%	13.4
Pharmaceutical	11,734	11,696	37.3	36.2
Medical Devices	6,826	7,953	27.2	28.9
Total [1]	20,347	21,590	29.0	29.0
Less: Expenses not allocated to segments [2]	1,151	1,027		
Earnings before provision for taxes on income	$ 19,196	20,563	27.4%	27.7

[1] See Note 18 to the Consolidated Financial Statements for more details.

[2] Amounts not allocated to segments include interest (income) expense, noncontrolling interests, and general corporate (income) expense.

Consumer Segment: In 2015, the Consumer segment income before tax as a percent to sales was 13.2%, versus 13.4% in 2014, primarily due to lower divestiture gains in 2015 versus 2014. In 2015, the Consumer segment tax included a gain of $0.3 billion from divestitures, primarily the divestiture of the SPLENDA® brand. In 2014, the Consumer segment included a gain of $0.5 billion from divestitures, primarily the divestiture of the K-Y® brand. In 2014, the Consumer segment income before tax as a percent to sales was 13.4%, flat to the prior year.

Pharmaceutical Segment: In 2015, the Pharmaceutical segment income before tax as a percent to sales was 37.3% versus 36.2% in 2014. The favorable income before tax was primarily due to higher gains recognized in 2015 partially offset by a sales decline of OLYSIO®/SOVRIAD®(simeprevir), increased investment spending and negative currency impacts as compared to 2014. Included in 2015 was a gain of $1.0 billion on the U.S. divestiture of NUCYNTA®, as well as receipt of a contingent payment and a positive adjustment to previous reserve estimates, including Managed Medicaid rebates. Additionally, the Pharmaceutical segment income before tax in 2014 was negatively impacted by $0.2 billion for an additional year of the Branded Prescription Drug Fee and higher intangible asset amortization expense of $0.3 billion primarily related to the write-down of INCIVO®(telaprevir).

In 2014, the Pharmaceutical segment income before tax as a percent to sales was 36.2% versus 32.6% in 2013. The favorable income before tax was attributable to strong sales volume growth, particularly sales of OLYSIO®/SOVRIAD® (simeprevir), positive sales mix of higher margin products and cost containment initiatives realized in selling, marketing and administrative expenses. This was partially offset by $0.2 billion for an additional year of the Branded Prescription Drug Fee and a $0.1 billion intangible asset write-down related to INCIVO®(telaprevir). Additionally, 2013 included a net gain of $0.4 billion on equity investment transactions, primarily the sale of Elan American Depositary Shares, and a positive adjustment of $0.2 billion to previous estimates for Managed Medicaid rebates, partially offset by higher write-downs of $0.4 billion for the impairment of IPR&D as compared to 2014.

Medical Devices Segment: In 2015, the Medical Devices segment income before tax as a percent to sales was 27.2% versus 28.9% in 2014 primarily due to a restructuring charge of $0.6 billion, an intangible asset write-down of $0.3 billion related to Acclarent, and lower gains of $0.5 billion on divestitures as compared to 2014. In 2015, the Medical Devices segment included gains of $1.4 billion, primarily for the divestiture of the Cordis business versus a gain of $1.9 billion recorded in 2014 for the divestiture of the Ortho-Clinical Diagnostics business. The 2015 income before tax was favorably impacted by lower net litigation expense of $0.9 billion, which included a gain from the litigation settlement agreement of $0.6 billion with Guidant, and lower Synthes integration costs of $0.6 billion in 2015 as compared to 2014.

In 2014, Medical Devices segment income before tax as a percent to sales was 28.9% versus 18.5% in 2013. The favorable income before tax was attributable to the net gain of $1.9 billion on the divestiture of the Ortho-Clinical Diagnostics business in 2014 and lower litigation expense of $1.1 billion as compared to 2013.

Restructuring: The Company announced restructuring actions in its Medical Devices segment that are expected to result in annualized pre-tax cost savings of $800 million to $1.0 billion, the majority of which is expected to be realized by the end of 2018, including approximately $200 million savings in 2016. The savings will provide the Company with added flexibility and resources to fund investment in new growth opportunities and innovative solutions for customers and patients. The Company estimates that, in connection with its plans, it will record pre-tax restructuring charges of approximately $2.0 billion to $2.4 billion, most of which are expected to be incurred by 2017. In the fiscal fourth quarter of 2015, the Company recorded a pre-tax charge of $0.6 billion, of which $81 million is included in cost of products sold. See Note 22 to the Consolidated Financial Statements for additional details related to the restructuring.

Provision for Taxes on Income: The worldwide effective income tax rate was 19.7% in 2015, 20.6% in 2014 and 10.6% in 2013. The 2015 effective tax rate decrease of 0.9% as compared to 2014 was primarily attributable to the increases in taxable income in lower tax jurisdictions relative to higher tax jurisdictions and a tax benefit resulting from a restructuring of international affiliates. Additionally, the 2014 effective tax rate was affected by the items mentioned below.

The increase in the 2014 effective tax rate, as compared to 2013, was attributable to the following: the divestiture of the Ortho-Clinical Diagnostics business at an approximate 44% effective tax rate, litigation accruals at low tax rates, the mix of earnings into higher tax jurisdictions, primarily the U.S., the accrual of an additional year of the Branded Prescription Drug Fee, which is not tax deductible, and additional U.S. tax expense related to a planned increase in dividends from current year foreign earnings as compared to the prior year. These increases to the 2014 effective tax rate were partially offset by a tax benefit of $0.4 billion associated with the Conor Medsystems divestiture.

The 2014 effective tax rate was also reduced as the Company adjusted its unrecognized tax benefits as a result of (i) the federal appeals court's decision in OMJ Pharmaceuticals, Inc.'s litigation regarding credits under former Section 936 of the Internal Revenue Code (see Note 21 to the Consolidated Financial Statements for additional information), and (ii) a settlement of substantially all issues related to the Company's U.S. Internal Revenue Service audit of tax years 2006 - 2009.

The 2013 effective tax rate was reduced by a tax benefit associated with the write-off of assets for tax purposes associated with Scios, Inc., and the inclusion of both the 2013 and 2012 benefit from the Research and Development tax credit and the Controlled Foreign Corporation look-through provisions, because those provisions were enacted into law in January 2013 and were retroactive to January 1, 2012.

Liquidity and Capital Resources

Liquidity & Cash Flows

Cash and cash equivalents were $13.7 billion at the end of 2015 as compared to $14.5 billion at the end of 2014. The primary sources and uses of cash that contributed to the $0.8 billion decrease were approximately $19.3 billion of cash generated from operating activities offset by $7.7 billion net cash used by investing activities, and $10.8 billion net cash used by financing activities, and $1.5 billion due to the effect on exchange rate changes on cash and cash equivalents. In addition, the Company had $24.6 billion in marketable securities at the end of 2015 and $18.6 billion at the end of 2014. See Note 1 to the Consolidated Financial Statements for additional details on cash, cash equivalents and marketable securities.

Cash flow from operations of $19.3 billion was the result of $15.4 billion of net earnings and $5.4 billion of non-cash charges and other adjustments for depreciation and amortization, stock-based compensation and assets write-downs, primarily related to Acclarent and Venezuela write-downs, reduced by $2.6 billion from net gains on sale of assets/businesses, and $1.2 billion related to deferred taxes, accounts receivable and inventories. Additional sources of operating cash flow of $2.2 billion resulted from a decrease in other current and non-current assets and an increase in other current and non-current liabilities.

Investing activities use of $7.7 billion was primarily for net purchases of investments in marketable securities of $6.7 billion, additions to property, plant and equipment of $3.5 billion, and acquisitions, net of cash acquired of $1.0 billion, partially offset by $3.5 billion of proceeds from the disposal of assets/businesses.

Financing activities use of $10.8 billion was primarily for dividends to shareholders of $8.2 billion and $5.3 billion for the repurchase of common stock. Financing activities also included a source of $1.4 billion from net proceeds of short and long-term debt and $1.3 billion of net proceeds from stock options exercised and associated tax benefits.

On October 13, 2015, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $10.0 billion of the Company's shares of common stock. As of January 3, 2016, $1.0 billion has been repurchased under the program. The repurchase program has no time limit and may be suspended for periods or discontinued at any time. Any shares acquired will be available for general corporate purposes. The Company intends to finance the share repurchase program through available cash and access to the capital markets. The previous share repurchase program approved on July 21, 2014, authorizing the Company to purchase up to $5.0 billion of the Company's shares of common stock, was completed on April 28, 2015.

In 2015, the Company continued to have access to liquidity through the commercial paper market. The Company has a shelf registration with the U.S. Securities and Exchange Commission that enables the Company to issue debt securities and warrants to purchase debt securities on a timely basis. For additional details on borrowings, see Note 7 to the Consolidated Financial Statements.

The Company anticipates that operating cash flows, existing credit facilities and access to the capital markets will provide sufficient resources to fund operating needs in 2016.

Concentration of Credit Risk

Global concentration of credit risk with respect to trade accounts receivables continues to be limited due to the large number of customers globally and adherence to internal credit policies and credit limits. Economic challenges in Italy, Spain, Greece and Portugal (the Southern European Region) have impacted certain payment patterns, which have historically been longer than those experienced in the U.S. and other international markets. The total net trade accounts receivable balance in the Southern European Region was approximately $1.3 billion as of January 3, 2016 and $1.8 billion as of December 28, 2014. Approximately $0.8 billion as of January 3, 2016 and approximately $1.1 billion as of December 28, 2014 of the Southern European Region net trade accounts receivable balance related to the Company's Consumer, Vision Care and Diabetes Care businesses as well as certain Pharmaceutical and Medical Devices customers which are in line with historical collection patterns.

The remaining balance of net trade accounts receivable in the Southern European Region has been negatively impacted by the timing of payments from certain government owned or supported health care customers, as well as certain distributors of the Pharmaceutical and Medical Devices local affiliates. The total net trade accounts receivable balance for these customers were approximately $0.5 billion at January 3, 2016 and $0.7 billion at December 28, 2014. The Company continues to receive payments from these customers and, in some cases, late payments with interest. For customers where payment is expected over periods of time longer than one year, revenue and trade receivables have been discounted over the estimated period of time for collection. Allowances for doubtful accounts have been increased for these customers, but have been immaterial to date. The Company will continue to work closely with these customers on payment plans, monitor the economic situation and take appropriate actions as necessary.

Financing and Market Risk

The Company uses financial instruments to manage the impact of foreign exchange rate changes on cash flows. Accordingly, the Company enters into forward foreign exchange contracts to protect the value of certain foreign currency assets and liabilities and to hedge future foreign currency transactions primarily related to product costs. Gains or losses on these contracts are offset by the gains or losses on the underlying transactions. A 10% appreciation of the U.S. Dollar from the January 3, 2016 market rates would increase the unrealized value of the Company’s forward contracts by $15 million. Conversely, a 10% depreciation of the U.S. Dollar from the January 3, 2016 market rates would decrease the unrealized value of the Company’s forward contracts by $18 million. In either scenario, the gain or loss on the forward contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated earnings and cash flows.

The Company hedges the exposure to fluctuations in currency exchange rates, and the effect on certain assets and liabilities in foreign currency, by entering into currency swap contracts. A 1% change in the spread between U.S. and foreign interest rates on the Company’s interest rate sensitive financial instruments would either increase or decrease the unrealized value of the Company’s swap contracts by approximately $115 million. In either scenario, at maturity, the gain or loss on the swap contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated cash flows.

The Company does not enter into financial instruments for trading or speculative purposes. Further, the Company has a policy of only entering into contracts with parties that have at least an investment grade credit rating. The counter-parties to these contracts are major financial institutions and there is no significant concentration of exposure with any one counter-party. Management believes the risk of loss is remote.

The Company invests in both fixed rate and floating rate interest earning securities which carry a degree of interest rate risk. The fair market value of fixed rate securities may be adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than predicted if interest rates fall. A 1% (100 basis points) change in spread on the Company’s interest rate sensitive investments would either increase or decrease the unrealized value of cash equivalents and current marketable securities by approximately $314 million.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2015, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 15, 2016. Interest charged on borrowings under the credit line agreement is based on either bids provided by banks, the prime rate or London Interbank Offered Rates (LIBOR), plus applicable margins. Commitment fees under the agreement are not material.

Total borrowings at the end of 2015 and 2014 were $19.9 billion and $18.8 billion, respectively. The increase in borrowings between 2015 and 2014 was a result of financing for the Company's share repurchase program. In 2015, net cash

(cash and current marketable securities, net of debt) was $18.5 billion compared to net cash of $14.3 billion in 2014. Total debt represented 21.8% of total capital (shareholders' equity and total debt) in 2015 and 21.2% of total capital in 2014. Shareholders' equity per share at the end of 2015 was $25.82 compared to $25.06 at year-end 2014, an increase of 3.0%.

A summary of borrowings can be found in Note 7 to the Consolidated Financial Statements.

Contractual Obligations and Commitments

The Company's contractual obligations are primarily for leases, debt and unfunded retirement plans. There are no other significant obligations. To satisfy these obligations, the Company will use cash from operations. The following table summarizes the Company's contractual obligations and their aggregate maturities as of January 3, 2016 (see Notes 7, 10 and 16 to the Consolidated Financial Statements for further details):

(Dollars in Millions)	Debt Obligations	Interest on Debt Obligations	Unfunded Retirement Plans	Operating Leases	Total
2016	$ 2,104	586	76	224	2,990
2017	1,790	554	77	194	2,615
2018	1,501	490	82	136	2,209
2019	1,587	446	88	90	2,211
2020	683	373	93	74	1,223
After 2020	7,296	4,303	559	109	12,267
Total	**$ 14,961**	**6,752**	**975**	**827**	**23,515**

For tax matters, see Note 8 to the Consolidated Financial Statements.

Dividends

The Company increased its dividend in 2015 for the 53rd consecutive year. Cash dividends paid were $2.95 per share in 2015 compared with dividends of $2.76 per share in 2014, and $2.59 per share in 2013. The dividends were distributed as follows:

	2015	2014	2013
First quarter	$ 0.70	0.66	0.61
Second quarter	0.75	0.70	0.66
Third quarter	0.75	0.70	0.66
Fourth quarter	0.75	0.70	0.66
Total	**$ 2.95**	**2.76**	**2.59**

On January 4, 2016, the Board of Directors declared a regular quarterly cash dividend of $0.75 per share, payable on March 8, 2016, to shareholders of record as of February 23, 2016. The Company expects to continue the practice of paying regular cash dividends.

Other Information

Critical Accounting Policies and Estimates

Management's discussion and analysis of results of operations and financial condition are based on the Company's consolidated financial statements that have been prepared in accordance with accounting principles generally accepted in the U.S. (GAAP). The preparation of these financial statements requires that management make estimates and assumptions that affect the amounts reported for revenues, expenses, assets, liabilities and other related disclosures. Actual results may or may not differ from these estimates. The Company believes that the understanding of certain key accounting policies and estimates are essential in achieving more insight into the Company's operating results and financial condition. These key accounting policies include revenue recognition, income taxes, legal and self-insurance contingencies, valuation of long-lived assets, assumptions used to determine the amounts recorded for pensions and other employee benefit plans and accounting for stock based awards.

Revenue Recognition: The Company recognizes revenue from product sales when goods are shipped or delivered, and title and risk of loss pass to the customer. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns and discounts to customers are accounted for as reductions in sales in the same period the related sales are recorded.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including prices charged by competitors. Rebates, which include the Medicaid rebate provision, are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns are estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales return accruals.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual net trade sales during the fiscal reporting years 2015, 2014 and 2013.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the year incurred. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on estimated sales volumes for the incentive period and are recorded as products are sold. The Company also earns service revenue for co-promotion of certain products. For all years presented, service revenues were less than 1% of total revenues and are included in sales to customers. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue.

In addition, the Company enters into collaboration arrangements that contain multiple revenue generating activities. Amounts due from collaborative partners for these arrangements are recognized as each activity is performed or delivered, based on the relative fair value. Upfront fees received as part of these arrangements are deferred and recognized over the performance period. See Note 1 to the Consolidated Financial Statements for additional disclosures on collaborations.

Reasonably likely changes to assumptions used to calculate the accruals for rebates, returns and promotions are not anticipated to have a material effect on the financial statements. The Company currently discloses the impact of changes to assumptions in the quarterly or annual filing in which there is a material financial statement impact.

Below are tables that show the progression of accrued rebates, returns, promotions, reserve for doubtful accounts and reserve for cash discounts by segment of business for the fiscal years ended January 3, 2016 and December 28, 2014.

Consumer Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits	Balance at End of Period
2015				
Accrued rebates [1]	$ 122	581	(564)	139
Accrued returns	77	84	(107)	54
Accrued promotions	241	1,846	(1,675)	412
Subtotal	$ 440	2,511	(2,346)	605
Reserve for doubtful accounts	18	5	(5)	18
Reserve for cash discounts	22	206	(211)	17
Total	$ 480	2,722	(2,562)	640
2014				
Accrued rebates[1]	$ 137	619	(634)	122
Accrued returns	80	102	(105)	77
Accrued promotions	321	1,850	(1,930)	241
Subtotal	$ 538	2,571	(2,669)	440
Reserve for doubtful accounts	25	5	(12)	18
Reserve for cash discounts	24	215	(217)	22
Total	$ 587	2,791	(2,898)	480

(1) Includes reserve for customer rebates of $31 million at January 3, 2016 and $37 million at December 28, 2014, recorded as a contra asset.

Pharmaceutical Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits	Balance at End of Period
2015				
Accrued rebates [1]	$ 2,717	10,449	(9,715)	3,451
Accrued returns	422	52	(70)	404
Accrued promotions	34	127	(150)	11
Subtotal	$ 3,173	10,628	(9,935)	3,866
Reserve for doubtful accounts	41	30	(25)	46
Reserve for cash discounts	51	625	(613)	63
Total	$ 3,265	11,283	(10,573)	3,975
2014				
Accrued rebates [1]	$ 1,985	7,652	(6,920)	2,717
Accrued returns	372	83	(33)	422
Accrued promotions	96	34	(96)	34
Subtotal	$ 2,453	7,769	(7,049)	3,173
Reserve for doubtful accounts	95	4	(58)	41
Reserve for cash discounts	61	576	(586)	51
Total	$ 2,609	8,349	(7,693)	3,265

(1) Includes reserve for customer rebates of $64 million at January 3, 2016 and $70 million* at December 28, 2014, recorded as a contra asset. *Prior year amount has been reclassified to conform to current year presentation.

Medical Devices Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits	Balance at End of Period
2015				
Accrued rebates[1]	$ 844	5,216	(4,871)	1,189
Accrued returns	188	556	(505)	239
Accrued promotions	53	95	(101)	47
Subtotal	$ 1,085	5,867	(5,477)	1,475
Reserve for doubtful accounts	216	13	(25)	204
Reserve for cash discounts	16	877	(873)	20
Total	$ 1,317	6,757	(6,375)	1,699
2014				
Accrued rebates[1]	$ 801	4,663	(4,620)	844
Accrued returns	180	395	(387)	188
Accrued promotions	66	35	(48)	53
Subtotal	$ 1,047	5,093	(5,055)	1,085
Reserve for doubtful accounts	213	62	(59)	216
Reserve for cash discounts	18	815	(817)	16
Total	$ 1,278	5,970	(5,931)	1,317

(1) Includes reserve for customer rebates of $411 million at January 3, 2016 and $354 million at December 28, 2014, recorded as a contra asset.

Income Taxes: Income taxes are recorded based on amounts refundable or payable for the current year and include the results of any difference between U.S. GAAP accounting and tax reporting, recorded as deferred tax assets or liabilities. The Company estimates deferred tax assets and liabilities based on enacted tax regulations and rates. Future changes in tax laws and rates may affect recorded deferred tax assets and liabilities.

The Company has unrecognized tax benefits for uncertain tax positions. The Company follows U.S. GAAP, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Management believes that changes in these estimates would not have a material effect on the Company's results of operations, cash flows or financial position.

At January 3, 2016 and December 28, 2014, the cumulative amounts of undistributed international earnings were approximately $58.0 billion and $53.4 billion, respectively. At January 3, 2016 and December 28, 2014, the Company's foreign subsidiaries held balances of cash, cash equivalents and marketable securities in the amounts of $38.2 billion and $32.9 billion, respectively. The Company has not provided deferred taxes on the undistributed earnings from certain international subsidiaries where the earnings are considered to be permanently reinvested. The Company intends to continue to reinvest these earnings in international operations. If the Company decided at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company does not determine the deferred tax liability associated with these undistributed earnings, as such determination is not practical.

See Note 8 to the Consolidated Financial Statements for further information regarding income taxes.

Legal and Self Insurance Contingencies: The Company records accruals for various contingencies, including legal proceedings and product liability claims as these arise in the normal course of business. The accruals are based on management’s judgment as to the probability of losses and, where applicable, actuarially determined estimates. The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated. Additionally, the Company records insurance receivable amounts from third-party insurers when recovery is probable. As appropriate, reserves against these receivables are recorded for estimated amounts that may not be collected from third-party insurers.

The Company follows the provisions of U.S. GAAP when recording litigation related contingencies. A liability is recorded when a loss is probable and can be reasonably estimated. The best estimate of a loss within a range is accrued; however, if no estimate in the range is better than any other, the minimum amount is accrued.

See Notes 1 and 21 to the Consolidated Financial Statements for further information regarding product liability and legal proceedings. 610

Long-Lived and Intangible Assets: The Company assesses changes in economic conditions and makes assumptions regarding estimated future cash flows in evaluating the value of the Company's property, plant and equipment, goodwill and intangible assets. As these assumptions and estimates may change over time, it may or may not be necessary for the Company to record impairment charges.

Employee Benefit Plans: The Company sponsors various retirement and pension plans, including defined benefit, defined contribution and termination indemnity plans, which cover most employees worldwide. These plans are based on assumptions for the discount rate, expected return on plan assets, mortality rates, expected salary increases, health care cost trend rates and attrition rates. See Note 10 to the Consolidated Financial Statements for further details on these rates and the effect a rate change to the health care cost trend would have on the Company's results of operations.

Stock Based Compensation: The Company recognizes compensation expense associated with the issuance of equity instruments to employees for their services. Based on the type of equity instrument, the fair value is estimated on the date of grant using either the Black-Scholes option valuation model or a combination of both the Black-Scholes option valuation model and Monte Carlo valuation model, and is expensed in the financial statements over the service period. The input assumptions used in determining fair value are the expected life, expected volatility, risk-free rate and expected dividend yield. For performance share units the fair market value is calculated for each of the three component goals at the date of grant. The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award, discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. See Note 17 to the Consolidated Financial Statements for additional information.

New Accounting Pronouncements

Refer to Note 1 to the Consolidated Financial Statements for recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of January 3, 2016.

Economic and Market Factors

The Company is aware that its products are used in an environment where, for more than a decade, policymakers, consumers and businesses have expressed concerns about the rising cost of health care. In response to these concerns, the Company has a long-standing policy of pricing products responsibly. For the period 2005 - 2015, in the United States, the weighted average compound annual growth rate of the Company's net price increases for health care products (prescription and over-the-counter drugs, hospital and professional products) was below the U.S. Consumer Price Index (CPI).

The Company operates in certain countries where the economic conditions continue to present significant challenges. The Company continues to monitor these situations and take appropriate actions. Inflation rates continue to have an effect on worldwide economies and, consequently, on the way companies operate. The Company has accounted for operations in Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. In the face of increasing costs, the Company strives to maintain its profit margins through cost reduction programs, productivity improvements and periodic price increases.

The Venezuelan government has established alternative systems and offerings of various foreign currency exchanges. During 2015, the Company primarily utilized the official government rate of 6.3 Bolivares Fuertes to one U.S. Dollar in preparing its consolidated financial statements. During 2014, the Company applied to settle an outstanding dividend payable at one of the alternative foreign exchange rates. As a result, the Company has applied this alternative exchange rate to translate certain transactions, as appropriate. Through the fourth quarter of 2015, the number of the Company's transactions conducted at the official rate declined from prior quarters. As a result, the Company determined that it was no longer likely that all outstanding net monetary assets would be settled at the official government rate of 6.3 Bolivares Fuertes to one U.S. Dollar. Therefore, the Company recorded a charge of $161 million to revalue its net monetary assets in Venezuela at one of the government's alternative exchange rates (SIMADI) and impair its non-monetary assets. After the revaluation, as of January 3, 2016, the Company's Venezuelan subsidiaries represented less than 0.1% of the Company's consolidated assets and liabilities. Due to continuing uncertain economic conditions in Venezuela, it is possible that additional charges may be recorded in the future. Any additional charges are not expected to have a material adverse effect on the Company's 2016 full year results.

While the Company continues to do business in Greece, the Company closely monitors the economic situation. As of January 3, 2016, the Company's Greek subsidiaries represented 0.3% and 0.4% of the Company's consolidated assets and revenues, respectively.

The Company is exposed to fluctuations in currency exchange rates. A 1% change in the value of the U.S. Dollar as compared to all foreign currencies in which the Company had sales, income or expense in 2015 would have increased or decreased the translation of foreign sales by approximately $340 million and income by $90 million.

The Company faces various worldwide health care changes that may continue to result in pricing pressures that include health care cost containment and government legislation relating to sales, promotions and reimbursement of health care products.

Changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing health care insurance coverage, as a result of the current global economic downturn, may continue to impact the Company's businesses.

The Company also operates in an environment increasingly hostile to intellectual property rights. Firms have filed Abbreviated New Drug Applications or Biosimilar Biological Product Applications with the FDA or otherwise challenged the coverage and/or validity of the Company's patents, seeking to market generic or biosimilar forms of many of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the event the Company is not successful in defending the patent claims challenged in the resulting lawsuits, generic or biosimilar versions of the products at issue will be introduced to the market, resulting in the potential for substantial market share and revenue losses for those products, and which may result in a non-cash impairment charge in any associated intangible asset. There is also a risk that one or more competitors could launch a generic or biosimilar version of the product at issue following regulatory approval even though one or more valid patents are in place. For further information, see the discussion on "REMICADE® Related Cases" and "Litigation Against Filers of Abbreviated New Drug Applications" in Note 21 to the Consolidated Financial Statements.

Legal Proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability, intellectual property, commercial and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of business.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. The Company has accrued for certain litigation matters and continues to monitor each related legal issue and adjust accruals for new information and further developments in accordance with Accounting Standards Codification (ASC) 450-20-25. For these and other litigation and regulatory matters currently disclosed for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions. The ability to make such estimates and judgments can be affected by various factors, including whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; or there are numerous parties involved.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution of, or increase in accruals for, one or more of these matters in any reporting period may have a material adverse effect on the Company's results of operations and cash flows for that period.

See Note 21 to the Consolidated Financial Statements for further information regarding legal proceedings.

Common Stock Market Prices

The Company's Common Stock is listed on the New York Stock Exchange under the symbol JNJ. As of February 19, 2016, there were 158,749 record holders of Common Stock of the Company. The composite market price ranges for Johnson & Johnson Common Stock during 2015 and 2014 were:

	2015		2014	
	High	Low	High	Low
First quarter	$ 106.50	97.15	98.47	86.09
Second quarter	104.48	97.01	105.97	96.05
Third quarter	101.36	81.79	108.77	98.80
Fourth quarter	105.49	89.90	109.49	95.10
Year-end close	$102.72		105.06	

Cautionary Factors That May Affect Future Results

This Annual Report contains forward-looking statements. Forward-looking statements do not relate strictly to historical or current facts and anticipate results based on management's plans that are subject to uncertainty. Forward-looking statements may be identified by the use of words such as "plans," "expects," "will," "anticipates," "estimates" and other words of similar meaning in conjunction with, among other things, discussions of future operations, financial performance, the Company's strategy for growth, product development, regulatory approval, market position and expenditures.

Forward-looking statements are based on current expectations of future events. The Company cannot guarantee that any forward-looking statement will be accurate, although the Company believes that it has been reasonable in its expectations and assumptions. Investors should realize that if underlying assumptions prove inaccurate or that known or unknown risks or uncertainties materialize, actual results could vary materially from the Company's expectations and projections. Investors are therefore cautioned not to place undue reliance on any forward-looking statements. The Company does not undertake to update any forward-looking statements as a result of new information or future events or developments.

Risks and uncertainties include, but are not limited to: economic factors, such as interest rate and currency exchange rate fluctuations; competition, including technological advances, new products and patents attained by competitors; challenges and uncertainties inherent in new product development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success of new and existing products; challenges to patents; the impact of patent expirations; the ability of the company to successfully execute strategic plans, including restructuring plans; the potential that the expected benefits and opportunities related to the restructuring may not be realized or may take longer to realize than expected; significant adverse litigation or government action, including related to product liability claims; impact of business combinations and divestitures; market conditions and the possibility that the on-going share repurchase program may be suspended or discontinued; significant changes in customer relationships or changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; trends toward health care cost containment; increased scrutiny of the health care industry by government agencies; financial instability of international economies and legal systems and sovereign risk; manufacturing difficulties or delays, internally or within the supply chain; complex global supply chains with increasing regulatory requirements; product efficacy or safety concerns resulting in product recalls or regulatory action; disruptions due to natural disasters; and the potential failure to meet obligations in compliance agreements with government bodies.

A discussion of these and other factors that could cause actual results to differ materially from expectations can be found in this Report for the fiscal year ended January 3, 2016, including in Exhibit 99. The Company notes these factors as permitted by the Private Securities Litigation Reform Act of 1995.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The information called for by this item is incorporated herein by reference to Item 7 "Management's Discussion and Analysis of Results of Operations and Financial Condition - Liquidity and Capital Resources - Financing and Market Risk" of this Report; and Note 1 "Summary of Significant Accounting Policies - Financial Instruments" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Audited Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
At January 3, 2016 and December 28, 2014
(Dollars in Millions Except Share and Per Share Amounts) (Note 1)

		2015	2014
Assets			
Current assets			
Cash and cash equivalents (Notes 1 and 2)	$	13,732	14,523
Marketable securities (Notes 1 and 2)		24,644	18,566
Accounts receivable trade, less allowances for doubtful accounts $268 (2014, $275)		10,734	10,985
Inventories (Notes 1 and 3)		8,053	8,184
Prepaid expenses and other receivables		3,047	3,486
Total current assets		**60,210**	**55,744**
Property, plant and equipment, net (Notes 1 and 4)		15,905	16,126
Intangible assets, net (Notes 1 and 5)		25,764	27,222
Goodwill (Notes 1 and 5)		21,629	21,832
Deferred taxes on income (Note 1 and 8)		5,490	6,202
Other assets		4,413	3,232
Total assets	**$**	**133,411**	**130,358**
Liabilities and Shareholders' Equity			
Current liabilities			
Loans and notes payable (Note 7)	$	7,004	3,638
Accounts payable		6,668	7,633
Accrued liabilities		5,411	6,553
Accrued rebates, returns and promotions		5,440	4,010
Accrued compensation and employee related obligations		2,474	2,751
Accrued taxes on income (Note 8)		750	446
Total current liabilities		**27,747**	**25,031**
Long-term debt (Note 7)		12,857	15,122
Deferred taxes on income (Note 1 & 8)		2,562	2,447
Employee related obligations (Notes 9 and 10)		8,854	9,972
Other liabilities		10,241	8,034
Total liabilities		**62,261**	**60,606**
Shareholders' equity			
Preferred stock — without par value (authorized and unissued 2,000,000 shares)		—	—
Common stock — par value $1.00 per share (Note 12) (authorized 4,320,000,000 shares; issued 3,119,843,000 shares)		3,120	3,120
Accumulated other comprehensive income (Note 13)		(13,165)	(10,722)
Retained earnings		103,879	97,245
		93,834	89,643
Less: common stock held in treasury, at cost (Note 12) (364,681,000 shares and 336,620,000 shares)		22,684	19,891
Total shareholders' equity		**71,150**	**69,752**
Total liabilities and shareholders' equity	**$**	**133,411**	**130,358**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EARNINGS
(Dollars and Shares in Millions Except Per Share Amounts) (Note 1)

		2015	2014	2013
Sales to customers	$	70,074	74,331	71,312
Cost of products sold		21,536	22,746	22,342
Gross profit		48,538	51,585	48,970
Selling, marketing and administrative expenses		21,203	21,954	21,830
Research and development expense		9,046	8,494	8,183
In-process research and development		224	178	580
Interest income		(128)	(67)	(74)
Interest expense, net of portion capitalized (Note 4)		552	533	482
Other (income) expense, net		(2,064)	(70)	2,498
Restructuring (Note 22)		509	—	—
Earnings before provision for taxes on income		19,196	20,563	15,471
Provision for taxes on income (Note 8)		3,787	4,240	1,640
Net earnings	**$**	**15,409**	**16,323**	**13,831**
Net earnings per share (Notes 1 and 15)				
Basic	**$**	**5.56**	**5.80**	**4.92**
Diluted	**$**	**5.48**	**5.70**	**4.81**
Cash dividends per share	**$**	**2.95**	**2.76**	**2.59**
Average shares outstanding (Notes 1 and 15)				
Basic		**2,771.8**	**2,815.2**	**2,809.2**
Diluted		**2,812.9**	**2,863.9**	**2,877.0**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Dollars in Millions) (Note 1)

	2015	2014	2013
Net earnings	$ 15,409	16,323	13,831
Other comprehensive income (loss), net of tax			
Foreign currency translation	(3,632)	(4,601)	94
Securities:			
Unrealized holding gain (loss) arising during period	471	156	225
Reclassifications to earnings	(124)	(5)	(314)
Net change	347	151	(89)
Employee benefit plans:			
Prior service cost amortization during period	(21)	(18)	9
Prior service credit (cost) - current year	(39)	211	(27)
Gain amortization during period	624	400	515
Gain (loss) - current year	307	(4,098)	2,203
Effect of exchange rates	148	197	8
Net change	1,019	(3,308)	2,708
Derivatives & hedges:			
Unrealized gain (loss) arising during period	(115)	92	344
Reclassifications to earnings	(62)	(196)	(107)
Net change	(177)	(104)	237
Other comprehensive income (loss)	(2,443)	(7,862)	2,950
Comprehensive income	$ 12,966	8,461	16,781

The tax effects in other comprehensive income for the fiscal years ended 2015, 2014 and 2013 respectively: Securities; $187 million, $81 million and $48 million, Employee Benefit Plans; $519 million, $1,556 million and $1,421 million, Derivatives & Hedges; $95 million, $56 million and $128 million.

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY
(Dollars in Millions) (Note 1)

	Total	Retained Earnings	Accumulated Other Comprehensive Income	Common Stock Issued Amount	Treasury Stock Amount
Balance, December 30, 2012	**$ 64,826**	**85,992**	**(5,810)**	**3,120**	**(18,476)**
Net earnings	13,831	13,831			
Cash dividends paid	(7,286)	(7,286)			
Employee compensation and stock option plans	3,285	(82)			3,367
Repurchase of common stock	(3,538)	(2,947)			(591)
Other	(15)	(15)			
Other comprehensive income (loss), net of tax	2,950		2,950		
Balance, December 29, 2013	**74,053**	**89,493**	**(2,860)**	**3,120**	**(15,700)**
Net earnings	16,323	16,323			
Cash dividends paid	(7,768)	(7,768)			
Employee compensation and stock option plans	2,164	(769)			2,933
Repurchase of common stock	(7,124)				(7,124)
Other	(34)	(34)			
Other comprehensive income (loss), net of tax	(7,862)		(7,862)		
Balance, December 28, 2014	**69,752**	**97,245**	**(10,722)**	**3,120**	**(19,891)**
Net earnings	15,409	15,409			
Cash dividends paid	(8,173)	(8,173)			
Employee compensation and stock option plans	1,920	(577)			2,497
Repurchase of common stock	(5,290)				(5,290)
Other	(25)	(25)			
Other comprehensive income (loss), net of tax	(2,443)		(2,443)		
Balance, January 3, 2016	**$ 71,150**	**103,879**	**(13,165)**	**3,120**	**(22,684)**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Dollars in Millions) (Note 1)

		2015	2014	2013
Cash flows from operating activities				
Net earnings	$	15,409	16,323	13,831
Adjustments to reconcile net earnings to cash flows from operating activities:				
Depreciation and amortization of property and intangibles		3,746	3,895	4,104
Stock based compensation		874	792	728
Venezuela adjustments		122	87	108
Asset write-downs		624	410	739
Net gain on sale of assets/businesses		(2,583)	(2,383)	(113)
Net gain on equity investment transactions		—	—	(417)
Deferred tax provision		(270)	441	(607)
Accounts receivable allowances		18	(28)	(131)
Changes in assets and liabilities, net of effects from acquisitions and divestitures:				
Increase in accounts receivable		(433)	(247)	(632)
Increase in inventories		(449)	(1,120)	(622)
(Decrease)/Increase in accounts payable and accrued liabilities		(3)	955	1,821
Decrease/(Increase) in other current and non-current assets		65	442	(1,693)
Increase/(Decrease) in other current and non-current liabilities		2,159	(1,096)	298
Net cash flows from operating activities		**19,279**	**18,471**	**17,414**
Cash flows from investing activities				
Additions to property, plant and equipment		(3,463)	(3,714)	(3,595)
Proceeds from the disposal of assets/businesses, net		3,464	4,631	458
Acquisitions, net of cash acquired (Note 20)		(954)	(2,129)	(835)
Purchases of investments		(40,828)	(34,913)	(18,923)
Sales of investments		34,149	24,119	18,058
Other (primarily intangibles)		(103)	(299)	(266)
Net cash used by investing activities		**(7,735)**	**(12,305)**	**(5,103)**
Cash flows from financing activities				
Dividends to shareholders		(8,173)	(7,768)	(7,286)
Repurchase of common stock		(5,290)	(7,124)	(3,538)
Proceeds from short-term debt		2,416	1,863	1,411
Retirement of short-term debt		(1,044)	(1,267)	(1,397)
Proceeds from long-term debt		75	2,098	3,607
Retirement of long-term debt		(68)	(1,844)	(1,593)
Proceeds from the exercise of stock options/excess tax benefits		1,295	1,782	2,649
Other		(57)	—	56
Net cash used by financing activities		**(10,846)**	**(12,260)**	**(6,091)**
Effect of exchange rate changes on cash and cash equivalents		(1,489)	(310)	(204)
(Decrease)/Increase in cash and cash equivalents		(791)	(6,404)	6,016
Cash and cash equivalents, beginning of year (Note 1)		14,523	20,927	14,911
Cash and cash equivalents, end of year (Note 1)	**$**	**13,732**	**14,523**	**20,927**
Supplemental cash flow data				
Cash paid during the year for:				
Interest	$	617	603	596
Interest, net of amount capitalized		515	488	491
Income taxes		2,865	3,536	3,155

Supplemental schedule of non-cash investing and financing activities				
Treasury stock issued for employee compensation and stock option plans, net of cash proceeds		1,196	1,170	743
Conversion of debt		16	17	22
Acquisitions				
Fair value of assets acquired	$	1,174	2,167	1,028
Fair value of liabilities assumed and noncontrolling interests		(220)	(38)	(193)
Net cash paid for acquisitions	**$**	**954**	**2,129**	**835**

See Notes to Consolidated Financial Statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Johnson & Johnson and its subsidiaries (the Company). Intercompany accounts and transactions are eliminated.

Description of the Company And Business Segments

The Company has approximately 127,100 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world and its primary focus is on products related to human health and well-being.

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. The Consumer segment includes a broad range of products used in the baby care, oral care, skin care, over-the-counter pharmaceutical, women's health and wound care markets. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on five therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, and cardiovascular and metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, cardiovascular, diabetes care and vision care fields, which are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

New Accounting Pronouncements

Recently Adopted Accounting Pronouncements

During the fiscal second quarter of 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update 2015-04: Practical Expedient for the Measurement Date of an Employer's Defined Benefit Obligation and Plan Assets. This update provides a practical expedient option to entities that have defined benefit plans and have a fiscal year-end that does not coincide with a calendar month-end. This option allows an entity to elect to measure defined benefit plan assets and obligations using the calendar month-end that is closest to its fiscal year-end. This update will be effective for the Company for all annual and interim periods beginning after December 15, 2015 and if the practical expedient is elected by an entity, it is required to be adopted on a prospective basis. Early adoption is permitted. The Company has elected to adopt the practical expedient to measure its defined benefit plans. This election did not have a material impact on the Company's consolidated financial statements.

During the fiscal fourth quarter of 2015, the FASB issued Accounting Standard Update 2015-17 Income Taxes: Balance Sheet Classification of Deferred Taxes. To simplify the presentation of deferred income taxes, the amendments in this update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. This update is required to be effective for all public Companies for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Earlier application is permitted. The Company has elected to early adopt this standard on a retrospective basis. The 2014 Consolidated Balance Sheet reclassification reduced current assets by $3.6 billion, increased non-current assets by $2.8 billion and reduced liabilities by $0.8 billion.

Recently Issued Accounting Standards

Not Adopted as of January 3, 2016

During the fiscal first quarter of 2016, the FASB issued Accounting Standard Update 2016-01: Recognition and Measurement of Financial Assets and Financial Liabilities. The amendments in this update supersede the guidance to classify equity securities with readily determinable fair values into different categories (that is, trading or available-for-sale) and require equity securities to be measured at fair value with changes in the fair value recognized through net income. The standard amends financial reporting by providing relevant information about an entity's equity investments and reducing the number of items that are recognized in other comprehensive income. This update will be effective for the Company for annual periods beginning after December 15, 2017, and interim periods within those annual periods. The Company is currently assessing the impact of the future adoption of this standard on its financial statements.

During the fiscal second quarter of 2015, the FASB issued Accounting Standard Update 2015-03: Simplifying the Presentation of Debt Issuance Costs. This update requires capitalized debt issuance costs to be presented as a reduction to the carrying value of debt instead of being classified as a deferred charge, as currently required. This update will be effective for the Company for all annual and interim periods beginning after December 15, 2015 and is required to be applied retroactively for all periods presented. This update will not have a material impact on the presentation of the Company's financial position.

During the fiscal second quarter of 2015, the FASB issued Accounting Standard Update 2015-11: Simplifying the Measurement of Inventory. This update requires inventory to be measured at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. This update will be effective for the Company for all annual and interim periods beginning after December 15, 2016. The amendments in this update should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. This update will not have a material impact on the presentation of the Company's financial position.

During the fiscal third quarter of 2015, the FASB issued Accounting Standard Update 2015-16 Business Combinations: Simplifying the Accounting for Measurement-Period Adjustments. The amendments in this update require that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. This update will be effective for the Company for all annual and interim periods beginning after December 15, 2015. The amendments in this update should be applied prospectively to adjustments to provisional amounts that occur after the effective date of this update with earlier application permitted for financial statements that have not been issued. This update is not expected to have a material impact on the Company's consolidated financial statements.

During the fiscal second quarter of 2014, the FASB issued Accounting Standards Update 2014-09: Revenue from Contracts with Customers. This standard replaces substantially all current revenue recognition accounting guidance. During the fiscal third quarter of 2015, the FASB approved a one year deferral to the effective date to be adopted by all public companies for all annual periods and interim reporting periods beginning after December 15, 2017. Early adoption of this standard is permitted but not before the original effective date for all annual periods and interim reporting periods beginning after December 15, 2016. The Company is currently assessing the impact of the future adoption of this standard on its financial statements.

During the fiscal second quarter of 2014, the FASB issued amended guidance Accounting Standards Update No. 2014-10: Development Stage Entities: Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entity Guidance in Topic 810, Consolidation. The change in the current guidance will require the Company to determine if it should consolidate one of these entities based on the change in the consolidation analysis. This update to the consolidation analysis will become effective for all annual periods and interim reporting periods beginning after December 15, 2015. The adoption of this standard is not expected to have a material impact on the presentation of the Company's consolidated financial statements.

During the fiscal third quarter of 2014, the FASB issued Accounting Standards Update No. 2014-15: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. This standard requires management to evaluate, for each annual and interim reporting period, whether there are conditions and events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date the financial statements are issued or are available to be issued. If substantial doubt is raised, additional disclosures around management's plan to alleviate these doubts are required. This update will become effective for all annual periods and interim reporting periods ending after December 15, 2016. This standard is not expected to have any impact on current disclosures in the financial statements.

Cash Equivalents

The Company classifies all highly liquid investments with stated maturities of three months or less from date of purchase as cash equivalents and all highly liquid investments with stated maturities of greater than three months from the date of purchase as current marketable securities. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating. The Company invests its cash primarily in reverse repurchase agreements (RRAs), government securities and obligations, corporate debt securities and money market funds.

RRAs are collateralized by deposits in the form of 'Government Securities and Obligations' for an amount not less than 102% of their value. The Company does not record an asset or liability as the Company is not permitted to sell or repledge the associated collateral. The Company has a policy that the collateral has at least an A (or equivalent) credit rating. The Company utilizes a third party custodian to manage the exchange of funds and ensure that collateral received is maintained at 102% of the value of the RRAs on a daily basis. RRAs with stated maturities of greater than three months from the date of purchase are classified as marketable securities.

Investments

Investments classified as held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings. Investments classified as available-for-sale are carried at estimated fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income. Available-for-sale securities available for current operations are classified as current assets. Management determines the appropriate classification of its investment in debt and equity securities at the time of purchase and re-evaluates such determination at each balance sheet date. The Company periodically reviews its investments in equity securities for impairment and adjusts these investments to their fair value when a decline in market value is deemed to be other than temporary. If losses on these securities are considered to be other than temporary, the loss is recognized in earnings.

Property, Plant and Equipment and Depreciation

Property, plant and equipment are stated at cost. The Company utilizes the straight-line method of depreciation over the estimated useful lives of the assets:

Building and building equipment	20 - 30 years
Land and leasehold improvements	10 - 20 years
Machinery and equipment	2 - 13 years

The Company capitalizes certain computer software and development costs, included in machinery and equipment, when incurred in connection with developing or obtaining computer software for internal use. Capitalized software costs are amortized over the estimated useful lives of the software, which generally range from 3 to 8 years.

The Company reviews long-lived assets to assess recoverability using undiscounted cash flows. When certain events or changes in operating or economic conditions occur, an impairment assessment may be performed on the recoverability of the carrying value of these assets. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows.

Revenue Recognition

The Company recognizes revenue from product sales when the goods are shipped or delivered and title and risk of loss pass to the customer. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns and discounts to customers are accounted for as reductions in sales in the same period the related sales are recorded.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including prices charged by competitors. Rebates, which include Medicaid, are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns are generally estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales returns accruals.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual sales to customers during the fiscal reporting years 2015, 2014 and 2013.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the year incurred. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. The Company also earns service revenue for co-promotion of certain products and includes it in sales to customers. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue.

Shipping and Handling
Shipping and handling costs incurred were $996 million, $1,068 million and $1,128 million in 2015, 2014 and 2013, respectively, and are included in selling, marketing and administrative expense. The amount of revenue received for shipping and handling is less than 0.5% of sales to customers for all periods presented.

Inventories
Inventories are stated at the lower of cost or market determined by the first-in, first-out method.

Intangible Assets and Goodwill
The authoritative literature on U.S. GAAP requires that goodwill and intangible assets with indefinite lives be assessed annually for impairment. The Company completed the annual impairment test for 2015 in the fiscal fourth quarter. Future impairment tests will be performed annually in the fiscal fourth quarter, or sooner if warranted. Purchased in-process research and development is accounted for as an indefinite lived intangible asset until the underlying project is completed, at which point the intangible asset will be accounted for as a definite lived intangible asset, or abandoned, at which point the intangible asset will be written off or partially impaired.

Intangible assets that have finite useful lives continue to be amortized over their useful lives, and are reviewed for impairment when warranted by economic conditions. See Note 5 for further details on Intangible Assets and Goodwill.

Financial Instruments
As required by U.S. GAAP, all derivative instruments are recorded on the balance sheet at fair value. Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value, with Level 1 having the highest priority and Level 3 having the lowest. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The Company documents all relationships between hedged items and derivatives. The overall risk management strategy includes reasons for undertaking hedge transactions and entering into derivatives. The objectives of this strategy are: (1) minimize foreign currency exposure’s impact on the Company’s financial performance; (2) protect the Company’s cash flow from adverse movements in foreign exchange rates; (3) ensure the appropriateness of financial instruments; and (4) manage the enterprise risk associated with financial institutions. See Note 6 for additional information on Financial Instruments.

Product Liability
Accruals for product liability claims are recorded, on an undiscounted basis, when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated based on existing information and actuarially determined estimates where applicable. The accruals are adjusted periodically as additional information becomes available. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated.

As a result of cost and availability factors, effective November 1, 2005, the Company ceased purchasing third-party product liability insurance. The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated. Based on the availability of prior coverage, receivables for insurance recoveries related to product liability claims are recorded on an undiscounted basis, when it is probable that a recovery will be realized. As appropriate, reserves against these receivables are recorded for estimated amounts that may not be collected from third-party insurers.

Concentration of Credit Risk
Global concentration of credit risk with respect to trade accounts receivables continues to be limited due to the large number of customers globally and adherence to internal credit policies and credit limits. Economic challenges in Italy, Spain, Greece and Portugal (the Southern European Region) have impacted certain payment patterns, which have historically been longer than those experienced in the U.S. and other international markets. The total net trade accounts receivable balance in the Southern European Region was approximately $1.3 billion as of January 3, 2016 and approximately $1.8 billion as of December 28, 2014. Approximately $0.8 billion as of January 3, 2016 and approximately $1.1 billion as of December 28, 2014 of the Southern European Region net trade accounts receivable balance related to the Company's Consumer, Vision Care and Diabetes Care businesses as well as certain Pharmaceutical and Medical Devices customers which are in line with historical collection patterns.

The remaining balance of net trade accounts receivable in the Southern European Region has been negatively impacted by the timing of payments from certain government owned or supported health care customers, as well as certain distributors of the Pharmaceutical and Medical Devices local affiliates. The total net trade accounts receivable balance for these customers

were approximately $0.5 billion at January 3, 2016 and $0.7 billion at December 28, 2014. The Company continues to receive payments from these customers and, in some cases, late payments with interest. For customers where payment is expected over periods of time longer than one year, revenue and trade receivables have been discounted over the estimated period of time for collection. Allowances for doubtful accounts have been increased for these customers, but have been immaterial to date. The Company will continue to work closely with these customers on payment plans, monitor the economic situation and take appropriate actions as necessary.

Research and Development

Research and development expenses are expensed as incurred. Upfront and milestone payments made to third parties in connection with research and development collaborations are expensed as incurred up to the point of regulatory approval. Payments made to third parties subsequent to regulatory approval are capitalized and amortized over the remaining useful life of the related product. Amounts capitalized for such payments are included in other intangibles, net of accumulated amortization.

The Company enters into collaborative arrangements, typically with other pharmaceutical or biotechnology companies, to develop and commercialize drug candidates or intellectual property. These arrangements typically involve two (or more) parties who are active participants in the collaboration and are exposed to significant risks and rewards dependent on the commercial success of the activities. These collaborations usually involve various activities by one or more parties, including research and development, marketing and selling and distribution. Often, these collaborations require upfront, milestone and royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development. Amounts due from collaborative partners related to development activities are generally reflected as a reduction of research and development expense because the performance of contract development services is not central to the Company's operations. In general, the income statement presentation for these collaborations is as follows:

Nature/Type of Collaboration	Statement of Earnings Presentation
Third-party sale of product	Sales to customers
Royalties/milestones paid to collaborative partner (post-regulatory approval)*	Cost of products sold
Royalties received from collaborative partner	Other income (expense), net
Upfront payments & milestones paid to collaborative partner (pre-regulatory approval)	Research and development expense
Research and development payments to collaborative partner	Research and development expense
Research and development payments received from collaborative partner	Reduction of Research and development expense

* Milestones are capitalized as intangible assets and amortized to cost of goods sold over the useful life.

For all years presented, there was no individual project that represented greater than 5% of the total annual consolidated research and development expense.

The Company has a number of products and compounds developed in collaboration with strategic partners including XARELTO®, co-developed with Bayer HealthCare AG and IMBRUVICA®, developed in collaboration and co-marketed with Pharmacyclics LLC, an AbbVie company.

Advertising

Costs associated with advertising are expensed in the year incurred and are included in selling, marketing and administrative expenses. Advertising expenses worldwide, which comprised television, radio, print media and Internet advertising, were $2.5 billion, $2.6 billion and $2.5 billion in 2015, 2014 and 2013, respectively.

Income Taxes
Income taxes are recorded based on amounts refundable or payable for the current year and include the results of any difference between U.S. GAAP accounting and tax reporting, recorded as deferred tax assets or liabilities. The Company estimates deferred tax assets and liabilities based on enacted tax regulations and rates. Future changes in tax laws and rates may affect recorded deferred tax assets and liabilities in the future.

The Company has unrecognized tax benefits for uncertain tax positions. The Company follows U.S. GAAP which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Management believes that changes in these estimates would not have a material effect on the Company's results of operations, cash flows or financial position.

At January 3, 2016 and December 28, 2014, the cumulative amounts of undistributed international earnings were approximately $58.0 billion and $53.4 billion, respectively. At January 3, 2016 and December 28, 2014, the Company's foreign subsidiaries held balances of cash, cash equivalents and marketable securities in the amounts of $38.2 billion and $32.9 billion, respectively. The Company has not provided deferred taxes on the undistributed earnings from certain international subsidiaries where the earnings are considered to be permanently reinvested. The Company intends to continue to reinvest these earnings in international operations. If the Company decided at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company does not determine the deferred tax liability associated with these undistributed earnings, as such determination is not practical.

See Note 8 to the Consolidated Financial Statements for further information regarding income taxes.

Net Earnings Per Share
Basic earnings per share is computed by dividing net earnings available to common shareholders by the weighted average number of common shares outstanding for the period. Diluted earnings per share reflects the potential dilution that could occur if securities were exercised or converted into common stock using the treasury stock method.

Use of Estimates
The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the amounts reported. Estimates are used when accounting for sales discounts, rebates, allowances and incentives, product liabilities, income taxes, depreciation, amortization, employee benefits, contingencies and intangible asset and liability valuations. Actual results may or may not differ from those estimates.

The Company follows the provisions of U.S. GAAP when recording litigation related contingencies. A liability is recorded when a loss is probable and can be reasonably estimated. The best estimate of a loss within a range is accrued; however, if no estimate in the range is better than any other, the minimum amount is accrued.

Annual Closing Date
The Company follows the concept of a fiscal year, which ends on the Sunday nearest to the end of the month of December. Normally each fiscal year consists of 52 weeks, but every five or six years the fiscal year consists of 53 weeks, as was the case in 2015, and will be the case again in 2020.

Reclassification
Certain prior period amounts have been reclassified to conform to current year presentation.

2. Cash, Cash Equivalents and Current Marketable Securities

At the end of 2015 and 2014, cash, cash equivalents and current marketable securities were comprised of:

(Dollars in Millions)	2015					
	Carrying Amount	Unrecognized Gain	Unrecognized Loss	Estimated Fair Value	Cash Equivalents	Current Marketable Securities
Cash	$ 1,832	—	—	1,832	1,832	—
U.S. Gov't Securities[1]	14,641	1	(2)	14,640	650	13,991
Other Sovereign Securities[1]	2,122	—	—	2,122	933	1,189
U.S. Reverse repurchase agreements[1]	1,579	—	—	1,579	1,579	—
Other Reverse repurchase agreements[1]	2,200	—	—	2,200	2,200	—
Corporate debt securities[1]	2,941	—	—	2,941	1,793	1,148
Money market funds	3,855	—	—	3,855	3,855	—
Time deposits[1]	890	—	—	890	890	—
	Carrying Amount	Unrealized Gain	Unrealized Loss	Estimated Fair Value		
Gov't Securities	7,307	1	(34)	7,274	—	7,274
Corporate debt securities	1,046	1	(5)	1,042	—	1,042
Available for Sale[2]	$ 8,353	2	(39)	8,316	—	8,316
Total cash, cash equivalents and current marketable securities					$ 13,732	24,644

(Dollars in Millions)	2014					
	Carrying Amount	Unrecognized Gain	Unrecognized Loss	Estimated Fair Value	Cash Equivalents	Current Marketable Securities
Cash	$ 2,336	—	—	2,336	2,336	—
U.S. Gov't Securities[1]	16,345	1	(1)	16,345	1,950	14,395
Other Sovereign Securities[1]	4,265	—	—	4,265	978	3,287
U.S. Reverse repurchase agreements[1]	4,387	—	—	4,387	4,387	—
Other Reverse repurchase agreements[1]	2,348	—	—	2,348	2,348	—
Corporate debt securities[1]	1,343	—	—	1,343	459	884
Money market funds	1,352	—	—	1,352	1,352	—
Time deposits[1]	$ 713	—	—	713	713	—
Total cash, cash equivalents and current marketable securities					$ 14,523	18,566

[1] Held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings.
[2] Available for sale securities are reported at fair value with unrealized gains and losses reported net of taxes in other comprehensive income.

Fair value of government securities and obligations and corporate debt securities were estimated using quoted broker prices and significant other observable inputs.

The contractual maturities of substantially all available for sale securities are from one to five years at January 3, 2016.

The Company invests its excess cash in both deposits with major banks throughout the world and other high-quality money market instruments. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating.

3. Inventories

At the end of 2015 and 2014, inventories were comprised of:

(Dollars in Millions)		2015	2014
Raw materials and supplies	$	936	1,214
Goods in process		2,241	2,461
Finished goods		4,876	4,509
Total inventories	**$**	**8,053**	**8,184**

4. Property, Plant and Equipment

At the end of 2015 and 2014, property, plant and equipment at cost and accumulated depreciation were:

(Dollars in Millions)		2015	2014
Land and land improvements	$	780	833
Buildings and building equipment		9,829	10,046
Machinery and equipment		22,511	22,206
Construction in progress		3,528	3,600
Total property, plant and equipment, gross	$	36,648	36,685
Less accumulated depreciation		20,743	20,559
Total property, plant and equipment, net	**$**	**15,905**	**16,126**

The Company capitalizes interest expense as part of the cost of construction of facilities and equipment. Interest expense capitalized in 2015, 2014 and 2013 was $102 million, $115 million and $105 million, respectively.

Depreciation expense, including the amortization of capitalized interest in 2015, 2014 and 2013, was $2.5 billion, $2.5 billion and $2.7 billion, respectively.

Upon retirement or other disposal of property, plant and equipment, the costs and related amounts of accumulated depreciation or amortization are eliminated from the asset and accumulated depreciation accounts, respectively. The difference, if any, between the net asset value and the proceeds are recorded in earnings.

5. Intangible Assets and Goodwill

At the end of 2015 and 2014, the gross and net amounts of intangible assets were:

(Dollars in Millions)		2015	2014
Intangible assets with definite lives:			
Patents and trademarks — gross	$	8,299	9,074
Less accumulated amortization		4,745	4,700
Patents and trademarks — net	**$**	**3,554**	**4,374**
Customer relationships and other intangibles — gross	$	17,583	17,970
Less accumulated amortization		5,816	5,227
Customer relationships and other intangibles — net	**$**	**11,767**	**12,743**
Intangible assets with indefinite lives:			
Trademarks	$	7,023	7,263
Purchased in-process research and development		3,420	2,842
Total intangible assets with indefinite lives	**$**	**10,443**	**10,105**
Total intangible assets — net	**$**	**25,764**	**27,222**

Goodwill as of January 3, 2016 and December 28, 2014, as allocated by segment of business, was as follows:

(Dollars in Millions)	Consumer	Pharmaceutical	Med Devices	Total
Goodwill at December 29, 2013	$ 8,531	2,068	12,199	22,798
Goodwill, related to acquisitions	13	665	—	678
Goodwill, related to divestitures	(138)	—	(603)	(741)
Currency translation/other	(731)	(107)	(65)	(903)
Goodwill at December 28, 2014	$ 7,675	2,626	11,531	21,832
Goodwill, related to acquisitions	110	366	34	510
Goodwill, related to divestitures	(119)	(17)	(57)	(193)
Currency translation/other	(426)	(86)	(8)	(520)
Goodwill at January 3, 2016	**$ 7,240**	**2,889**	**11,500**	**21,629**

The weighted average amortization periods for patents and trademarks and customer relationships and other intangible assets are 18 years and 24 years, respectively. The amortization expense of amortizable assets included in cost of products sold was $1.2 billion, $1.4 billion and $1.4 billion before tax, for the fiscal years ended January 3, 2016, December 28, 2014 and December 29, 2013, respectively. The estimated amortization expense for the five succeeding years approximates $1.2 billion before tax, per year. Intangible asset write-downs are included in Other (income) expense, net.

See Note 20 to the Consolidated Financial Statements for additional details related to acquisitions and divestitures.

6. Fair Value Measurements

The Company uses forward foreign exchange contracts to manage its exposure to the variability of cash flows, primarily related to the foreign exchange rate changes of future intercompany products and third-party purchases of materials denominated in a foreign currency. The Company uses cross currency interest rate swaps to manage currency risk primarily related to borrowings. Both types of derivatives are designated as cash flow hedges.

Additionally, the Company uses interest rate swaps as an instrument to manage interest rate risk related to fixed rate borrowings. These derivatives are treated as fair value hedges. The Company may use forward foreign exchange contracts designated as net investment hedges. Additionally, the Company uses forward foreign exchange contracts to offset its exposure to certain foreign currency assets and liabilities. These forward foreign exchange contracts are not designated as hedges and therefore, changes in the fair values of these derivatives are recognized in earnings, thereby offsetting the current earnings effect of the related foreign currency assets and liabilities.

The Company does not enter into derivative financial instruments for trading or speculative purposes, or that contain credit risk related contingent features or requirements to post collateral by either the Company or the counter-party. On an ongoing basis, the Company monitors counterparty credit ratings. The Company considers credit non-performance risk to be low, because the Company primarily enters into agreements with commercial institutions that have at least an investment grade credit rating. Refer to the table on significant financial assets and liabilities measured at fair value contained in this footnote for receivables and payables with these commercial institutions. As of January 3, 2016, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of $31.2 billion, $2.3 billion and $2.2 billion, respectively.

All derivative instruments are recorded on the balance sheet at fair value. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The designation as a cash flow hedge is made at the entrance date of the derivative contract. At inception, all derivatives are expected to be highly effective. Changes in the fair value of a derivative that is designated as a cash flow hedge and is highly effective are recorded in accumulated other comprehensive income until the underlying transaction affects earnings, and are then reclassified to earnings in the same account as the hedged transaction. Gains and losses associated with interest rate swaps and changes in fair value of hedged debt attributable to changes in interest rates are recorded to interest expense in the period in which they occur. Gains and losses on net investment hedges are accounted for through the currency translation account and are insignificant. On an ongoing basis, the Company assesses whether each derivative continues to be highly effective in offsetting changes of hedged items. If and when a derivative is no longer expected to be highly effective, hedge accounting is discontinued. Hedge ineffectiveness, if any, is included in current period earnings in Other (income) expense, net for forward foreign exchange contracts and cross currency interest rate swaps. For interest rate swaps designated as fair value hedges, hedge ineffectiveness, if any, is included in current period earnings within interest expense. For the current reporting period, hedge ineffectiveness associated with interest rate swaps was not material.

As of January 3, 2016, the balance of deferred net losses on derivatives included in accumulated other comprehensive income was $36 million after-tax. For additional information, see the Consolidated Statements of Comprehensive Income and Note 13. The Company expects that substantially all of the amounts related to forward foreign exchange contracts will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months, excluding interest rate contracts. The amount ultimately realized in earnings may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity of the derivative.

The following table is a summary of the activity related to derivatives designated as cash flow hedges for the fiscal years ended January 3, 2016 and December 28, 2014:

(Dollars in Millions)	Gain/(Loss) Recognized In Accumulated OCI[1]		Gain/(Loss) Reclassified From Accumulated OCI Into Income[1]		Gain/(Loss) Recognized In Other Income/Expense[2]	
Cash Flow Hedges by Income Statement Caption	**2015**	**2014**	**2015**	**2014**	**2015**	**2014**
Sales to customers [3]	$ (83)	(106)	(126)	(3)	(5)	(5)
Cost of products sold [3]	(22)	58	122	204	14	2
Research and development expense [3]	(3)	39	6	7	1	—
Interest (income)/Interest expense, net [4]	(40)	21	—	(15)	—	—
Other (income) expense, net [3]	33	80	60	3	1	—
Total	**$ (115)**	**92**	**62**	**196**	**11**	**(3)**

All amounts shown in the table above are net of tax.

(1) Effective portion

(2) Ineffective portion

(3) Forward foreign exchange contracts

(4) Cross currency interest rate swaps

For the fiscal years ended January 3, 2016 and December 28, 2014, a loss of $34 million and a gain of $5 million, respectively, was recognized in Other (income) expense, net, relating to forward foreign exchange contracts not designated as hedging instruments.

Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described below with Level 1 having the highest priority and Level 3 having the lowest.

The fair value of a derivative financial instrument (i.e. forward foreign exchange contracts, interest rate contracts) is the aggregation by currency of all future cash flows discounted to its present value at the prevailing market interest rates and subsequently converted to the U.S. Dollar at the current spot foreign exchange rate. The Company does not believe that fair values of these derivative instruments materially differ from the amounts that could be realized upon settlement or maturity, or that the changes in fair value will have a material effect on the Company's results of operations, cash flows or financial position. The Company also holds equity investments which are classified as Level 1 and debt securities which are classified as Level 2. The Company did not have any other significant financial assets or liabilities which would require revised valuations under this standard that are recognized at fair value.

The following three levels of inputs are used to measure fair value:

Level 1 — Quoted prices in active markets for identical assets and liabilities.

Level 2 — Significant other observable inputs.

Level 3 — Significant unobservable inputs.

The Company's significant financial assets and liabilities measured at fair value as of January 3, 2016 and December 28, 2014 were as follows:

(Dollars in Millions)	2015 Level 1	2015 Level 2	2015 Level 3	2015 Total	2014 Total [1]
Derivatives designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts [7]	$ —	452	—	452	996
Interest rate contracts [2][4][7]	—	28	—	28	31
Total	—	**480**	—	**480**	**1,027**
Liabilities:					
Forward foreign exchange contracts [8]	—	358	—	358	751
Interest rate contracts [3][4][8]	—	241	—	241	8
Total	—	**599**	—	**599**	**759**
Derivatives not designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts [7]	—	33	—	33	29
Liabilities:					
Forward foreign exchange contracts [8]	—	41	—	41	51
Available For Sale Other Investments:					
Equity investments [5]	1,494	—	—	1,494	679
Debt securities [6]	$ —	8,316	—	8,316	—

(1) 2014 assets and liabilities are all classified as Level 2 with the exception of equity investments of $679 million, which are classified as Level 1.
(2) Includes $20 million and $29 million of non-current assets for the fiscal years ending January 3, 2016 and December 28, 2014, respectively.
(3) Includes $239 million and $8 million of non-current liabilities for the fiscal years ending January 3, 2016 and December 28, 2014, respectively.
(4) Includes cross currency interest rate swaps and interest rate swaps.
(5) Classified as non-current other assets. The carrying amount of the equity investments were $528 million and $284 million as of January 3, 2016 and December 28, 2014, respectively. The unrealized gains were $979 million and $406 million as of January 3, 2016 and December 28, 2014, respectively. The unrealized losses were $13 million and $11 million as of January 3, 2016 and December 28, 2014, respectively.
(6) Classified as current marketable securities.
(7) Classified as other current assets.
(8) Classified as accounts payable.

See Notes 2 and 7 for financial assets and liabilities held at carrying amount on the Consolidated Balance Sheet.

7. Borrowings

The components of long-term debt are as follows:

(Dollars in Millions)	2015	Effective Rate %	2014	Effective Rate %
2.15% Notes due 2016	$ 900	2.22%	898	2.22
3 month LIBOR+0.07% FRN due 2016	800	0.48	800	0.31
0.70% Notes due 2016	398	0.74	398	0.74
5.55% Debentures due 2017	1,000	5.55	1,000	5.55
1.125% Notes due 2017	700	1.15	697	1.15
5.15% Debentures due 2018	899	5.15	898	5.15
1.65% Notes due 2018	602	1.70	597	1.70
4.75% Notes due 2019 (1B Euro 1.0882)(2)/(1B Euro 1.2199)(3)	1,085 (2)	5.83	1,216 (3)	5.83
1.875% Notes due 2019	502	1.93	497	1.93
3% Zero Coupon Convertible Subordinated Debentures due 2020	137	3.00	158	3.00
2.95% Debentures due 2020	545	3.15	543	3.15
3.55% Notes due 2021	448	3.67	446	3.67
2.45% Notes due 2021	349	2.48	349	2.48
6.73% Debentures due 2023	250	6.73	250	6.73
3.375% Notes due 2023	811	3.17	812	3.17
5.50% Notes due 2024 (500MM GBP 1.4818)(2)/(500MM GBP 1.5542)(3)	737 (2)	6.75	772 (3)	6.75
6.95% Notes due 2029	297	7.14	297	7.14
4.95% Debentures due 2033	500	4.95	500	4.95
4.375% Notes due 2033	864	4.24	865	4.23
5.95% Notes due 2037	996	5.99	995	5.99
5.85% Debentures due 2038	700	5.86	700	5.86
4.50% Debentures due 2040	540	4.63	539	4.63
4.85% Notes due 2041	298	4.89	298	4.89
4.50% Notes due 2043	499	4.52	499	4.52
Other	104	—	105	—
Subtotal	**14,961** (4)	**4.06%** (1)	**15,129** (4)	**4.08** (1)
Less current portion	2,104		7	
Total long-term debt	**$ 12,857**		**15,122**	

(1) Weighted average effective rate.
(2) Translation rate at January 3, 2016.
(3) Translation rate at December 28, 2014.
(4) The excess of the fair value over the carrying value of debt was $1.7 billion in 2015 and $2.2 billion in 2014.

Fair value of the non-current debt was estimated using market prices, which were corroborated by quoted broker prices and significant other observable inputs.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2015, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 15, 2016. Interest charged on borrowings under the credit line agreements is based on either bids provided by banks, the prime rate or London Interbank Offered Rates (LIBOR), plus applicable margins. Commitment fees under the agreements are not material.

Throughout 2015, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $7.0 billion at the end of 2015, of which $4.6

billion was borrowed under the Commercial Paper Program. The remainder principally represents local borrowing by international subsidiaries.

Aggregate maturities of long-term obligations commencing in 2016 are:

(Dollars in Millions)					
2016	**2017**	**2018**	**2019**	**2020**	**After 2020**
$2,104	1,790	1,501	1,587	683	7,296

8. Income Taxes

The provision for taxes on income consists of:

(Dollars in Millions)	2015	2014	2013
Currently payable:			
U.S. taxes	$ 2,748	2,625	594
International taxes	1,309	1,174	1,653
Total currently payable	4,057	3,799	2,247
Deferred:			
U.S. taxes	37	(258)	(251)
International taxes	(307)	699	(356)
Total deferred	(270)	441	(607)
Provision for taxes on income	**$ 3,787**	**4,240**	**1,640**

A comparison of income tax expense at the U.S. statutory rate of 35% in 2015, 2014 and 2013, to the Company's effective tax rate is as follows:

(Dollars in Millions)	2015	2014	2013
U.S.	$ 8,179	8,001	4,261
International	11,017	12,562	11,210
Earnings before taxes on income:	$ 19,196	20,563	15,471
Tax rates:			
U.S. statutory rate	35.0 %	35.0	35.0
International operations excluding Ireland	(6.7)	(7.0)	(10.6)
Ireland and Puerto Rico operations[1]	(8.7)	(6.9)	(9.0)
Research and orphan drug tax credits	(0.2)	(0.3)	(0.8)
U.S. state and local	0.4	1.0	0.4
U.S. manufacturing deduction	(0.6)	(0.6)	(0.8)
U.S. tax on international income	0.2	1.4	1.7
U.S. tax benefit on asset/business disposals	—	(1.9)	(5.1)
All other	0.3	(0.1)	(0.2)
Effective tax rate	19.7 %	20.6	10.6

[1]The Company has subsidiaries operating in Puerto Rico under various tax incentives.

The 2015 effective tax rate decrease as compared to 2014 was primarily attributable to the increases in taxable income in lower tax jurisdictions relative to higher tax jurisdictions and a tax benefit resulting from a restructuring of international affiliates. Additionally, the 2014 effective tax rate was affected by the items mentioned below.

The increase in the 2014 effective tax rate, as compared to 2013, was attributable to the following: the divestiture of the Ortho-Clinical Diagnostics business at an approximate 44% effective tax rate, litigation accruals at low tax rates, the mix of earnings into higher tax jurisdictions, primarily the U.S., the accrual of an additional year of the Branded Prescription Drug Fee, which is not tax deductible, and additional U.S. tax expense related to a planned increase in dividends from current year foreign earnings as compared to the prior year. These increases to the 2014 effective tax rate were partially offset by a tax benefit of $0.4 billion associated with the Conor Medsystems divestiture.

The 2013 effective tax rate was reduced by a tax benefit associated with the write-off of assets for tax purposes associated with Scios, Inc., and the inclusion of both the 2013 and 2012 benefit from the Research and Development tax credit and the Controlled Foreign Corporation look-through provisions, because those provisions were enacted into law in January 2013 and were retroactive to January 1, 2012.

The 2014 effective tax rate was also reduced as the Company adjusted its unrecognized tax benefits as a result of (i) the federal appeals court's decision in OMJ Pharmaceuticals, Inc.'s litigation regarding credits under former Section 936 of the Internal Revenue Code (see Note 21 to the Consolidated Financial Statements for additional information), and (ii) a settlement of substantially all issues related to the Company's U.S. Internal Revenue Service audit of tax years 2006 - 2009. The impact of the settlement is reflected in the U.S. tax on international income and the All other line items within the above reconciliation.

The items noted above reflect the key drivers of the rate reconciliation.

Temporary differences and carryforwards for 2015 and 2014 were as follows:

	2015 Deferred Tax		2014 Deferred Tax	
(Dollars in Millions)	**Asset**	**Liability**	**Asset**	**Liability**
Employee related obligations	$ 2,863		3,426	
Stock based compensation	790		799	
Depreciation		(247)		(564)
Non-deductible intangibles		(6,663)		(6,671)
International R&D capitalized for tax	1,318		1,433	
Reserves & liabilities	1,801		1,497	
Income reported for tax purposes	960		1,067	
Net operating loss carryforward international	997		949	
Miscellaneous international	922 (1)	(249)	1,128 (1)	(305)
Miscellaneous U.S.	436		996	
Total deferred income taxes	**$ 10,087**	**(7,159)**	**11,295**	**(7,540)**

(1) The $922 million in 2015 was net of a valuation allowance related to Belgium of $196 million. The $1,128 million in 2014 was net of a valuation allowance related to Belgium of $172 million.

The Company has wholly-owned international subsidiaries that have cumulative net losses. The Company believes that it is more likely than not that these subsidiaries will realize future taxable income sufficient to utilize these deferred tax assets.

The following table summarizes the activity related to unrecognized tax benefits:

(Dollars in Millions)	**2015**	**2014**	**2013**
Beginning of year	$ 2,465	2,729	3,054
Increases related to current year tax positions	570	281	643
Increases related to prior period tax positions	182	295	80
Decreases related to prior period tax positions	(79)	(288)	(574)
Settlements	(4)	(477)	(418)
Lapse of statute of limitations	(54)	(75)	(56)
End of year	**$ 3,080**	**2,465**	**2,729**

The unrecognized tax benefits of $3.1 billion at January 3, 2016, if recognized, would affect the Company's annual effective tax rate. The Company conducts business and files tax returns in numerous countries and currently has tax audits in progress with a number of tax authorities. The IRS has completed its audit for the tax years through 2009 and is currently auditing the tax years 2010-2012. In other major jurisdictions where the Company conducts business, the years remain open generally back to the year 2004. The Company believes it is possible that audits may be completed by tax authorities in some jurisdictions over the next twelve months. However, the Company is not able to provide a reasonably reliable estimate of the timing of any other future tax payments relating to uncertain tax positions.

The Company classifies liabilities for unrecognized tax benefits and related interest and penalties as long-term liabilities. Interest expense and penalties related to unrecognized tax benefits are classified as income tax expense. The Company recognized after tax interest expense of $44 million, $12 million and $40 million in 2015, 2014 and 2013, respectively. The total amount of accrued interest was $366 million and $298 million in 2015 and 2014, respectively.

9. Employee Related Obligations

At the end of 2015 and 2014, employee related obligations recorded on the Consolidated Balance Sheets were:

(Dollars in Millions)	2015	2014
Pension benefits	$ 3,857	4,547
Postretirement benefits	2,738	3,161
Postemployment benefits	2,092	2,062
Deferred compensation	584	599
Total employee obligations	9,271	10,369
Less current benefits payable	417	397
Employee related obligations — non-current	**$ 8,854**	**9,972**

Prepaid employee related obligations of $256 million and $233 million for 2015 and 2014, respectively, are included in Other assets on the Consolidated Balance Sheets.

10. Pensions and Other Benefit Plans

The Company sponsors various retirement and pension plans, including defined benefit, defined contribution and termination indemnity plans, which cover most employees worldwide. The Company also provides post-retirement benefits, primarily health care, to all eligible U.S. retired employees and their dependents.

Many international employees are covered by government-sponsored programs and the cost to the Company is not significant.

Retirement plan benefits for employees hired before January 1, 2015 are primarily based on the employee's compensation during the last three to five years before retirement and the number of years of service. In 2014, the Company announced that the U.S. Defined Benefit plan was amended to adopt a new benefit formula, effective for employees hired on or after January 1, 2015. The benefits are calculated using a new formula based on employee compensation over total years of service.

International subsidiaries have plans under which funds are deposited with trustees, annuities are purchased under group contracts, or reserves are provided.

The Company does not fund retiree health care benefits in advance and has the right to modify these plans in the future.

As described in Note 1 to the Consolidated Financial Statements, the Company has elected to early adopt a practical expedient beginning for the fiscal year end 2015 to measure its defined benefit plans using the calendar month end closest to its fiscal year end. In 2015 and 2014 the Company used December 31, 2015 and December 28, 2014, respectively, as the measurement date for all U.S. and international retirement and other benefit plans.

Net periodic benefit costs for the Company's defined benefit retirement plans and other benefit plans for 2015, 2014 and 2013 include the following components:

	Retirement Plans			Other Benefit Plans		
(Dollars in Millions)	2015	2014	2013	2015	2014	2013
Service cost	$ 1,037	882	906	257	211	196
Interest cost	988	1,018	908	186	197	151
Expected return on plan assets	(1,809)	(1,607)	(1,447)	(7)	(7)	(6)
Amortization of prior service cost (credit)	2	6	6	(33)	(34)	(2)
Amortization of net transition obligation	—	1	1	—	—	—
Recognized actuarial losses	745	460	681	201	136	111
Curtailments and settlements	8	(17)	—	—	—	2
Net periodic benefit cost	**$ 971**	**743**	**1,055**	**604**	**503**	**452**

Amounts expected to be recognized in net periodic benefit cost in the coming year for the Company's defined benefit retirement plans and other postretirement plans:

(Dollars in Millions)	
Amortization of net transition obligation	$ —
Amortization of net actuarial losses	638
Amortization of prior service credit	29

Unrecognized gains and losses for the U.S. pension plans are amortized over the average remaining future service for each plan. For plans with no active employees, they are amortized over the average life expectancy. The amortization of gains and losses for the other U.S. benefit plans is determined by using a 10% corridor of the greater of the market value of assets or the accumulated postretirement benefit obligation. Total unamortized gains and losses in excess of the corridor are amortized over the average remaining future service.

Prior service costs/benefits for the U.S. pension plans are amortized over the average remaining future service of plan participants at the time of the plan amendment. Prior service cost/benefit for the other U.S. benefit plans is amortized over the average remaining service to full eligibility age of plan participants at the time of the plan amendment.

The following table represents the weighted-average actuarial assumptions:

	Retirement Plans			Other Benefit Plans		
Worldwide Benefit Plans	**2015**	**2014**	**2013**	**2015**	**2014**	**2013**
Net Periodic Benefit Cost						
Discount rate	3.78%	4.78	4.25	4.31	5.25	4.55
Rate of increase in compensation levels	4.05%	4.08	4.08	4.11	4.29	4.28
Expected long-term rate of return on plan assets	8.53%	8.46	8.45			
Benefit Obligation						
Discount rate	4.11%	3.78	4.78	4.63	4.31	5.25
Rate of increase in compensation levels	4.01%	4.05	4.08	4.28	4.11	4.29

The Company's discount rates are determined by considering current yield curves representing high quality, long-term fixed income instruments. The resulting discount rates are consistent with the duration of plan liabilities. For the fiscal year 2016, the Company will change its methodology in determining service and interest cost from the single weighted average discount rate approach to duration specific spot rates along that yield curve to the plans' liability cash flows, which management has concluded is a more precise estimate. Prior to this change in methodology, the Company measured service and interest costs utilizing a single weighted-average discount rate derived from the yield curve used to measure the plan obligations. The Company has accounted for this change as a change in accounting estimate and, accordingly, has accounted for it on a prospective basis. This change will not impact the benefit obligation and will not have a material impact to the 2016 full year results.

The expected rates of return on plan asset assumptions represent the Company's assessment of long-term returns on diversified investment portfolios globally. The assessment is determined using projections from external financial sources, long-term historical averages, actual returns by asset class and the various asset class allocations by market.

In 2014, for measurement of U.S. retirement benefit obligations, the mortality assumption was updated to a newly established 2014 mortality table resulting in an increase to the projected benefit obligation.

The following table displays the assumed health care cost trend rates, for all individuals:

Health Care Plans	2015	2014
Health care cost trend rate assumed for next year	6.60%	6.00%
Rate to which the cost trend rate is assumed to decline (ultimate trend)	4.50%	4.50%
Year the rate reaches the ultimate trend rate	2038	2032

A one-percentage-point change in assumed health care cost trend rates would have the following effect:

(Dollars in Millions)	One-Percentage-Point Increase	One-Percentage-Point Decrease
Health Care Plans		
Total interest and service cost	$ 36	(29)
Post-retirement benefit obligation	$ 417	(326)

The following table sets forth information related to the benefit obligation and the fair value of plan assets at year-end 2015 and 2014 for the Company's defined benefit retirement plans and other post-retirement plans:

	Retirement Plans		Other Benefit Plans	
(Dollars in Millions)	**2015**	**2014**	**2015**	**2014**
Change in Benefit Obligation				
Projected benefit obligation — beginning of year	$ 26,889	21,488	5,081	4,407
Service cost	1,037	882	257	211
Interest cost	988	1,018	186	197
Plan participant contributions	48	59	—	—
Amendments	60	(60)	—	(254)
Actuarial (gains) losses	(1,578)	5,395	(400)	1,030
Divestitures & acquisitions	(5)	(121)	—	—
Curtailments, settlements & restructuring	(20)	(53)	(3)	—
Benefits paid from plan	(773)	(813)	(420)	(493)
Effect of exchange rates	(791)	(906)	(32)	(17)
Projected benefit obligation — end of year	**$ 25,855**	**26,889**	**4,669**	**5,081**
Change in Plan Assets				
Plan assets at fair value — beginning of year	$ 22,575	20,901	79	87
Actual return on plan assets	298	2,078	1	8
Company contributions	752	1,176	414	477
Plan participant contributions	48	59	—	—
Settlements	(20)	(40)	—	—
Divestitures & acquisitions	(5)	(109)	—	—
Benefits paid from plan assets	(773)	(813)	(420)	(493)
Effect of exchange rates	(621)	(677)	—	—
Plan assets at fair value — end of year	**$ 22,254**	**22,575**	**74**	**79**
Funded status — end of year	**$ (3,601)**	**(4,314)**	**(4,595)**	**(5,002)**
Amounts Recognized in the Company's Balance Sheet consist of the following:				
Non-current assets	$ 256	233	—	—
Current liabilities	(77)	(74)	(324)	(309)
Non-current liabilities	(3,780)	(4,473)	(4,271)	(4,693)
Total recognized in the consolidated balance sheet — end of year	**$ (3,601)**	**(4,314)**	**(4,595)**	**(5,002)**
Amounts Recognized in Accumulated Other Comprehensive Income consist of the following:				
Net actuarial loss	$ 6,501	7,547	2,013	2,611
Prior service cost (credit)	34	(33)	(185)	(225)
Unrecognized net transition obligation	—	1	—	—
Total before tax effects	**$ 6,535**	**7,515**	**1,828**	**2,386**
Accumulated Benefit Obligations — end of year	**$ 23,262**	**23,816**		

(Dollars in Millions)	Retirement Plans 2015	Retirement Plans 2014	Other Benefit Plans 2015	Other Benefit Plans 2014
Amounts Recognized in Net Periodic Benefit Cost and Other Comprehensive Income				
Net periodic benefit cost	**$ 971**	**743**	**604**	**503**
Net actuarial (gain) loss	(75)	4,942	(389)	1,015
Amortization of net actuarial loss	(745)	(460)	(201)	(136)
Prior service cost (credit)	60	(60)	—	(253)
Amortization of prior service (cost) credit	(2)	(6)	33	34
Effect of exchange rates	(218)	(273)	(1)	—
Total recognized in other comprehensive income, before tax	**$ (980)**	**4,143**	**(558)**	**660**
Total recognized in net periodic benefit cost and other comprehensive income	**$ (9)**	**4,886**	**46**	**1,163**

The Company plans to continue to fund its U.S. Qualified Plans to comply with the Pension Protection Act of 2006. International Plans are funded in accordance with local regulations. Additional discretionary contributions are made when deemed appropriate to meet the long-term obligations of the plans. For certain plans, funding is not a common practice, as funding provides no economic benefit. Consequently, the Company has several pension plans that are not funded.

In 2015, the Company contributed $435 million and $317 million to its U.S. and international pension plans, respectively.

The following table displays the funded status of the Company's U.S. Qualified & Non-Qualified pension plans and international funded and unfunded pension plans at December 31, 2015 and December 28, 2014, respectively:

	U.S. Plans				International Plans			
	Qualified Plans		Non-Qualified Plans		Funded Plans		Unfunded Plans	
(Dollars in Millions)	2015	2014	2015	2014	2015	2014	2015	2014
Plan Assets	$ 15,113	15,201	—	—	7,141	7,374	—	—
Projected Benefit Obligation	15,280	15,571	1,675	1,683	8,542	9,203	358	432
Accumulated Benefit Obligation	13,876	13,875	1,411	1,363	7,661	8,205	314	373
Over (Under) Funded Status								
Projected Benefit Obligation	$ (167)	(370)	(1,675)	(1,683)	(1,401)	(1,829)	(358)	(432)
Accumulated Benefit Obligation	1,237	1,326	(1,411)	(1,363)	(520)	(831)	(314)	(373)

Plans with accumulated benefit obligations in excess of plan assets have an accumulated benefit obligation, projected benefit obligation and plan assets of $4.5 billion, $5.3 billion and $1.9 billion, respectively, at the end of 2015, and $8.2 billion, $9.4 billion and $5.3 billion, respectively, at the end of 2014.

The following table displays the projected future benefit payments from the Company's retirement and other benefit plans:

(Dollars in Millions)	2016	2017	2018	2019	2020	2021-2025
Projected future benefit payments						
Retirement plans	$ 839	872	911	967	1,031	6,098
Other benefit plans	$ 331	322	315	312	310	1,499

The following table displays the projected future minimum contributions to the unfunded retirement plans. These amounts do not include any discretionary contributions that the Company may elect to make in the future.

(Dollars in Millions)	2016	2017	2018	2019	2020	2021-2025
Projected future contributions	$ 76	77	82	88	93	559

Each pension plan is overseen by a local committee or board that is responsible for the overall administration and investment of the pension plans. In determining investment policies, strategies and goals, each committee or board considers factors including, local pension rules and regulations; local tax regulations; availability of investment vehicles (separate accounts, commingled accounts, insurance funds, etc.); funded status of the plans; ratio of actives to retirees; duration of liabilities; and other relevant factors including: diversification, liquidity of local markets and liquidity of base currency. A majority of the Company's pension funds are open to new entrants and are expected to be on-going plans. Permitted investments are primarily liquid and/or listed, with little reliance on illiquid and non-traditional investments such as hedge funds.

The Company's retirement plan asset allocation at the end of 2015 and 2014 and target allocations for 2016 are as follows:

	Percent of Plan Assets		Target Allocation
	2015	2014	2016
Worldwide Retirement Plans			
Equity securities	79%	77%	74%
Debt securities	21	23	26
Total plan assets	**100%**	**100%**	**100%**

Determination of Fair Value of Plan Assets

The Plan has an established and well-documented process for determining fair values. Fair value is based upon quoted market prices, where available. If listed prices or quotes are not available, fair value is based upon models that primarily use, as inputs, market-based or independently sourced market parameters, including yield curves, interest rates, volatilities, equity or debt prices, foreign exchange rates and credit curves.

While the Plan believes its valuation methods are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

Valuation Hierarchy

The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described in the table below with Level 1 having the highest priority and Level 3 having the lowest.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Following is a description of the valuation methodologies used for the investments measured at fair value.

- *Short-term investments* — Cash and quoted short-term instruments are valued at the closing price or the amount held on deposit by the custodian bank. Other investments are through investment vehicles valued using the Net Asset Value (NAV) provided by the administrator of the fund. The NAV is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding. The NAV is a quoted price in a market that is not active and classified as Level 2.
- *Government and agency securities* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified within Level 1 of the valuation hierarchy. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows. When quoted market prices for a security are not available in an active market, they are classified as Level 2.
- *Debt instruments* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified as Level 1. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows and are classified as Level 2. Level 3 debt instruments are priced based on unobservable inputs.
- *Equity securities* — Common stocks are valued at the closing price reported on the major market on which the individual securities are traded. Substantially all common stock is classified within Level 1 of the valuation hierarchy.
- *Commingled funds* — These investment vehicles are valued using the NAV provided by the fund administrator. The NAV is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding. Assets in the Level 2 category have a quoted market price in a market that is not active.

- *Insurance contracts* — The instruments are issued by insurance companies. The fair value is based on negotiated value and the underlying investments held in separate account portfolios as well as considering the credit worthiness of the issuer. The underlying investments are government, asset-backed and fixed income securities. In general, insurance contracts are classified as Level 3 as there are no quoted prices nor other observable inputs for pricing.
- *Other assets* — Other assets are represented primarily by limited partnerships and real estate investments, as well as commercial loans and commercial mortgages that are not classified as corporate debt. Other assets that are exchange listed and actively traded are classified as Level 1, while inactively traded assets are classified as Level 2. Most limited partnerships represent investments in private equity and similar funds that are valued by the general partners. Certain of these limited partnerships, as well as any other assets valued using unobservable inputs, are classified as Level 3.

The following table sets forth the Retirement Plans' investments measured at fair value as of December 31, 2015 and December 28, 2014:

	Quoted Prices in Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs (Level 3)		Total Assets	
(Dollars in Millions)	**2015**	**2014**	**2015**	**2014**	**2015**	**2014**	**2015**	**2014**
Short-term investment funds	$ 184	168	312	551	—	—	496	719
Government and agency securities	—	—	1,767	1,934	—	—	1,767	1,934
Debt instruments	—	—	1,050	1,143	1	1	1,051	1,144
Equity securities	11,317	11,204	11	21	—	—	11,328	11,225
Commingled funds	—	—	7,189	7,205	33	46	7,222	7,251
Insurance contracts	—	—	—	—	23	24	23	24
Other assets	—	1	314	214	53	63	367	278
Investments at fair value	**$ 11,501**	**11,373**	**10,643**	**11,068**	**110**	**134**	**22,254**	**22,575**

The Company's Other Benefit Plans are unfunded except for U.S. commingled funds (Level 2) of $74 million and $79 million at December 31, 2015 and December 28, 2014, respectively.

The fair value of Johnson & Johnson Common Stock directly held in plan assets was $751 million (3.4% of total plan assets) at December 31, 2015 and $778 million (3.4% of total plan assets) at December 28, 2014.

Level 3 Gains and Losses

The table below sets forth a summary of changes in the fair value of the Plan's Level 3 assets for the years ended December 31, 2015 and December 28, 2014:

(Dollars in Millions)	**Debt Instruments**	**Equity Securities**	**Commingled Funds**	**Insurance Contracts**	**Other Assets**	**Total Level 3**
Balance December 29, 2013	$ 1	4	44	23	69	141
Realized gains (losses)	—	—	—	—	(5)	(5)
Unrealized gains (losses)	—	—	2	—	—	2
Purchases, sales, issuances and settlements, net	—	—	(2)	3	(1)	—
Transfers in/out and exchange rate changes	—	(4)	2	(2)	—	(4)
Balance December 28, 2014	1	—	46	24	63	134
Realized gains (losses)	—	—	1	—	(2)	(1)
Unrealized gains (losses)	—	—	(11)	—	(5)	(16)
Purchases, sales, issuances and settlements, net	—	—	(2)	1	(2)	(3)
Transfers in/out and exchange rate changes	—	—	(1)	(2)	(1)	(4)
Balance December 31, 2015	**$ 1**	**—**	**33**	**23**	**53**	**110**

11. Savings Plan

The Company has voluntary 401(k) savings plans designed to enhance the existing retirement programs covering eligible employees. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which he/she is eligible. Total Company matching contributions to the plans were $187 million, $172 million and $164 million in 2015, 2014 and 2013, respectively.

12. Capital and Treasury Stock

Changes in treasury stock were:

	Treasury Stock	
(Amounts in Millions Except Treasury Stock Shares in Thousands)	Shares	Amount
Balance at December 30, 2012	341,354	$ 18,476
Employee compensation and stock option plans	(48,555)	(3,367)
Repurchase of common stock	6,416	591
Balance at December 29, 2013	299,215	15,700
Employee compensation and stock option plans	(32,302)	(2,933)
Repurchase of common stock	69,707	7,124
Balance at December 28, 2014	336,620	19,891
Employee compensation and stock option plans	(24,413)	(2,497)
Repurchase of common stock	52,474	5,290
Balance at January 3, 2016	364,681	$ 22,684

Aggregate shares of common stock issued were approximately 3,119,843,000 shares at the end of 2015, 2014 and 2013.

Cash dividends paid were $2.95 per share in 2015, compared with dividends of $2.76 per share in 2014, and $2.59 per share in 2013.

On October 13, 2015, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $10.0 billion of the Company's shares of common stock. The repurchase program has no time limit and may be suspended for periods or discontinued at any time. Any shares acquired will be available for general corporate purposes. The Company intends to finance the share repurchase program through available cash and access to the capital markets. As of January 3, 2016, $1.0 billion has been repurchased under the program.

On July 21, 2014, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's shares of common stock. This share repurchase program was completed on April 28, 2015.

13. Accumulated Other Comprehensive Income

Components of other comprehensive income (loss) consist of the following:

(Dollars in Millions)	Foreign Currency Translation	Gain/(Loss) On Securities	Employee Benefit Plans	Gain/ (Loss) On Derivatives & Hedges	Total Accumulated Other Comprehensive Income (Loss)
December 30, 2012	$ (296)	195	(5,717)	8	(5,810)
Net 2013 changes	94	(89)	2,708	237	2,950
December 29, 2013	(202)	106	(3,009)	245	(2,860)
Net 2014 changes	(4,601)	151	(3,308)	(104)	(7,862)
December 28, 2014	(4,803)	257	(6,317)	141	(10,722)
Net 2015 changes	(3,632)	347	1,019	(177)	(2,443)
January 3, 2016	$ (8,435)	604	(5,298)	(36)	(13,165)

Amounts in accumulated other comprehensive income are presented net of the related tax impact. Foreign currency translation is not adjusted for income taxes where it relates to permanent investments in international subsidiaries. For additional details on comprehensive income see the Consolidated Statements of Comprehensive Income.

Details on reclassifications out of Accumulated Other Comprehensive Income:
Gain/(Loss) On Securities - reclassifications released to Other (income) expense, net.
Employee Benefit Plans - reclassifications are included in net periodic benefit cost. See Note 10 for additional details.
Gain/(Loss) On Derivatives & Hedges - reclassifications to earnings are recorded in the same account as the hedged transaction. See Note 6 for additional details.

14. International Currency Translation

For translation of its subsidiaries operating in non-U.S. Dollar currencies, the Company has determined that the local currencies of its international subsidiaries are the functional currencies except those in highly inflationary economies, which are defined as those which have had compound cumulative rates of inflation of 100% or more during the past three years, or where a substantial portion of its cash flows are not in the local currency.

In consolidating international subsidiaries, balance sheet currency effects are recorded as a component of accumulated other comprehensive income. This equity account includes the results of translating certain balance sheet assets and liabilities at current exchange rates and some accounts at historical rates, except for those located in highly inflationary economies. The translation of balance sheet accounts for highly inflationary economies are reflected in the operating results.

A rollforward of the changes during 2015, 2014 and 2013 for foreign currency translation adjustments is included in Note 13.

Net currency transaction gains and losses included in Other (income) expense were losses of $104 million, $156 million and $186 million in 2015, 2014 and 2013, respectively.

15. Earnings Per Share

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal years ended January 3, 2016, December 28, 2014 and December 29, 2013:

(In Millions Except Per Share Amounts)	2015	2014	2013
Basic net earnings per share	$ 5.56	5.80	4.92
Average shares outstanding — basic	2,771.8	2,815.2	2,809.2
Potential shares exercisable under stock option plans	141.5	142.6	148.5
Less: shares repurchased under treasury stock method	(102.6)	(96.5)	(103.3)
Convertible debt shares	2.2	2.6	3.0
Accelerated share repurchase program	—	—	19.6
Adjusted average shares outstanding — diluted	2,812.9	2,863.9	2,877.0
Diluted net earnings per share	$ 5.48	5.70	4.81

The diluted net earnings per share calculation included the dilutive effect of convertible debt that is offset by the related reduction in interest expense of $3 million after-tax for years 2015 and 2014 and $4 million for year 2013.

The diluted net earnings per share calculation for 2015, 2014 and 2013 included all shares related to stock options, as the exercise price of all options was less than the average market value of the Company's stock.

The diluted net earnings per share calculation for the fiscal year ended December 29, 2013 included the dilutive effect of 19.6 million shares, related to the accelerated share repurchase program, associated with the acquisition of Synthes, Inc. in the fiscal year 2012.

16. Rental Expense and Lease Commitments

Rentals of space, vehicles, manufacturing equipment and office and data processing equipment under operating leases were approximately $316 million, $341 million and $363 million in 2015, 2014 and 2013, respectively.

The approximate minimum rental payments required under operating leases that have initial or remaining non-cancelable lease terms in excess of one year at January 3, 2016 are:

(Dollars in Millions)

2016	2017	2018	2019	2020	After 2020	Total
$224	194	136	90	74	109	827

Commitments under capital leases are not significant.

17. Common Stock, Stock Option Plans and Stock Compensation Agreements

At January 3, 2016, the Company had 2 stock-based compensation plans. The shares outstanding are for contracts under the Company's 2005 Long-Term Incentive Plan and the 2012 Long-Term Incentive Plan. The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan. Under the 2012 Long-Term Incentive Plan, the Company may issue up to 650 million shares of common stock, plus any shares canceled, expired, forfeited, or not issued from the 2005 Long-Term Incentive Plan subsequent to April 26, 2012. Shares available for future grants under the 2012 Long-Term Incentive Plan were 486 million at the end of 2015.

The compensation cost that has been charged against income for these plans was $874 million, $792 million and $728 million for 2015, 2014 and 2013, respectively. The total income tax benefit recognized in the income statement for share-based compensation costs was $253 million, $259 million and $243 million for 2015, 2014 and 2013, respectively. The total unrecognized compensation cost was $744 million, $722 million and $636 million for 2015, 2014 and 2013, respectively. The weighted average period for this cost to be recognized was 0.98 years, 1.18 years and 1.26 years for 2015, 2014, and 2013, respectively. Share-based compensation costs capitalized as part of inventory were insignificant in all periods.

The Company settles employee benefit equity issuances with treasury shares. Treasury shares are replenished throughout the year for the number of shares used to settle employee benefit equity issuances.

Stock Options

Stock options expire 10 years from the date of grant and vest over service periods that range from 6 months to 4 years. All options are granted at the average of the high and low prices of the Company’s Common Stock on the New York Stock Exchange on the date of grant.

The fair value of each option award was estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the following table. For 2014 and 2013 grants, expected volatility represents a blended rate of 4-year daily historical average volatility rate, and a 5-week average implied volatility rate based on at-the-money traded Johnson & Johnson options with a life of 2 years. For 2015 grants, expected volatility represents a blended rate of 10-year weekly historical overall volatility rate, and a 5-week average implied volatility rate based on at-the-money traded Johnson & Johnson options with a life of 2 years. For all grants, historical data is used to determine the expected life of the option. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant.

The average fair value of options granted was $10.68, $8.42 and $4.88, in 2015, 2014 and 2013, respectively. The fair value was estimated based on the weighted average assumptions of:

	2015	2014	2013
Risk-free rate	1.77%	1.87%	1.01%
Expected volatility	15.48%	14.60%	14.04%
Expected life (in years)	7.0	6.0	6.0
Expected dividend yield	2.90%	3.10%	3.40%

A summary of option activity under the Plan as of January 3, 2016, December 28, 2014 and December 29, 2013, and changes during the years ending on those dates is presented below:

(Shares in Thousands)	Outstanding Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (Dollars in Millions)
Shares at December 30, 2012	134,351	$ 61.58	$ 1,061
Options granted	29,010	72.54	
Options exercised	(41,357)	59.99	
Options canceled/forfeited	(2,448)	65.89	
Shares at December 29, 2013	119,556	64.70	3,306
Options granted	24,356	90.44	
Options exercised	(25,319)	62.31	
Options canceled/forfeited	(2,881)	75.48	
Shares at December 28, 2014	115,712	70.37	4,014
Options granted	20,484	100.06	
Options exercised	(16,683)	62.53	
Options canceled/forfeited	(2,996)	82.22	
Shares at January 3, 2016	**116,517**	**$ 76.41**	**$ 3,065**

The total intrinsic value of options exercised was $644 million, $954 million and $941 million in 2015, 2014 and 2013, respectively.

The following table summarizes stock options outstanding and exercisable at January 3, 2016:

(Shares in Thousands)	Outstanding			Exercisable	
Exercise Price Range	Options	Average Life[1]	Average Exercise Price	Options	Average Exercise Price
$52.13-$58.33	8,694	3.1	$58.32	8,694	$58.32
$58.34-$62.20	17,644	2.6	$61.21	17,644	$61.21
$62.62-$65.62	22,139	3.4	$64.55	21,726	$64.54
$66.07-$72.54	25,617	7.0	$72.52	217	$69.77
$90.44-$100.48	42,423	8.6	$94.98	64	$90.47
	116,517	**5.9**	**$76.41**	**48,345**	**$62.26**

[1] Average contractual life remaining in years.

Stock options outstanding at December 28, 2014 and December 29, 2013 were 115,712 and an average life of 5.7 years and 119,556 and an average life of 5.1 years, respectively. Stock options exercisable at December 28, 2014 and December 29, 2013 were 57,846 at an average price of $61.94 and 75,210 at an average price of $62.01, respectively.

Restricted Share Units and Performance Share Units

The Company grants restricted share units which vest over service periods that range from 6 months to 3 years. The Company also grants performance share units, which are paid in shares of Johnson & Johnson Common Stock after the end of a three-year performance period. Whether any performance share units vest, and the amount that does vest, is tied to the completion of service periods that range from 6 months to 3 years and the achievement, over a three-year period, of three equally-weighted goals that directly align with or help drive long-term total shareholder return: operational sales, adjusted operational earnings per share, and relative total shareholder return. The number of shares actually earned at the end of the three-year period will vary, based only on actual performance, from 0% to 200% of the target number of performance share units granted.

A summary of the restricted share units and performance share units activity under the Plans as of January 3, 2016 is presented below:

(Shares in Thousands)	Outstanding Restricted Share Units	Outstanding Performance Share Units
Shares at December 30, 2012	31,834	285
Granted	10,582	1,290
Issued	(10,078)	—
Canceled/forfeited	(1,721)	(40)
Shares at December 29, 2013	30,617	1,535
Granted	8,487	1,113
Issued	(9,685)	(19)
Canceled/forfeited	(1,726)	(98)
Shares at December 28, 2014	27,693	2,531
Granted	7,637	931
Issued	(10,164)	(285)
Canceled/forfeited	(1,281)	(99)
Shares at January 3, 2016	23,885	3,078

The average fair value of the restricted share units granted was $91.65, $83.01 and $65.90 in 2015, 2014 and 2013, respectively, using the fair market value at the date of grant. The fair value of restricted share units was discounted for dividends, which are not paid on the restricted share units during the vesting period. The fair value of restricted share units issued was $597.6 million, $541.0 million and $569.2 million in 2015, 2014 and 2013, respectively.

The weighted average fair value of the performance share units granted was $93.54, $85.94 and $73.42 in 2015, 2014 and 2013, calculated using the weighted average fair market value for each of the three component goals at the date of grant.

The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. The fair value of performance share units issued was $16.7 million and $1.4 million in 2015 and 2014, respectively. No performance share units vested in 2013.

18. Segments of Business and Geographic Areas

(Dollars in Millions)	Sales to Customers 2015	2014	2013
Consumer —			
United States	$ 5,222	5,096	5,162
International	8,285	9,400	9,535
Total	**13,507**	**14,496**	**14,697**
Pharmaceutical —			
United States	18,333	17,432	13,948
International	13,097	14,881	14,177
Total	**31,430**	**32,313**	**28,125**
Medical Devices —			
United States	12,132	12,254	12,800
International	13,005	15,268	15,690
Total	**25,137**	**27,522**	**28,490**
Worldwide total	**$ 70,074**	**74,331**	**71,312**

(Dollars in Millions)	Income Before Tax 2015 [3]	2014 [4]	2013 [5]	Identifiable Assets 2015	2014
Consumer	$ 1,787	1,941	1,973	20,772	21,813
Pharmaceutical	11,734	11,696	9,178	26,144	25,803
Medical Devices	6,826	7,953	5,261	40,979	41,445
Total	20,347	21,590	16,412	87,895	89,061
Less: Expense not allocated to segments [1]	1,151	1,027	941		
General corporate [2]				45,516	41,297
Worldwide total	**$ 19,196**	**20,563**	**15,471**	**$ 133,411**	**130,358**

(Dollars in Millions)	Additions to Property, Plant & Equipment 2015	2014	2013	Depreciation and Amortization 2015	2014	2013
Consumer	$ 544	581	533	$ 559	577	539
Pharmaceutical	1,063	977	856	929	1,053	1,075
Medical Devices	1,631	1,807	1,724	1,945	1,974	2,224
Segments total	3,238	3,365	3,113	3,433	3,604	3,838
General corporate	225	349	482	313	291	266
Worldwide total	**$ 3,463**	**3,714**	**3,595**	**$ 3,746**	**3,895**	**4,104**

(Dollars in Millions)	Sales to Customers 2015	2014	2013	Long-Lived Assets (6) 2015	2014
United States	$ 35,687	34,782	31,910	36,609	36,835
Europe	15,995	18,947	18,599	20,167	21,559
Western Hemisphere excluding U.S.	6,045	7,160	7,421	2,881	3,210
Asia-Pacific, Africa	12,347	13,442	13,382	2,493	2,438
Segments total	70,074	74,331	71,312	62,150	64,042
General corporate				1,148	1,138
Other non long-lived assets				70,113	65,178
Worldwide total	**$ 70,074**	**74,331**	**71,312**	**133,411**	**130,358**

See Note 1 for a description of the segments in which the Company operates.

Export sales are not significant. In 2015 and 2014, the Company had one wholesaler distributing products for all three segments that represented approximately 12.5% and 11.0%, respectively, of the total consolidated revenues. In 2013, the Company did not have a customer that represented 10.0% of total revenues.

(1) Amounts not allocated to segments include interest (income) expense, noncontrolling interests and general corporate (income) expense.

(2) General corporate includes cash, cash equivalents and marketable securities.

(3) The Medical Devices segment includes a restructuring charge of $590 million, an intangible asset write-down of $346 million related to Acclarent, Synthes integration costs of $196 million and $148 million expense for the cost associated with the DePuy ASR™ Hip program. Includes $224 million of in-process research and development expense, comprised of $214 million and $10 million in the Pharmaceutical and Medical Devices segments, respectively. Includes net litigation expense of $141 million comprised of $136 million in the Pharmaceutical segment and $5 million in the Medical Devices segment, which included the gain from the litigation settlement agreement with Guidant for $600 million. The Medical Devices Segment includes a gain of $1.3 billion from the divestiture of the Cordis business. The Pharmaceutical segment includes a gain of $981 million from the U.S. divestiture of NUCYNTA® and a positive adjustment of $0.5 billion to previous reserve estimates, including Managed Medicaid rebates. The Consumer segment includes a gain of $229 million from the divestiture of SPLENDA® brand.

(4) Includes net litigation expense of $1,253 million comprised of $907 million, $259 million and $87 million in the Medical Devices, Pharmaceutical and Consumer segments, respectively. Includes $178 million of in-process research and development expense, comprised of $147 million and $31 million in the Pharmaceutical and Medical Devices segments, respectively. The Medical Devices segment includes a net gain of $1,899 million from the divestiture of the Ortho-Clinical Diagnostics business, Synthes integration costs of $754 million and $126 million expense for the cost associated with the DePuy ASR™ Hip program. The Pharmaceutical segment includes an additional year of the Branded Prescription Drug Fee of $220 million and a positive adjustment of $0.1 billion to previous reserve estimates.

(5) Includes $2,276 million of net litigation expense comprised of $1,975 million and $301 million in the Medical Devices and Pharmaceutical segments, respectively. Includes $683 million of Synthes integration/transaction costs in the Medical Devices segment. Includes $580 million of in-process research and development expense, comprised of $514 million and $66 million in the Pharmaceutical and Medical Devices segments, respectively. The Medical Devices segment also includes $251 million expense for the cost associated with the DePuy ASR™ Hip program. Includes $98 million of income related to other adjustments comprised of $55 million and $43 million in the Consumer and Pharmaceutical segments, respectively.

(6) Long-lived assets include property, plant and equipment, net for 2015, and 2014 of $15,905 and $16,126, respectively, and intangible assets and goodwill, net for 2015 and 2014 of $47,393 and $49,054, respectively.

19. Selected Quarterly Financial Data (unaudited)

Selected unaudited quarterly financial data for the years 2015 and 2014 are summarized below:

	2015				2014			
(Dollars in Millions Except Per Share Data)	First Quarter [1]	Second Quarter [2]	Third Quarter [3]	Fourth Quarter [4]	First Quarter [5]	Second Quarter [6]	Third Quarter [7]	Fourth Quarter [8]
Segment sales to customers								
Consumer	$ 3,390	3,483	3,314	3,320	3,557	3,744	3,589	3,606
Pharmaceutical	7,726	7,946	7,694	8,064	7,498	8,509	8,307	7,999
Medical Devices	6,258	6,358	6,094	6,427	7,060	7,242	6,571	6,649
Total sales	17,374	17,787	17,102	17,811	18,115	19,495	18,467	18,254
Gross profit	12,092	12,430	11,878	12,138	12,660	13,456	13,068	12,401
Earnings before provision for taxes on income	5,575	5,741	4,122	3,758	5,424	5,626	6,810	2,703
Net earnings	4,320	4,516	3,358	3,215	4,727	4,326	4,749	2,521
Basic net earnings per share	$ 1.55	1.63	1.21	1.16	1.67	1.53	1.69	0.90
Diluted net earnings per share	$ 1.53	1.61	1.20	1.15	1.64	1.51	1.66	0.89

(1) The first quarter of 2015 includes a net litigation gain of $253 million after-tax ($402 million before-tax) and $122 million after-tax ($139 million before-tax) for costs associated with the DePuy ASR™ Hip program.

(2) The second quarter of 2015 includes net litigation expense of $23 million after-tax ($134 million before-tax).

(3) The third quarter of 2015 includes net litigation expense of $348 million after-tax ($409 million before-tax).

(4) The fourth quarter of 2015 includes a restructuring charge of $415 million after-tax ($590 million before-tax), $156 million after-tax ($214 million before-tax) from impairment of in-process research and development and Synthes integration costs of $59 million after-tax ($83 million before-tax). Additionally, the fourth quarter of 2015 includes the gain on the Cordis divestiture.

(5) The first quarter of 2014 includes Synthes integration costs of $84 million after-tax ($118 million before-tax) and a $398 million tax benefit associated with Conor Medsystems.

(6) The second quarter of 2014 includes litigation expense of $342 million after-tax ($276 million before-tax) and Synthes integration costs of $104 million after-tax ($144 million before-tax).

(7) The third quarter of 2014 includes an additional year of the Branded Prescription Drug Fee of $220 million after and before tax, litigation expense of $231 million after-tax ($285 million before-tax), Synthes integration costs of $130 million after-tax ($167 million before-tax) and $111 million after-tax ($126 million before-tax) for costs associated with the DePuy ASR™ Hip program. Additionally, the fiscal third quarter of 2014 includes a net gain of $1.1 billion after-tax ($1.9 billion before-tax) for the divestiture of the Ortho-Clinical Diagnostics business.

(8) The fourth quarter of 2014 includes litigation expense, primarily related to product liability and patent litigation of $652 million after-tax ($692 million before-tax), Synthes integration costs of $237 million after-tax ($325 million before-tax) and $115 million after-tax ($156 million before-tax) from impairment of in-process research and development.

20. Business Combinations and Divestitures

Certain businesses were acquired for $954 million in cash and $220 million of liabilities assumed during 2015. The assumed liabilities primarily represent the fair value of the contingent consideration of $210 million. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2015 acquisitions primarily included: XO1 Limited, a privately-held biopharmaceutical company developing an anti-thrombin antibody and Novira Therapeutics, Inc., a privately held clinical-stage biopharmaceutical company developing innovative therapies for curative treatment of chronic hepatitis B virus infection.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $1,173 million and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately $839 million has been identified as the value of IPR&D primarily associated with the acquisitions of XO1 Limited and Novira Therapeutics, Inc. The value of the IPR&D was calculated using cash flow projections discounted for the inherent risk in the projects.

The IPR&D related to the acquisition of XO1 Limited of $360 million is associated with a recombinant human antibody developed to mimic the activity of a human antibody which appears to produce an anticoagulated state without predisposition to bleeding. A probability of success factor of 36.0% was used to reflect inherent clinical and regulatory risk. The discount rate applied was 11.75%.

The IPR&D related to the acquisition of Novira Therapeutics, Inc. of $396 million is associated with its lead candidate NVR 3-778 which is an investigational small molecule, direct-acting antiviral, for oral administration in patients with HBV that inhibits the HBV core or capsid protein. A probability of success factor of 51.0% was used to reflect inherent clinical and regulatory risk. The discount rate applied was 16.0%.

Certain businesses were acquired for $2,129 million in cash and $38 million of liabilities assumed during 2014. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2014 acquisitions included: Covagen AG, a privately-held, biopharmaceutical company specializing in the development of multispecific protein therapeutics through the FynomAb® technology platform; Alios BioPharma, Inc., a privately-held, clinical stage biopharmaceutical company focused on developing therapies for viral diseases; and the ORSL™ electrolyte ready-to-drink brand from Jagdale Industries Ltd. The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $2,069 million and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately $1,913 million has been identified as the value of IPR&D associated with the acquisitions of Covagen AG and Alios BioPharma, Inc. The value of the IPR&D was calculated using cash flow projections discounted for the inherent risk in the projects.

The IPR&D related to the acquisition of Alios BioPharma, Inc. (Alios) of $1,688 million is associated with Alios' lead compound AL-8176, an orally administered antiviral therapy for treatment of infants with respiratory syncytial virus (RSV). A probability of success factor of 60.0% was used to reflect inherent clinical and regulatory risk. The discount rate applied was 11.4%. The IPR&D related to the acquisition of Covagen AG of $225 million is associated with Covagen's lead compound COVA-322, currently in Phase 1b study for psoriasis and holding potential as a treatment for a broad range of inflammatory diseases including rheumatoid arthritis. A probability of success factor of 26.0% was used to reflect inherent clinical and regulatory risk. The discount rate applied was 12.5%. During 2015, the Company recorded a charge for the impairment of the IPR&D related to the acquisition of Covagen AG.

Certain businesses were acquired for $835 million in cash and $193 million of liabilities assumed during 2013. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The assumed liabilities primarily represent the fair value of the contingent consideration which may be payable related to the acquisition of Aragon Pharmaceuticals, Inc., a privately-held, pharmaceutical discovery and development company focused on drugs to treat hormonally-driven cancers. As per terms of the agreement, additional payments of up to $350 million may be paid in the future based on reaching predetermined milestones.

The 2013 acquisitions included: Flexible Stenting Solutions, Inc., a leading developer of innovative flexible peripheral arterial, venous and biliary stents; Shanghai Elsker Mother & Baby Co., Ltd, a baby care company in China and Aragon Pharmaceuticals, Inc.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $941 million and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately $831 million has been identified as the value of IPR&D primarily associated with the acquisitions of Aragon Pharmaceuticals, Inc.

The IPR&D related to the acquisition of Aragon Pharmaceuticals, Inc. of $810 million is associated with Aragon's androgen receptor antagonist program for treatment of hormonally-driven cancers. The value of the IPR&D was calculated using cash flow projections discounted for the inherent risk in such projects. Probability of success factors ranging from 37% - 52.0% were used to reflect inherent clinical and regulatory risk. The discount rate applied was 15.5%.

In 2012, the Company completed the acquisition of Synthes, Inc. for a purchase price of $20.2 billion in cash and stock. In connection with the acquisition of Synthes, Inc. the Company entered into two accelerated share repurchase (ASR) agreements. In 2013, the Company settled the remaining liabilities under the ASR agreements. While the Company believes that the transactions under each ASR agreement and a series of related internal transactions were consummated in a tax efficient manner in accordance with applicable law, it is possible that the Internal Revenue Service could assert one or more contrary positions to challenge the transactions from a tax perspective. If challenged, an amount up to the total purchase price for the Synthes shares could be treated as subject to applicable U.S. tax at approximately the statutory rate to the Company, plus interest.

Supplemental pro forma information for 2015, 2014 and 2013 in accordance with U.S. GAAP standards related to business combinations, and goodwill and other intangible assets, is not provided, as the impact of the aforementioned acquisitions did not have a material effect on the Company's results of operations, cash flows or financial position.

During 2015, the Company divestitures included: The Cordis business to Cardinal Health; the SPLENDA® brand to Heartland Food Products Group and the U.S. license rights to NUCYNTA® (tapentadol), NUCYNTA® ER (tapentadol extended-release tablets), and NUCYNTA® (tapentadol) oral solution. In 2015, the pre-tax gains on the divestitures of businesses were approximately $2.6 billion. As of January 3, 2016, assets held for sale were not material.

During 2014, the Company divestitures included: The Ortho-Clinical Diagnostics business to The Carlyle Group; the K-Y® brand to Reckitt Benckiser Group PLC in the U.S. and certain other markets; and the BENECOL® brand to Raisio plc. In 2014, the pre-tax gains on the divestitures of businesses were approximately $2.4 billion. The Company completed the divestiture of its Ortho-Clinical Diagnostics business to The Carlyle Group for approximately $4.0 billion and the Company recorded a pre-tax gain of approximately $1.9 billion. Ortho-Clinical Diagnostics' results are included in the Company's Medical Devices segment.

During 2013, the Company divestitures included: women's sanitary protection products in the U.S., Canada and the Caribbean to Energizer Holdings, Inc.; Rolaids® to Chattem, Inc.; DORIBAX® rights to Shionogi; and the sale of certain consumer brands and certain pharmaceutical products. In 2013, the pre-tax gains on the divestitures of businesses were $0.1 billion.

21. Legal Proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability, intellectual property, commercial and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of their business.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of January 3, 2016, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions. The ability to make such estimates and judgments can be affected by various factors, including whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; or there are numerous parties involved.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution of, or increase in accruals for, one or more of these matters in any reporting period may have a material adverse effect on the Company's results of operations and cash flows for that period.

PRODUCT LIABILITY

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While these subsidiaries believe they have substantial defenses, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damage and other losses. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

The most significant of these cases include the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, the PINNACLE® Acetabular Cup System, pelvic meshes, RISPERDAL®, and XARELTO®. As of January 3, 2016, in the United States there were approximately 5,300 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, 8,700 with respect to the PINNACLE® Acetabular Cup System, 46,700 with respect to pelvic meshes, 10,700 with respect to RISPERDAL®, and 5,000 with respect to XARELTO®.

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System used in hip replacement surgery. Claims for personal injury have been made against DePuy and Johnson & Johnson. The number of pending lawsuits is expected to fluctuate as certain lawsuits are settled or dismissed and additional lawsuits are filed. Cases filed in federal courts in the United States have been organized as a

multi-district litigation in the United States District Court for the Northern District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada and Australia. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR™ Hip System plaintiffs to establish a program to settle claims with eligible ASR Hip patients in the United States who had surgery to replace their ASR Hips, known as revision surgery, as of August 31, 2013. This settlement covered approximately 8,000 patients. In February 2015, DePuy reached an additional agreement which would effectively extend the existing settlement program to ASR Hip patients who had revision surgeries after August 31, 2013 and prior to February 1, 2015. This second agreement is estimated to cover approximately 1,800 additional patients. The estimated cost of these agreements is covered by existing accruals. This settlement program is expected to bring to a close significant ASR Hip litigation activity in the United States. However, many lawsuits in the United States will remain, and the settlement program does not address litigation outside of the United States. The Company continues to receive information with respect to potential costs associated with this recall on a worldwide basis. The Company has established accruals for the costs associated with the DePuy ASR™ Hip program and related product liability litigation. Changes to these accruals may be required in the future as additional information becomes available.

Claims for personal injury have also been made against DePuy and Johnson & Johnson relating to DePuy's PINNACLE® Acetabular Cup System used in hip replacement surgery. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Texas. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom. The Company has established an accrual to cover only defense costs in connection with product liability litigation associated with DePuy's PINNACLE® Acetabular Cup System. Changes to this accrual may be required in the future as additional information becomes available.

Claims for personal injury have been made against Ethicon, Inc. (Ethicon) and Johnson & Johnson arising out of Ethicon's pelvic mesh devices used to treat stress urinary incontinence and pelvic organ prolapse. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Southern District of West Virginia. In addition, class actions and individual personal injury cases or claims have been commenced in Australia, Belgium, Canada, England, Israel, Italy, the Netherlands, Scotland and Venezuela, seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices. The Company has established an accrual with respect to product liability litigation associated with Ethicon's pelvic mesh products. Changes to this accrual may be required in the future as additional information becomes available.

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and Johnson & Johnson arising out of the use of RISPERDAL®, indicated for the treatment of schizophrenia, acute manic or mixed episodes associated with bipolar I disorder and irritability associated with autism, and related compounds. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has established an accrual with respect to product liability litigation associated with RISPERDAL®. Changes to this accrual may be required in the future as additional information becomes available.

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and Johnson & Johnson arising out of the use of XARELTO®, an oral anticoagulant. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Eastern District of Louisiana. In addition, cases have been filed in state courts across the United States and many cases have been consolidated into a state mass tort litigation in Philadelphia, Pennsylvania. Class action lawsuits also have been filed in Canada. The Company has established an accrual with respect to product liability litigation associated with XARELTO®. Changes to this accrual may be required in the future as additional information becomes available.

INTELLECTUAL PROPERTY

Certain subsidiaries of Johnson & Johnson are subject, from time to time, to legal proceedings and claims related to patent, trademark and other intellectual property matters arising out of their businesses. Many of these matters involve challenges to the coverage and/or validity of the patents on various products and allegations that certain of the Company's products infringe the patents of third parties. Although these subsidiaries believe that they have substantial defenses to these challenges and allegations with respect to all significant patents, there can be no assurance as to the outcome of these matters. A loss in any of these cases could adversely affect the ability of these subsidiaries to sell their products, result in loss of sales due to loss of market exclusivity, and require the payment of past damages and future royalties, and which may result in a non-cash impairment charge for any associated intangible asset. The most significant of these matters are described below.

Medical Devices

In January 2010, Tyco Healthcare Group, LP (Tyco) and U.S. Surgical Corporation (now Covidien plc) filed a lawsuit against Ethicon Endo-Surgery, Inc. (EES) in the United States District Court for the District of Connecticut alleging that EES's HARMONIC® shears infringed three Tyco patents. The case was tried in July 2012, and in March 2013, the Court ruled that some of EES's HARMONIC® shears infringed Tyco's patents and ordered EES to pay damages of approximately $176 million, but declined to order injunctive relief. EES appealed and in December 2014, the United States Court of Appeals for the Federal Circuit reversed the District Court's ruling and found all the asserted claims invalid. In July 2015, Tyco filed a motion for review with the United States Supreme Court. In July 2014, Covidien filed another patent infringement lawsuit against EES in the United States District Court for the District of Connecticut seeking damages and a preliminary injunction, alleging that EES's newest version of its harmonic scalpels, the HARMONIC ACE®+ 7 Shears and the HARMONIC ACE®+ Shears, infringed the three Tyco patents asserted in the previous case. The claims asserted by Covidien in this case are the same claims that were declared invalid in December 2014 by the Court of Appeals in the Tyco case discussed above. In November 2015, the United States Supreme Court denied Tyco's petition for review; therefore, both cases have been dismissed.

In November 2007, Roche Diagnostics Operations, Inc., et al. (Roche) filed a patent infringement lawsuit against LifeScan, Inc. (LifeScan) in the United States District Court for the District of Delaware, alleging LifeScan's OneTouch® Line of Blood Glucose Monitoring Systems infringe two patents related to the use of microelectrode sensors. Roche is seeking monetary damages and injunctive relief. In September 2009, LifeScan obtained a favorable ruling on claim construction that precluded a finding of infringement. Roche appealed and the Court of Appeals reversed the District Court's ruling on claim construction and remanded the case to the District Court for new findings on the issue. In December 2014, the District Court ruled in LifeScan's favor and reinstated the original claim construction. In February 2015, Roche appealed the ruling, and in February 2016, oral argument took place at the Court of Appeals. The parties are awaiting a decision.

In June 2009, Rembrandt Vision Technologies, L.P. (Rembrandt) filed a patent infringement lawsuit against Johnson & Johnson Vision Care, Inc. (JJVC) in the United States District Court for the Eastern District of Texas alleging that JJVC's manufacture and sale of its ACUVUE®ADVANCE® and ACUVUE® OASYS® Hydrogel Contact Lenses infringe their U.S. Patent No. 5,712,327 (the '327 patent). Rembrandt is seeking monetary relief. The case was transferred to the United States District Court for the Middle District of Florida. In May 2012, the jury returned a verdict holding that neither of the accused lenses infringes the '327 patent. Rembrandt appealed, and in August 2013, the United States Court of Appeals for the Federal Circuit affirmed the District Court's judgment. Rembrandt asked the District Court to grant it a new trial based on alleged new evidence, and in July 2014, the District Court denied Rembrandt's motion. Rembrandt has appealed the District Court's denial of its motion for a new trial.

In December 2009, the State of Israel filed a lawsuit in the District Court in Tel Aviv Jaffa against Omrix Biopharmaceuticals, Inc. and various affiliates (Omrix). In the lawsuit, the State claims that an employee of a government-owned hospital was the inventor on several patents related to fibrin glue technology that the employee developed while he was a government employee. The State claims that he had no right to transfer any intellectual property to Omrix because it belongs to the State. The State is seeking damages plus royalties on QUIXIL™ and EVICEL® products, or alternatively, transfer of the patents to the State. The case remains active, but no trial date has been set.

In September 2011, LifeScan, Inc. (LifeScan) filed a lawsuit against Shasta Technologies, LLC (Shasta), Instacare Corp (now Pharmatech Solutions, Inc. (Pharmatech)) and Conductive Technologies, Inc. (Conductive) in the United States District Court for the Northern District of California for patent infringement and false advertising for the making and marketing of a strip for use in LifeScan's OneTouch® Blood Glucose Meters. The defendants alleged that the three LifeScan patents-in-suit are invalid and challenged the validity of the asserted patents in the United States Patent and Trademark Office (USPTO). In April

2013, the defendants brought counterclaims for alleged antitrust violations and false advertising and those claims were stayed pending resolution of the patent infringement case. The validity of two of the patents was confirmed by the USPTO, but the USPTO determined that the third patent, U.S. Patent No. 7,250,105 (the '105 patent), is invalid. LifeScan lost an appeal of that decision, but is seeking a rehearing. LifeScan entered into a settlement agreement with Shasta and Conductive. A motion brought by Pharmatech for summary judgment of patent invalidity was argued in February 2016 and the parties are awaiting a decision. LifeScan's patent infringement and false advertising claims are scheduled to be tried in August 2016.

LifeScan filed a patent infringement lawsuit against UniStrip Technologies, LLC (UniStrip) in the United States District Court for the District of North Carolina in May 2014, alleging that the making and marketing of Unistrip's strips infringe the same patents asserted against Shasta above. That case has been stayed pending the outcome of the appeal of the USPTO's decision on the validity of the '105 patent. In July 2014, UniStrip brought a lawsuit against LifeScan in the United States District Court for the Eastern District of Pennsylvania, alleging antitrust violations relating to marketing practices for LifeScan strips.

In March 2013, Medinol Ltd. (Medinol) filed a patent infringement lawsuit against Cordis Corporation (Cordis) and Johnson & Johnson in the United States District Court for the Southern District of New York alleging that all of Cordis's sales of the CYPHER® and CYPHER SELECT™ Stents made in the United States since 2005 willfully infringed four of Medinol's patents directed to the geometry of articulated stents. Medinol is seeking damages and attorney's fees. After trial in January 2014, the District Court dismissed the case, finding Medinol unreasonably delayed bringing its claims, and Medinol did not appeal the decision. In September 2014, the District Court denied a motion by Medinol to vacate the judgment and grant it a new trial. Medinol's appeal of this decision has been dismissed. Medinol has filed a petition for review with the United States Supreme Court. Following the divestiture of Cordis, the Company retains any liability that may result from this case.

In December 2014, Bonutti Skeletal Innovations LLC (Bonutti) sued DePuy Synthes Sales, Inc. and DePuy Synthes Products, Inc. in the United States District Court for the District of Massachusetts, alleging that DePuy Synthes's product line of spine implants infringes six patents owned by Bonutti, generally covering wedge implants and their methods of implantation. Bonutti is seeking monetary damages and injunctive relief.

Pharmaceutical

In 2012 and 2013, Noramco, Inc. (Noramco) moved to intervene in several patent infringement lawsuits filed in the United States District Court for the Southern District of New York by Purdue Pharma L.P. and others (Purdue) against Noramco oxycodone customers, Impax Laboratories, Inc. (Impax), Teva Pharmaceuticals USA, Inc. (Teva), Amneal Pharmaceuticals, LLC (Amneal), Watson Laboratories, Inc.- Florida (Watson) and Andrx Labs, LLC (Andrx). The lawsuits are in response to the defendants' respective Abbreviated New Drug Applications seeking approval to market generic extended release oxycodone products before the expiration of certain Purdue patents. Three of the asserted patents relate to oxycodone and processes for making oxycodone, and Noramco has agreed to defend the lawsuits on behalf of Impax, Teva, Amneal, Watson, and Andrx. In April 2013, Watson and Andrx entered into a settlement with Purdue. The trial against Impax and Teva (and others) took place in September 2013, and Noramco defended Teva and Impax. In November 2013, Impax entered into a settlement with Purdue, and in December 2014, Teva entered into a settlement with Purdue. The District Court issued a decision in January 2014 invalidating the relevant Purdue patents and, based on that decision, subsequently dismissed the lawsuit against Amneal (and other parties not defended by Noramco). Purdue appealed the Court's decision. In February 2016, the Federal Circuit affirmed the District Court decision invalidating the Purdue patents. If Purdue ultimately prevails in its appeal of the invalidity decision, it can reinstitute its action against Amneal. In December 2015, Purdue filed another patent infringement action against Amneal in the District of Delaware asserting, among others, the three above-referenced patents and a newly issued patent relating to oxycodone and processes for making oxycodone.

Johnson & Johnson acquired the prostate cancer business of Aragon Pharmaceuticals, Inc. (Aragon), including ARN-509, a compound being tested for treatment of prostate cancer, in September 2013. Prior to the acquisition, in May 2011, Medivation, Inc. (Medivation) had sued Aragon and the University of California seeking rights to ARN-509. In December 2012, the State Court granted summary judgment to Aragon on Medivation's claims, awarding the rights of the ARN-509 compound to Aragon, and in January 2013, the Court dismissed the case against Aragon. Medivation has appealed.

REMICADE® Related Cases

In September 2013, JBI and NYU Langone Medical Center (NYU Medical Center) received an Office Action from the United States Patent and Trademark Office (USPTO) rejecting the claims in U.S. Patent No. 6,284,471 relating to REMICADE® (the '471 patent) in a reexamination proceeding instituted by a third party. The '471 patent is co-owned by JBI and NYU Medical Center, and NYU Medical Center granted JBI an exclusive license to NYU Medical Center's rights under the patent. Currently, the '471 patent in the United States expires in September 2018. JBI responded to that rejection in December 2013 and in August 2014, JBI and NYU Medical Center received a further rejection. JBI responded to the rejection by filing a further amendment and in November 2014, JBI's petition to enter the amendment was granted. The application was returned to the examiner for issuance of a new Office Action, which occurred in February 2015, further rejecting the patent. JBI responded to that rejection and in April 2015, the USPTO issued a further action maintaining its rejection of the '471 patent. In May 2015, JBI filed a notice of appeal to the USPTO's Patent Trial and Appeal Board, and the appeal is currently pending. The '471 patent remains a valid and enforceable patent as it undergoes reexamination at the USPTO. JBI will continue to defend the patent and, if necessary, will pursue all available appeals.

In August 2014, Celltrion filed for FDA approval to make and sell its own biosimilar version of REMICADE®. In March 2015, JBI filed a lawsuit in the United States District Court for the District of Massachusetts against Celltrion and Hospira seeking a declaratory judgment that their biosimilar product for which they are seeking FDA approval under the new Biologics Price Competition and Innovation Act (the BPCIA) infringes or potentially infringes six JBI patents. JBI is also seeking a declaratory judgment that defendants have failed to comply with certain procedural requirements of the BPCIA. In addition, JBI has moved for a preliminary and permanent injunction to prohibit Celltrion and Hospira from launching their biosimilar product until 180 days after they have given JBI a Notice of Commercial Marketing, such notice not to be given before FDA approval of Celltrion's product. Also in March 2015, JBI moved to stay all proceedings in the District Court with respect to the ‘471 patent, pending the USPTO re-examination proceeding. In August 2015, JBI also filed a motion seeking the District Court's permission to file a patent infringement lawsuit asserting U.S. Patent No. 7,598,083 (the '083 patent) against Celltrion and the manufacturer of the cell culture media that Celltrion uses to make its biosimilar product. Although the '083 patent is already asserted in the existing lawsuit, this would expand the claims to include any use of the cell media made in the United States to manufacture Celltrion's biosimilar. In February 2016, Celltrion and Hospira agreed not to launch their biosimilar product before June 30, 2016 and the '471 and '083 patents will be the two remaining patents in the lawsuit. In light of this representation, and because the Federal Circuit Court of Appeals is expected to decide this issue in an unrelated but similar case before June 29th, the Court denied JBI's motion for preliminary injunction, but noted that JBI may renew its motion following the Court of Appeals decision, if necessary, or if the Court of Appeals fails to decide the issue by June 29th. In addition, in February 2016, Celltrion and Hospira filed a motion for summary judgment of invalidity of the ‘471 patent.

In March 2013, Hospira Healthcare Corporation (Hospira) filed an impeachment proceeding against The Kennedy Institute of Rheumatology (Kennedy) challenging the validity of a Canadian patent related to REMICADE® (a Feldman patent), which is exclusively licensed to Janssen Biotech, Inc. (JBI). In October 2013, Kennedy, along with JBI, Janssen Inc. and Cilag GmbH International (both affiliates of JBI), filed a counterclaim for infringement against Celltrion Healthcare Co., Ltd., Celltrion Inc. (together, Celltrion) and Hospira. The counterclaim alleges that the products described in Celltrion’s and Hospira’s marketing applications to Health Canada for their subsequent entry biologics (SEB) to REMICADE® would infringe the Feldman patents owned by Kennedy. Discovery in the patent action is ongoing. Trial has been scheduled for September 2016.

In January 2014, Health Canada approved Celltrion’s SEB to REMICADE®, allowing Celltrion to market its biosimilar version of REMICADE® in Canada, regardless of the pending patent action. In June 2014, Hospira received approval for its SEB to REMICADE®. In July 2014, Janssen Inc. (Janssen) filed a lawsuit to compel the Canadian Minister of Health to withdraw the Notice of Compliance for Hospira’s SEB because Hospira did not serve a Notice of Allegation on Janssen to address the patent listed by Janssen on the Patent Register. In March 2015, the parties entered into a settlement agreement whereby Health Canada agreed to a Consent Judgment setting aside Hospira’s Notice of Compliance, subject to Health Canada's right to appeal, which appeal was filed in June 2015. Nevertheless, Hospira began marketing a biosimilar version of REMICADE® as a distributor under Celltrion's Notice of Compliance.

If any of the REMICADE® related patents discussed above is found to be invalid, any such patent could not be relied upon to prevent the introduction of biosimilar versions of REMICADE®. Biosimilar versions of REMICADE® have been introduced in certain markets outside the United States, resulting in a reduction in sales of REMICADE® in those markets. The timing of the possible introduction of a biosimilar version of REMICADE® in the United States is subject to enforcement of patent rights, approval by the FDA and compliance with the 180-day notice provisions of the BPCIA. In February 2016, the Arthritis Advisory Committee of the FDA recommended approval of Celltrion’s investigational biosimilar version of

REMICADE® by a vote of 21-3 across all eligible indications in the United States. There is a risk that a competitor could launch a biosimilar version of REMICADE® following FDA approval (subject to compliance with the 180-day notice provisions of the BPCIA), even though one or more valid patents are in place. Introduction to the U.S. market of a biosimilar version of REMICADE® will result in a reduction in U.S. sales of REMICADE®.

Litigation Against Filers of Abbreviated New Drug Applications (ANDAs)

The following summarizes lawsuits pending against generic companies that have filed Abbreviated New Drug Applications (ANDAs) with the FDA, or undertaken similar regulatory processes outside of the United States, seeking to market generic forms of products sold by various subsidiaries of Johnson & Johnson prior to expiration of the applicable patents covering those products. These ANDAs typically include allegations of non-infringement, invalidity and unenforceability of the applicable patents. In the event the subsidiaries are not successful in these actions, or the statutory 30-month stays of the ANDAs expire before the United States District Court rulings are obtained, the third-party companies involved will have the ability, upon approval of the FDA, to introduce generic versions of the products at issue to the market, resulting in the potential for substantial market share and revenue losses for those products, and which may result in a non-cash impairment charge in any associated intangible asset. In addition, from time to time, subsidiaries may settle these actions and such settlements can involve the introduction of generic versions of the products at issue to the market prior to the expiration of the relevant patents.

PREZISTA®

A number of generic companies have filed ANDAs seeking approval to market generic versions of PREZISTA®. In November 2010, Tibotec, Inc. (now Tibotec, LLC) and Tibotec Pharmaceuticals (now Janssen R&D Ireland) (collectively, Tibotec) filed a patent infringement lawsuit against Lupin, Ltd., Lupin Pharmaceuticals, Inc. (collectively, Lupin), Mylan, Inc. and Mylan Pharmaceuticals, Inc. (collectively, Mylan) in the United States District Court for the District of New Jersey in response to Lupin's and Mylan's respective ANDAs seeking approval to market generic versions of Tibotec's PREZISTA® product before the expiration of Tibotec's patent relating to PREZISTA®. Lupin and Mylan each filed counterclaims alleging non-infringement and invalidity. In July 2011, Tibotec filed another patent infringement lawsuit against Lupin in the United States District Court for the District of New Jersey in response to Lupin's supplement to its ANDA to add new dosage strengths for its proposed product. In August 2011, Tibotec and G.D. Searle & Company (G.D. Searle) filed a patent infringement lawsuit against Lupin and Mylan in response to their notice letters advising that their ANDAs are seeking approval to market generic versions of Tibotec's PREZISTA® product before the expiration of two additional patents relating to PREZISTA® that Tibotec exclusively licenses from G.D. Searle. In September 2011, the Court consolidated the above lawsuits (referred to here as the First Consolidated Action).

The approved New Drug Application for PREZISTA® was transferred from Tibotec, Inc. to Janssen Products, LP in December 2011. In 2012 and 2013, Janssen Products, LP and Janssen R&D Ireland (collectively, Janssen) added several patents that they own or exclusively license from G.D. Searle to the First Consolidated Action against Mylan and Lupin. In June 2013, Janssen and G.D. Searle dismissed their claims relating to the patents owned by G.D. Searle against Lupin and Mylan, based on those parties' agreement not to seek FDA approval of their respective ANDAs until the November 2017 expiration of the G.D. Searle patents. After a trial regarding the remaining patents in the First Consolidated Action, the Court issued a decision in August 2014 in favor of Janssen, holding that the asserted patents are valid and would be infringed by Lupin's and Mylan's marketing of their proposed products. Mylan and Lupin filed an appeal.

In July 2014, Janssen filed a patent infringement lawsuit against Mylan in the United States District Court for the District of New Jersey, alleging infringement of United States Patent No. 8,153,829. In November 2015, Janssen and Mylan entered into a confidential settlement. Pursuant to the settlement agreement, the parties are in the process of seeking a dismissal of this action. In addition, the appeal of the August 2014 decision as it relates to Mylan has been dismissed and remanded to the District Court where the parties are seeking a modification of the Court's 2014 order in accordance with the settlement agreement.

In May 2013, Lupin notified Janssen that it filed an ANDA seeking approval to market a new dosage strength of its generic version of PREZISTA®. In response, Janssen filed a patent infringement lawsuit in the United States District Court for the District of New Jersey, alleging that Lupin's new dosage strength would infringe the same patents that Janssen is asserting against Lupin in the original action. In March 2014, Janssen filed a patent infringement lawsuit against Lupin in the United States District Court for the District of New Jersey, alleging infringement of United States Patent No 8,518,987 (the '987 patent). In January 2015, the Court consolidated these lawsuits (referred to here as the Second Consolidated Action), and stayed them pending Lupin's appeal of the Court's decision in the First Consolidated Action. In April 2015, Lupin filed an Inter

Partes Review in the USPTO seeking to invalidate the ‘987 patent and in October 2015, the USPTO denied Lupin's petition. In January 2016, Janssen received a patent notice from Lupin advising that Lupin has amended its ANDA to reflect a new formulation of darunavir that Lupin alleges does not infringe the relevant Janssen patents, and in February 2016, Janssen filed a lawsuit asserting those patents against Lupin in the United States District Court for the District of New Jersey. In addition, in January 2016, Lupin filed a motion to stay and deactivate its appeal of the above-referenced August 2014 decision, and to remand the matter to the District Court where Lupin intends to modify the 2014 District Court order and injunction to allow Lupin to market its new formulation of darunavir before the expiration of the relevant patents.

Janssen filed a patent infringement lawsuit against Hetero Drugs, Ltd. Unit III and Hetero USA Inc. in March 2013 in the United States District Court for the District of New Jersey, alleging infringement of United States Patent Nos. 7,126,015 and 7,595,408. In October 2015, the parties stipulated to a Consent Judgment wherein the Hetero defendants admitted that the patents-in-suit are valid and would be infringed by the manufacture, importation, use or sale of Hetero’s ANDA product, and agreed to an injunction with respect to such product during the life of the patents-in-suit. Hetero reserved the right to develop non-infringing darunavir products and processes.

In August 2014, Janssen filed patent infringement lawsuits against Cipla Ltd. and Cipla USA, Inc. (collectively, Cipla) in the United States District Courts for the Districts of New Jersey and Delaware in response to Cipla’s ANDA seeking approval to market a generic version of Janssen’s PREZISTA® product before the expiration of certain of Janssen’s patents relating to PREZISTA®. Cipla filed counterclaims seeking declarations of noninfringement and invalidity of the patents-in-suit. In May 2015, Janssen and Cipla entered into a settlement agreement.

In response to its Notice of Allegation seeking approval to market a generic version of PREZISTA® in Canada before the expiration of Canadian Patent No. 2,485,834, Janssen Inc. and Janssen R&D Ireland filed a Notice of Application against Mylan Pharmaceuticals ULC in July 2014. In December 2014, Janssen R&D Ireland transferred its PREZISTA® patents to Janssen Sciences Ireland UC, and Janssen Sciences Ireland UC was substituted for Janssen R&D Ireland as plaintiff in the above-referenced actions. In February 2016, the parties entered into a confidential settlement and the Notice of Application has been dismissed.

In January 2015, Janssen Inc. and Janssen Sciences Ireland UC filed a Notice of Application against Teva Canada Limited in response to its Notice of Allegation seeking approval to market a generic version of PREZISTA® before the expiration of Canadian Patent No. 2,485,834. In October 2015, the parties entered into a settlement wherein Teva Canada Limited agreed to withdraw its Notice of Allegation without prejudice to file a new one in the future, and Janssen Inc. and Janssen Sciences Ireland UC agreed to dismiss their Notice of Application.

In each of the above lawsuits, Janssen sought or is seeking an Order enjoining the defendants from marketing their generic versions of PREZISTA® before the expiration of the relevant patents.

CONCERTA®

In May 2014, ALZA Corporation (ALZA) and Janssen Pharmaceuticals, Inc. (JPI) filed a patent infringement lawsuit in the United States District Court for the District of West Virginia against Mylan, Inc. and Mylan Pharmaceuticals, Inc. (Mylan) in response to its ANDA seeking approval to market a generic version of CONCERTA® before the expiration of United States Patent No. 8,163,798 (the '798 patent). Mylan filed counterclaims seeking declarations of invalidity and non-infringement of the patents-in-suit. In May 2015, Mylan sought leave to add a counterclaim for invalidity and non-infringement of U.S. Patent No. 8,629,179 (the '179 patent) and the Court denied Mylan's motion. In July 2015, Mylan filed a declaratory judgment action in the Eastern District of Pennsylvania seeking a declaration of invalidity and non-infringement of the '179 patent. In October 2015, the parties entered into a confidential settlement of both the West Virginia and Pennsylvania actions.

In December 2014, Janssen Inc. and ALZA filed a Notice of Application against Actavis Pharma Company (Actavis) in response to its Notice of Allegation seeking approval to market a generic version of CONCERTA® before the expiration of Canadian Patent No. 2,264,852 (the ‘852 patent). The hearing is scheduled for September 2016.

In February 2015, Janssen Inc. and ALZA filed a Notice of Application against Apotex Inc. (Apotex) in response to its Notice of Allegation seeking approval to market a generic version of CONCERTA® before the expiration of the '852 patent. In August 2015, Janssen Inc. and ALZA voluntarily dismissed the Notice of Application.

In each of the above lawsuits, ALZA and/or JPI sought or are seeking an Order enjoining the defendants from marketing their generic versions of CONCERTA® before the expiration of the relevant patents.

ZYTIGA®

In June and July 2015, Janssen Biotech, Inc. (JBI) received notices of paragraph IV certification from several companies advising of their respective ANDAs seeking approval for a generic version of ZYTIGA® before the expiration of one or more patents relating to ZYTIGA®. In July 2015, JBI, Janssen Oncology, Inc. and Janssen Research & Development, LLC (collectively, Janssen) and BTG International Ltd. (BTG) filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against several generic ANDA applicants (and certain of their affiliates and/or suppliers) in response to their respective ANDAs seeking approval to market a generic version of ZYTIGA® before the expiration of United States Patent Nos. 5,604,213 (the '213 patent) (expiring December 2016) and/or 8,822,438 (the '438 patent) (expiring August 2027). The generic companies include Actavis Laboratories, FL, Inc. (Actavis); Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC (collectively, Amneal); Apotex Inc. and Apotex Corp. (collectively, Apotex); Citron Pharma LLC (Citron); Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, Dr. Reddy's); Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, Mylan); Par Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc. (collectively, Par); Sun Pharmaceutical Industries Ltd. and Sun Pharmaceuticals Industries, Inc. (collectively, Sun); Teva Pharmaceuticals USA, Inc. (Teva); Wockhardt Bio A.G.; Wockhardt USA LLC and Wockhardt Ltd. (collectively, Wockhardt); West-Ward Pharmaceutical Corp. (West-Ward); and Hikma Pharmaceuticals, LLC (Hikma). The Court entered a stay of the New Jersey lawsuit against each of Par and Citron, as each agreed to be bound by the decision against the other defendants in the New Jersey action. In February 2016, the New Jersey Court set a trial date of October 2017.

In August 2015, Janssen and BTG filed an additional jurisdictional protective lawsuit against the Mylan defendants in the United States District Court for the Northern District of West Virginia. In October 2015, Mylan filed a motion to dismiss the New Jersey lawsuit for lack of personal jurisdiction and improper venue. In February 2016, the West Virginia Court stayed the West Virginia case pending a decision on Mylan's motion to dismiss in the New Jersey lawsuit, but set a conditional trial date of February 2018. The Court will dismiss the West Virginia lawsuit if Mylan's motion to dismiss in New Jersey is denied.

In August 2015, JBI received a notice of paragraph IV certification from Hetero USA Inc., the U.S. Regulatory Agent for Hetero Labs Limited Unit-V, a division of Hetero Labs Limited (collectively, Hetero) advising of Hetero's ANDA seeking approval for a generic version of ZYTIGA® before expiration of the '438 patent. In September 2015, Janssen and BTG filed an amended complaint in the New Jersey lawsuit to allege infringement of the '438 patent by Hetero.

The filing of the above-referenced lawsuits triggered a stay until October 2018 during which the FDA will not grant final approval of the generics' ANDAs unless there is an earlier district court decision finding the patents-in-suit invalid or not infringed.

In December 2015, Amerigen Pharmaceuticals Limited filed a petition for an Inter Partes Review in the USPTO seeking to invalidate the '438 patent.

In each of the above lawsuits, Janssen is seeking an Order enjoining the defendants from marketing their generic versions of ZYTIGA® before the expiration of the relevant patents.

COMPLERA®

In August and September 2015, Janssen Pharmaceutica NV and Janssen Sciences Ireland UC (collectively, Janssen) and Gilead Sciences, Inc. and Gilead Sciences Ireland UC (collectively, Gilead) filed patent infringement lawsuits in the United States District Court for the District of Delaware and West Virginia against Mylan, Inc. and Mylan Pharmaceuticals, Inc. (collectively, Mylan) in response to their ANDA seeking approval to market a generic version of COMPLERA® before the expiration of United States Patent Nos. 8,841,310; 7,125,879; and 8,101,629. In September 2015, Mylan filed an Answer in the West Virginia action that included counterclaims seeking declarations of invalidity and non-infringement of the patents-in-suit as well as United States Patent No. 8,080,551. In September 2015, Mylan filed a motion to dismiss the Delaware lawsuit for lack of personal jurisdiction. In January 2016, Janssen and Gilead filed a first amended complaint in the New Jersey Action adding claims for patent infringement with respect to United States Patent Nos. 7,399,856 and 7,563,922. In addition, in the New Jersey Action, the Court dismissed Mylan's motion to dismiss and set a trial date of February 2018, and in the West Virginia Action, the Court set a trial date of December 2017. In February 2016, Mylan renewed its motion to dismiss for lack of jurisdiction.

In each of the above lawsuits, Janssen is seeking an Order enjoining the defendants from marketing their generic versions of COMPLERA® before the expiration of the relevant patents.

XARELTO®

A number of generic companies have filed ANDAs seeking approval to market generic versions of XARELTO®. In October 2015, Janssen Pharmaceuticals, Inc. (JPI) and Bayer Pharma AG and Bayer Intellectual Property GmbH (collectively, Bayer) filed a patent infringement lawsuit against Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc., Breckenridge Pharmaceutical, Inc., Micro Labs USA Inc., Micro Labs Ltd., Mylan Pharmaceuticals Inc., Mylan Inc., Prinston Pharmaceutical, Inc., Sigmapharm Laboratories, LLC, Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. in the United States District Court for the District of Delaware in response to those parties' respective ANDAs seeking approval to market generic versions of XARELTO® before the expiration of Bayer's United States Patent Nos. 7,157,456, 7,585,860 and 7,592,339 relating to XARELTO®. JPI is the exclusive licensee of the asserted patents. JPI is seeking an Order enjoining the defendants from marketing their generic versions of XARELTO® before the expiration of the relevant patents. In November 2015, Mylan moved to dismiss the action. In December 2015, JPI, Bayer, and Mylan stipulated and agreed to dismiss the claims against Mylan Inc. and suspend further briefing and argument on Mylan's motion to dismiss pending appeals relating to personal jurisdiction over Mylan Pharmaceuticals Inc. in the District of Delaware.

In January 2016, JPI and Bayer received a paragraph IV notice from Invagen Pharmaceuticals Inc. (Invagen) advising that it is seeking FDA approval for a generic XARELTO® product before expiration of the relevant patents. In February 2016, JPI and Bayer filed a patent infringement action against Invagen asserting the same XARELTO® patents asserted in the original case, and the Invagen case has been consolidated with the original case. The Court set a trial date of March 2018.

GOVERNMENT PROCEEDINGS

Like other companies in the pharmaceutical and medical devices industries, Johnson & Johnson and certain of its subsidiaries are subject to extensive regulation by national, state and local government agencies in the United States and other countries in which they operate. As a result, interaction with government agencies is ongoing. The most significant litigation brought by, and investigations conducted by, government agencies are listed below. It is possible that criminal charges and substantial fines and/or civil penalties or damages could result from government investigations or litigation.

Average Wholesale Price (AWP) Litigation

Johnson & Johnson and several of its pharmaceutical subsidiaries (the J&J AWP Defendants), along with numerous other pharmaceutical companies, are defendants in a series of lawsuits in state and federal courts involving allegations that the pricing and marketing of certain pharmaceutical products amounted to fraudulent and otherwise actionable conduct because, among other things, the companies allegedly reported an inflated Average Wholesale Price (AWP) for the drugs at issue. Payors alleged that they used those AWPs in calculating provider reimbursement levels. Many of these cases, both federal actions and state actions removed to federal court, were consolidated for pre-trial purposes in a Multi-District Litigation (MDL) in the United States District Court for the District of Massachusetts.

The plaintiffs in these cases included three classes of private persons or entities that paid for any portion of the purchase of the drugs at issue based on AWP, and state government entities that made Medicaid payments for the drugs at issue based on AWP. In June 2007, after a trial on the merits, the MDL Court dismissed the claims of two of the plaintiff classes against the J&J AWP Defendants. In March 2011, the Court dismissed the claims of the third class against the J&J AWP Defendants without prejudice.

AWP cases brought by various Attorneys General have proceeded to trial against other manufacturers. Several state cases against certain subsidiaries of Johnson & Johnson have been settled, including the case in Alaska, which settled in April 2014, and cases are still pending in Illinois, New Jersey, Wisconsin and Utah. The cases in Illinois, New Jersey and Wisconsin have not yet proceeded to trial. In Utah, the claims brought by the Attorney General were dismissed by the Court in 2013, but the State may appeal the dismissal after the conclusion of similar pending matters against other defendants. The AWP case against the J&J AWP Defendants brought by the Attorney General of the Commonwealth of Pennsylvania was tried in Commonwealth Court in 2010. The Court found in the Commonwealth's favor with regard to certain of its claims under the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPL"), entered an injunction, and awarded $45 million in restitution and $6.5 million in civil penalties. The Court found in the J&J AWP Defendants' favor on the Commonwealth's claims of unjust enrichment, misrepresentation/fraud, civil conspiracy, and on certain of the Commonwealth's claims under the UTPL. The J&J AWP Defendants appealed the Commonwealth Court's UTPL ruling, and in June 2014, the Pennsylvania Supreme Court

vacated the judgment entered by the Commonwealth Court and remanded the case for further proceedings. On remand, in January 2015, the Commonwealth Court dismissed the monetary awards against the J&J AWP Defendants. In March 2015, the ruling was appealed back to the Pennsylvania Supreme Court. In December 2015, the Pennsylvania Supreme Court affirmed the Order of the Commonwealth Court dismissing the monetary awards against the J&J AWP Defendants.

RISPERDAL®

In November 2013, Johnson & Johnson and its subsidiary, Janssen Pharmaceuticals, Inc. (JPI), finalized previously disclosed settlement agreements with the United States Department of Justice and forty-five states resolving federal investigations and state Medicaid claims related to past promotional practices of RISPERDAL® from 1999 through 2005, and other matters. JPI had also settled alleged consumer fraud claims in connection with the sale and marketing of RISPERDAL® with thirty-six states and the District of Columbia in September 2012. In addition to these actions, the Attorneys General of several states brought actions against JPI, related to the sale and marketing of RISPERDAL®, seeking one or more of the following remedies: reimbursement of Medicaid or other public funds for RISPERDAL® prescriptions written for off-label use, compensation for treating their citizens for alleged adverse reactions to RISPERDAL®, civil fines or penalties for violations of state false claims acts or consumer fraud statutes, punitive damages, or other relief relating to alleged unfair business practices. Certain of these actions also sought injunctive relief relating to the promotion of RISPERDAL®. Many of the actions and claims brought by the state Attorneys General have been settled, either individually or as part of the settlements described above. The cases brought by the Attorneys General of Mississippi and Kentucky were settled in December 2015, without any admission of wrongdoing on the part of JPI. State cases that went to judgment after trial are discussed below.

In 2004, the Attorney General of West Virginia commenced a lawsuit against Janssen Pharmaceutica, Inc. (now JPI) based on claims of alleged consumer fraud as to DURAGESIC®, as well as RISPERDAL®. JPI was found liable and damages were assessed at $4.5 million. JPI filed an appeal, and in November 2010, the West Virginia Supreme Court of Appeals reversed the trial court's decision. In December 2010, the Attorney General of West Virginia dismissed the case as it related to RISPERDAL® without any payment. Thereafter, JPI settled the case insofar as it related to DURAGESIC®.

In 2004, the Attorney General of Louisiana filed a multi-count Complaint against Janssen Pharmaceutica, Inc. (now JPI). Johnson & Johnson was later added as a defendant. The case was tried in October 2010. The issue tried to the jury was whether Johnson & Johnson or JPI had violated the State's Medical Assistance Program Integrity Law (the Act) through misrepresentations allegedly made in the mailing of a November 2003 Dear Health Care Professional letter regarding RISPERDAL®. The jury returned a verdict that JPI and Johnson & Johnson had violated the Act and awarded $257.7 million in damages. The trial judge subsequently awarded the Attorney General counsel fees and expenses in the amount of $73 million. In January 2014, the Louisiana Supreme Court reversed the District Court’s judgment in favor of the Attorney General, and rendered judgment in favor of Johnson & Johnson and JPI. In April 2014, the Louisiana Supreme Court denied the Attorney General's petition seeking a rehearing of the appellate arguments, resulting in final dismissal of the case.

In 2007, the Office of General Counsel of the Commonwealth of Pennsylvania filed a lawsuit against Janssen Pharmaceutica, Inc. (now JPI) on a multi-Count Complaint related to Janssen Pharmaceutica's sale of RISPERDAL® to the Commonwealth's Medicaid program. The trial occurred in June 2010. The trial judge dismissed the case after the close of the plaintiff's evidence. The Commonwealth filed an appeal and in July 2012, the Pennsylvania Appeals Court upheld the dismissal of the Commonwealth's case.

In 2007, the Attorney General of South Carolina filed a lawsuit against Johnson & Johnson and Janssen Pharmaceutica, Inc. (now JPI) on several counts. In March 2011, the matter was tried to a jury on liability only, at which time the lawsuit was limited to claims of violation of the South Carolina Unfair Trade Practices Act, including, among others, questions of whether Johnson & Johnson or JPI engaged in unfair or deceptive acts or practices in the conduct of any trade or commerce by distributing the November 2003 Dear Health Care Professional letter regarding RISPERDAL® or in their use of the product's FDA-approved label. The jury found in favor of Johnson & Johnson and against JPI. In June 2011, the Court awarded civil penalties of approximately $327.1 million against JPI. JPI appealed this judgment and in February 2015, the South Carolina Supreme Court affirmed the trial court’s decision in part, reversed it in part and remanded the case back to the trial court. The net effect of the decision was to reduce the judgment to approximately $136 million, plus interest. In the first fiscal quarter of 2015, the Company accrued $136 million. In March 2015, JPI filed a Petition for Rehearing. In July 2015, the South Carolina Supreme Court granted the Petition and filed a substituted opinion. The new opinion reduced the judgment from approximately $136 million to approximately $124 million. In January 2016, the United States Supreme Court denied JPI's request for review, putting an end to this case.

In April 2012, in the lawsuit brought by the Attorney General of Arkansas, the jury found against both JPI and Johnson & Johnson, and the Court imposed penalties in the amount of approximately $1.2 billion. In January 2013, the trial court awarded attorney fees of approximately $181 million. JPI and Johnson & Johnson appealed both awards to the Arkansas Supreme Court, and in March 2014, the Arkansas Supreme Court dismissed the State's claim under the Arkansas Medicaid Fraud False Claims Act, as well as the approximately $1.2 billion in penalties, and reversed and remanded a claim under the Arkansas Deceptive Trade Practices Act. In April 2014, the Arkansas Supreme Court rejected a petition by the State for rehearing on the case. In May 2015, the matter settled for $7.75 million.

McNeil Consumer Healthcare

Starting in June 2010, McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. (now Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division) (McNeil Consumer Healthcare) and certain affiliates, including Johnson & Johnson (the Companies), received grand jury subpoenas from the United States Attorney's Office for the Eastern District of Pennsylvania requesting documents broadly relating to recalls of various products of McNeil Consumer Healthcare, and the FDA inspections of the Fort Washington, Pennsylvania and Lancaster, Pennsylvania manufacturing facilities, as well as certain documents relating to recalls of a small number of products of other subsidiaries. In addition, in February 2011, the government served McNEIL-PPC, Inc. (McNEIL-PPC) with a Civil Investigative Demand seeking records relevant to its investigation to determine if there was a violation of the Federal False Claims Act. In March 2015, McNEIL-PPC entered a guilty plea in the United States District Court for the Eastern District of Pennsylvania to a misdemeanor violation of the U.S. Food, Drug and Cosmetic Act. McNEIL-PPC agreed to pay a $20 million fine and a $5 million forfeiture to resolve the matter.

The Companies have also received Civil Investigative Demands from multiple State Attorneys General Offices broadly relating to the McNeil recall issues. The Companies continue to cooperate with these inquiries, which are being coordinated through a multi-state coalition. If a resolution cannot be reached with this multi-state coalition, it is possible that individual State Attorneys General Offices may file civil monetary claims against the Companies. In January 2011, the Oregon Attorney General filed a civil complaint against Johnson & Johnson, McNEIL-PPC and McNeil Healthcare LLC in state court alleging civil violations of the Oregon Unlawful Trade Practices Act relating to an earlier recall of a McNeil OTC product. In November 2012, the state court granted a motion by the Companies to dismiss Oregon's complaint in its entirety, with prejudice, and Oregon appealed that decision. In November 2015, the Court of Appeals of the State of Oregon reversed the trial court and reinstated Oregon's consumer protection claims. In December 2015, the Companies filed a petition for review with the Oregon Supreme Court.

Opioids Litigation

Along with other pharmaceutical companies, Johnson & Johnson (J&J) and Janssen Pharmaceuticals, Inc. (JPI) have been named in two lawsuits alleging claims related to marketing of opioids, including DURAGESIC®, NUCYNTA® and NUCYNTA® ER. In May 2014, Santa Clara and Orange Counties in California (the Counties) filed a complaint in state court in Orange County, California against numerous pharmaceutical manufacturers, including J&J and JPI, alleging claims related to opioid marketing practices, including false advertising, unfair competition, and public nuisance. The Counties seek injunctive and monetary relief. In February 2015, the defendants filed motions challenging the sufficiency of the complaint. In August 2015, the Court stayed the case until the FDA concludes its ongoing inquiry into the safety and effectiveness of long-term opioid treatment.

In June 2014, the City of Chicago filed a complaint in Cook County Circuit Court against the same group of pharmaceutical manufacturers, including J&J and JPI, alleging a number of claims related to opioid marketing practices, including consumer fraud violations and false claims, and seeking injunctive and monetary relief. The case was later removed to the United States District Court for the Northern District of Illinois, and in December 2014, J&J and JPI filed a motion to dismiss the City of Chicago's First Amended Complaint for failure to state a claim. In November 2015, J&J and JPI filed a motion to dismiss the City of Chicago's Second Amended Complaint for failure to state a claim.

In September 2014, the Tennessee Attorney General Division of Consumer Affairs issued a Request for Information to JPI and other pharmaceutical companies related to opioids marketing practices.

In August 2015, the New Hampshire Attorney General, Consumer Protection and Antitrust Bureau issued a subpoena to JPI and other pharmaceutical companies related to opioids marketing practices. JPI objected to private contingent fee counsel's participation in the investigation on the State's behalf, and in October 2015, the State moved to enforce the subpoena.

In December 2015, the State of Mississippi filed a complaint in the Chancery Court of the First Judicial District of Hinds County against the same group of pharmaceutical manufacturers, including J&J and JPI, alleging a number of claims related to opioid marketing practices. The State of Mississippi is seeking penalties and injunctive and monetary relief.

Other

In September 2011, Synthes, Inc. (Synthes) received a Civil Investigative Demand issued pursuant to the False Claims Act from the United States Attorney's Office for the Eastern District of Pennsylvania. The Demand sought information regarding allegations that fellowships had been offered to hospitals in exchange for agreements to purchase products. Synthes has produced documents and information in response to the Demand and is cooperating with the inquiry.

In May 2012, Acclarent, Inc. (Acclarent) received a subpoena from the United States Attorney's Office for the District of Massachusetts requesting documents broadly relating to the sales, marketing and alleged off-label promotion by Acclarent of the RELIEVA STRATUS® MicroFlow Spacer product (the STRATUS® Spacer). In April 2015, an Indictment was filed in the United States District Court for the District of Massachusetts charging the former President/CEO and Vice President of Sales of Acclarent (the former Acclarent officers). The Indictment charges the former Acclarent officers with various violations related to the off-label promotion of the STRATUS® Spacer. The allegations against the former Acclarent officers relate to the development, sale and marketing of the STRATUS® Spacer, as well as actions allegedly taken by the former Acclarent officers in connection with the acquisition of Acclarent by Ethicon, Inc. in 2010. There are no charges against Acclarent, Ethicon, Inc. or Johnson & Johnson.

In August 2012, DePuy Orthopaedics, Inc., DePuy, Inc. (now DePuy Synthes, Inc.), and Johnson & Johnson Services, Inc. (the Companies) received an informal request from the United States Attorney's Office for the District of Massachusetts and the Civil Division of the United States Department of Justice (the United States) for the production of materials relating to the ASR™ XL Hip device. In July 2014, the United States notified the United States District Court for the District of Massachusetts that it had declined to intervene in a *qui tam* case filed pursuant to the False Claims Act against the Companies. The District Court issued an order in August 2014 that publicly unsealed the United States' declination notice; however, the complaint in the matter remains under seal. In addition, in October 2013, a group of state Attorneys General issued Civil Investigative Demands relating to the development, sales and marketing of several of DePuy Orthopaedics, Inc.'s hip products. In July 2014, the Oregon Department of Justice, which was investigating these matters independently of the other states, announced a settlement of its ASR™ XL Hip device investigation for a total payment of $4 million to the State of Oregon.

In October 2012, Johnson & Johnson was contacted by the California Attorney General's office regarding a multi-state Attorney General investigation of the marketing of surgical mesh products for hernia and urogynecological purposes by Johnson & Johnson's subsidiary, Ethicon, Inc. (Ethicon). Johnson & Johnson and Ethicon have since entered into a series of tolling agreements with the 47 states and the District of Columbia participating in the multi-state investigation and have responded to Civil Investigative Demands served by certain of the participating states. The states are seeking monetary and injunctive relief.

In December 2012, Therakos, Inc. (Therakos), formerly a subsidiary of Johnson & Johnson and part of the Ortho-Clinical Diagnostics, Inc. (OCD) franchise, received a letter from the civil division of the United States Attorney's Office for the Eastern District of Pennsylvania informing Therakos that the United States Attorney's Office was investigating the sales and marketing of Uvadex® (methoxsalen) and the Uvar Xts® System during the period 2000 to the present. The United States Attorney's Office requested that OCD and Johnson & Johnson preserve documents that could relate to the investigation. Therakos was subsequently acquired by an affiliate of Gores Capital Partners III, L.P. in January 2013. OCD and Johnson & Johnson retain certain liabilities that may result from the investigation for activity that occurred prior to the sale of Therakos. In March 2014, the United States Attorney's Office requested that Johnson & Johnson produce certain documents, and Johnson & Johnson is cooperating with the request. Following the divestiture of OCD, Johnson & Johnson retains OCD's portion of any liability that may result from the investigation for activity that occurred prior to the sale of Therakos.

In recent years, Johnson & Johnson has received numerous requests from a variety of United States Congressional Committees to produce information relevant to ongoing congressional inquiries. It is the policy of Johnson & Johnson to cooperate with these inquiries by producing the requested information.

GENERAL LITIGATION

In September 2006, Johnson & Johnson filed a lawsuit against Guidant Corporation (Guidant) in the United States District Court for the Southern District of New York, alleging that Guidant breached provisions of a merger agreement between Johnson & Johnson and Guidant. In June 2011, Guidant filed a motion for summary judgment and in July 2014, the judge denied Guidant's motion. The trial concluded in January 2015 and in February 2015, before a decision was issued by the Court, Johnson & Johnson and Guidant entered into a settlement agreement, pursuant to which Guidant agreed to pay Johnson & Johnson $600 million and agreed that it will not sue Johnson & Johnson or its affiliates for patent infringement regarding certain stent products. Johnson & Johnson dismissed its action against Guidant with prejudice. The Company recorded a gain associated with this transaction in fiscal first quarter of 2015.

In June 2009, following the public announcement that Ortho-Clinical Diagnostics, Inc. (OCD) had received a grand jury subpoena from the United States Department of Justice, Antitrust Division, in connection with an investigation that has since been closed, multiple class action complaints were filed against OCD by direct purchasers seeking damages for alleged price fixing. These cases were consolidated for pre-trial purposes in the United States District Court for the Eastern District of Pennsylvania as *In re Blood Reagent Antitrust Litigation*. Following the divestiture of OCD, Johnson & Johnson retains any liability that may result from these cases. In August 2012, the District Court granted a motion filed by Plaintiffs for class certification. In April 2015, the United States Court of Appeals for the Third Circuit reversed the class certification ruling and remanded the case to the District Court for further proceedings. In October 2015, the District Court again granted the motion by Plaintiffs for class certification.

In September 2011, Johnson & Johnson, Johnson & Johnson Inc. and McNeil Consumer Healthcare Division of Johnson & Johnson Inc. received a Notice of Civil Claim filed by Nick Field in the Supreme Court of British Columbia, Canada (the BC Civil Claim). The BC Civil Claim is a putative class action brought on behalf of persons who reside in British Columbia and who purchased during the period between September 20, 2001 and in or about December 2010 one or more various McNeil infants' or children's over-the-counter medicines that were manufactured at the Fort Washington facility. The BC Civil Claim alleges that the defendants violated the BC Business Practices and Consumer Protection Act, and other Canadian statutes and common laws, by selling medicines that were allegedly not safe and/or effective or did not comply with Canadian Good Manufacturing Practices. The class certification hearing scheduled for October 2015 was adjourned, and there is currently no date set for that hearing.

In August 2014, United States Customs and Border Protection (US CBP) issued a Penalty Notice against Janssen Ortho LLC (Janssen Ortho), assessing penalties for the alleged improper classification of darunavir ethanolate (PREZISTA®) in connection with its importation into the United States. In October 2014, Janssen Ortho submitted a Petition for Relief in response to the Penalty Notice. In May 2015, US CBP issued an Amended Penalty Notice assessing substantial penalties and Janssen Ortho filed its Petition for Relief in July 2015.

In March 2015, Costco Wholesale Corporation (Costco) filed a complaint against Johnson & Johnson Vision Care, Inc. (JJVCI) in the United States District Court of the Northern District of California, alleging antitrust claims of an unlawful vertical price fixing agreement between JJVCI, Costco and unnamed other distributors and retailers. Costco alleges that the alleged agreements harmed competition by causing increases in the price Costco customers pay for JJVCI contact lenses. Costco is seeking an injunction and monetary damages. In June 2015, the case was transferred to the United States District Court for the Middle District of Florida along with related class action cases described below. In November 2015, the Court denied a JJVCI motion to dismiss.

In March and April 2015, over 30 putative class action complaints were filed by contact lens patients in a number of courts around the United States against Johnson & Johnson Vision Care, Inc. (JJVCI), other contact lens manufacturers, distributors, and retailers, alleging vertical and horizontal conspiracies to fix the retail prices of contact lenses. The complaints alleged that the manufacturers reached agreements between each other and certain distributors and retailers concerning the prices at which some contact lenses could be sold to consumers. The plaintiffs are seeking damages. All of the class action cases were transferred to the United States District Court for the Middle District of Florida in June 2015 along with the related case filed by Costco Wholesale Corporation described above. The plaintiffs filed a Consolidated Class Action complaint in November 2015, and in December 2015, JJVCI and other defendants filed motions to dismiss.

In April 2015, Johnson & Johnson Vision Care, Inc. (JJVCI) filed a complaint in the United States District Court for the District of Utah against the State of Utah seeking a declaratory judgment that a law passed by the state to ban unilateral pricing policies solely in the contact lens market violates the Commerce Clause of the United States Constitution. The Court denied JJVCI's motion for a preliminary injunction. JJVCI appealed. Argument on the appeal was held in August 2015.

In April 2015, Adimmune Corporation Ltd (Adimmune) commenced an arbitration in the International Court of Arbitration - International Chamber of Commerce against Crucell Switzerland AG (now Janssen Vaccines AG) and Crucell Holland BV (collectively, Crucell). Adimmune claims that Crucell breached certain agreements relating to the supply of flu antigen when Crucell ceased purchasing flu antigen from Adimmune. In December 2015, Adimmune filed its Statement of Claim seeking monetary damages.

In August 2015, two third-party payors filed a purported class action in the United States District Court for the Eastern District of Louisiana against Janssen Research & Development, LLC, Janssen Ortho LLC, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, and Johnson & Johnson (as well as certain Bayer entities), alleging that the defendants improperly marketed and promoted XARELTO® as safer and more effective than less expensive alternative medications while failing to fully disclose its risks. The complaint seeks damages in an unspecified amount.

Johnson & Johnson or its subsidiaries are also parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the cost of past and/or future remediation.

22. Restructuring

The Company announced restructuring actions in its Medical Devices segment to better serve the needs of patients and customers in today's evolving healthcare marketplace. The Company is undertaking actions to strengthen its go-to-market model, accelerate the pace of innovation, further prioritize key platforms and geographies, and streamline operations while maintaining high quality standards.

The Company estimates that, in connection with its plans, it will record pre-tax restructuring charges of approximately $2.0 billion to $2.4 billion, most of which are expected to be incurred by 2017. In the fiscal fourth quarter of 2015, the Company recorded a pre-tax charge of $590 million, of which $81 million is included in cost of products sold. The $590 million restructuring charge consists of severance costs of $484 million, asset write-offs of $86 million and $20 million in other costs, primarily related to supply contracts.

Additionally, as part of the plan, the Company expects that the restructuring actions will result in position eliminations of approximately 4 to 6 percent of the Medical Devices segment's global workforce over the next two years, subject to any consultation procedures in countries, where required.

The Company estimates that approximately one half of the cumulative pre-tax costs will result in cash outlays, including approximately $500 million of employee severance. Approximately one half of the cumulative pre-tax costs are non-cash, relating primarily to facility rationalization, inventory write-offs and intangible asset write-offs.

The following table summarizes the severance charges and the associated spending for the fiscal year ended 2015:

(Dollars in Millions)		Severance	Asset Write-offs	Other	Total
2015 restructuring charge	$	484	86	20	590
Current year activity		—	86	3	89
Reserve balance, January 3, 2016*	$	484	—	17	501

*Cash outlays for severance are expected to be substantially paid out over the next 24 months in accordance with the Company's plans and local laws.

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of Johnson & Johnson

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of earnings, statements of comprehensive income, statements of equity, and statements of cash flows present fairly, in all material respects, the financial position of Johnson & Johnson and its subsidiaries at January 3, 2016 and December 28, 2014, and the results of their operations and their cash flows for each of the three years in the period ended January 3, 2016 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of January 3, 2016, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Management's Report on Internal Control over Financial Reporting." Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 1 to the consolidated financial statements, the Company changed the manner in which it classifies deferred tax assets and liabilities in 2015.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP
PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 24, 2016

Management's Report on Internal Control Over Financial Reporting

Under Section 404 of the Sarbanes-Oxley Act of 2002, management is required to assess the effectiveness of the Company's internal control over financial reporting as of the end of each fiscal year and report, based on that assessment, whether the Company's internal control over financial reporting is effective.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is designed to provide reasonable assurance as to the reliability of the Company's financial reporting and the preparation of external financial statements in accordance with generally accepted accounting principles.

Internal controls over financial reporting, no matter how well designed, have inherent limitations. Therefore, internal control over financial reporting determined to be effective can provide only reasonable assurance with respect to financial statement preparation and may not prevent or detect all misstatements. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management has assessed the effectiveness of the Company's internal control over financial reporting as of January 3, 2016. In making this assessment, the Company used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework (2013)." These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. The Company's assessment included extensive documenting, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

Based on the Company's processes and assessment, as described above, management has concluded that, as of January 3, 2016, the Company's internal control over financial reporting was effective.

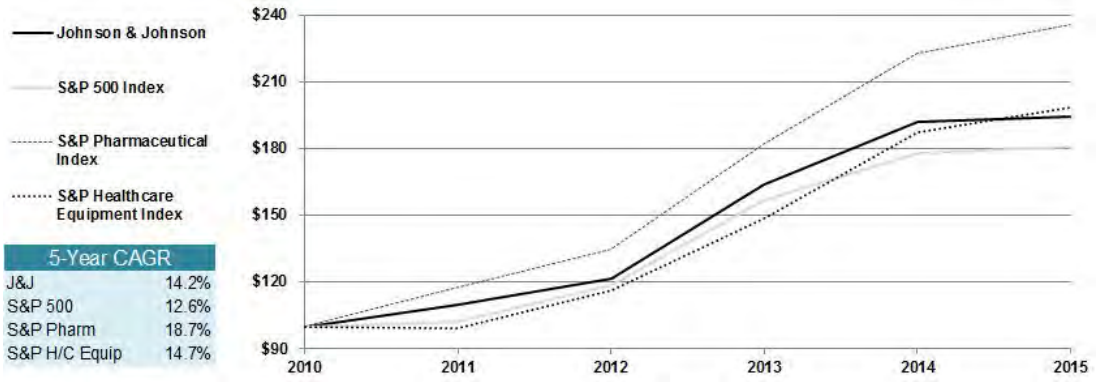
The effectiveness of the Company's internal control over financial reporting as of January 3, 2016 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which appears herein.

/s/ Alex Gorsky	/s/ Dominic J. Caruso
Alex Gorsky	Dominic J. Caruso
Chairman, Board of Directors	Vice President, Finance
Chief Executive Officer	Chief Financial Officer

Shareholder Return Performance Graphs

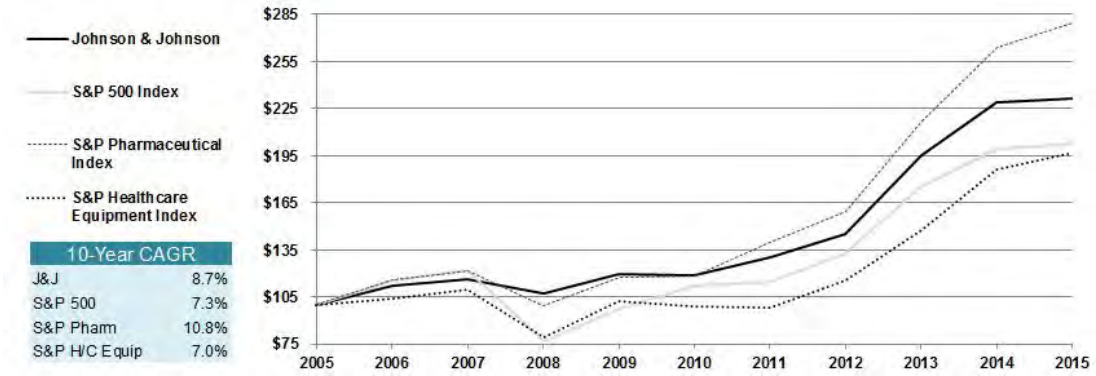
Set forth below are line graphs comparing the cumulative total shareholder return on the Company's Common Stock for periods of five years and ten years ending December 31, 2015, against the cumulative total return of the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index. The graphs and tables assume that $100 was invested on December 31, 2010 and December 31, 2005 in each of the Company's Common Stock, the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index and that all dividends were reinvested.

5 Year Shareholder Return Performance J&J vs. Indices



	2010	2011	2012	2013	2014	2015
Johnson & Johnson	$100.00	$109.89	$121.79	$163.95	$192.37	$194.59
S&P 500 Index	$100.00	$102.11	$118.44	$156.78	$178.22	$180.67
S&P Pharmaceutical Index	$100.00	$117.76	$134.75	$182.22	$222.70	$235.59
S&P Healthcare Equipment Index	$100.00	$99.20	$116.33	$148.54	$187.58	$198.78

10 Year Shareholder Return Performance J&J vs. Indices



	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Johnson & Johnson	$100.00	$112.44	$116.50	$107.45	$119.57	$118.87	$130.63	$144.77	$194.89	$228.67	$231.32
S&P 500 Index	$100.00	$115.78	$122.23	$77.00	$97.37	$112.03	$114.39	$132.68	$175.64	$199.67	$202.41
S&P Pharmaceutical Index	$100.00	$115.85	$121.25	$99.18	$117.65	$118.56	$139.62	$159.76	$216.04	$264.04	$279.32
S&P Healthcare Equipment Index	$100.00	$104.12	$109.47	$79.20	$102.01	$99.24	$98.45	$115.45	$147.42	$186.16	$197.28

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE 668

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures. At the end of the period covered by this Report, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Alex Gorsky, Chairman and Chief Executive Officer, and Dominic J. Caruso, Vice President, Finance and Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Gorsky and Caruso concluded that, as of the end of the period covered by this Report, the Company's disclosure controls and procedures were effective

Reports on Internal Control Over Financial Reporting. The information called for by this item is incorporated herein by reference to "Management's Report on Internal Control Over Financial Reporting", and the attestation regarding internal controls over financial reporting included in the "Report of Independent Registered Public Accounting Firm" included in Item 8 of this Report.

Changes in Internal Control Over Financial Reporting. During the fiscal quarter ended January 3, 2016, there were no changes in the Company's internal control over financial reporting identified in connection with the evaluation required under Rules 13a-15 and 15d-15 under the Exchange Act that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

The Company is implementing a multi-year, enterprise-wide initiative to integrate, simplify and standardize processes and systems for the human resources, information technology, procurement, supply chain and finance functions. These are enhancements to support the growth of the Company's financial shared service capabilities and standardize financial systems. This initiative is not in response to any identified deficiency or weakness in the Company's internal control over financial reporting. In response to this initiative, the Company has and will continue to align and streamline the design and operation of its financial control environment.

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information called for by this item is incorporated herein by reference to the discussion of the Audit Committee under the caption "Corporate Governance - Board Committees"; and the material under the captions "Item 1: Election of Directors" and "Stock Ownership and Section 16 Compliance – Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement; and the material under the caption "Executive Officers of the Registrant" in Part I of this Report.

The Company's Code of Business Conduct, which covers all employees (including the Chief Executive Officer, Chief Financial Officer and Controller), meets the requirements of the SEC rules promulgated under Section 406 of the Sarbanes-Oxley Act of 2002. The Code of Business Conduct is available on the Company's website at *www.investor.jnj.com/gov/policies.cfm*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code of Business Conduct or any waiver of the Code granted to the Chief Executive Officer, the Chief Financial Officer or the Controller will be posted on the Company's website at *www.investor.jnj.com/gov.cfm* within five business days (and retained on the website for at least one year).

In addition, the Company has adopted a Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers. The Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers is available on the Company's website at *www.investor.jnj.com/gov/policies.cfm*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code or any waiver of the Code granted to any member of the Board of Directors or any executive officer will be posted

on the Company's website at *www.investor.jnj.com/gov.cfm* within five business days (and retained on the website for at least one year).

Item 11. EXECUTIVE COMPENSATION

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1: Election of Directors – Director Compensation – Fiscal 2015," "Compensation Committee Report," "Compensation Discussion and Analysis" and "Executive Compensation Tables" in the Proxy Statement.

The material incorporated herein by reference to the material under the caption "Compensation Committee Report" in the Proxy Statement shall be deemed furnished, and not filed, in this Report and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, as a result of this furnishing, except to the extent that the Company specifically incorporates it by reference.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information called for by this item is incorporated herein by reference to the material under the caption "Stock Ownership and Section 16 Compliance" in the Proxy Statement; and Note 17 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements in Item 8 of this Report.

Equity Compensation Plan Information

The following table provides certain information as of January 3, 2016 concerning the shares of the Company's Common Stock that may be issued under existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights	Weighted Average Exercise Price of Outstanding Options and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans[2][3]
Equity Compensation Plans Approved by Security Holders[1]	143,479,580	$62.05	485,801,441
Equity Compensation Plans Not Approved by Security Holders	-	-	-
Total	143,479,580	$62.05	485,801,441

(1) Included in this category are the following equity compensation plans which have been approved by the Company's shareholders: 2005 Long-Term Incentive Plan and 2012 Long-Term Incentive Plan.

(2) This column excludes shares reflected under the column "Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights."

(3) The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information called for by this item is incorporated herein by reference to the material under the captions "Corporate Governance - Director Independence" and "Related Party Transactions" in the Proxy Statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information called for by this item is incorporated herein by reference to the material under the caption "Ratification of Appointment of Independent Registered Public Accounting Firm" in the Proxy Statement.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this report:

1. *Financial Statements*

   Consolidated Balance Sheets at end of Fiscal Years 2015 and 2014

   Consolidated Statements of Earnings for Fiscal Years 2015, 2014 and 2013

   Consolidated Statements of Comprehensive Income for Fiscal Years 2015, 2014 and 2013

   Consolidated Statements of Equity for Fiscal Years 2015, 2014 and 2013

   Consolidated Statements of Cash Flows for Fiscal Years 2015, 2014 and 2013

   Notes to Consolidated Financial Statements

   Report of Independent Registered Public Accounting Firm

   All schedules are omitted because they are not applicable or the required information is included in the financial statements or notes.

2. *Exhibits* Required *to be Filed by Item 601 of Regulation S-K*

   The information called for by this item is incorporated herein by reference to the Exhibit Index in this Report.

SIGNATURES

Pursuant to the requirements of Section 13 of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 24, 2016

JOHNSON & JOHNSON
(Registrant)

By /s/ A. Gorsky
A. Gorsky, Chairman, Board of Directors,
and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ A. Gorsky A. Gorsky	Chairman, Board of Directors, Chief Executive Officer, and Director (Principal Executive Officer)	February 24, 2016
/s/ D. J. Caruso D. J. Caruso	Chief Financial Officer and Vice President, Finance (Principal Financial Officer)	February 24, 2016
/s/ R. A. Kapusta R. A. Kapusta	Controller and Chief Accounting Officer (Principal Accounting Officer)	February 24, 2016
/s/ M. C. Beckerle M. C. Beckerle	Director	February 24, 2016
/s/ M. S. Coleman M. S. Coleman	Director	February 24, 2016
/s/ D. S. Davis D. S. Davis	Director	February 24, 2016
/s/ I. E. L. Davis I. E. L. Davis	Director	February 24, 2016

Signature	Title	Date
/s/ S. L. Lindquist S. L. Lindquist	Director	February 24, 2016
/s/ M. B. McClellan M. B. McClellan	Director	February 24, 2016
/s/ A. M. Mulcahy A. M. Mulcahy	Director	February 24, 2016
/s/ W. D. Perez W. D. Perez	Director	February 24, 2016
/s/ C. Prince C. Prince	Director	February 24, 2016
/s/ A. E. Washington A. E. Washington	Director	February 24, 2016
/s/ R. A. Williams R. A. Williams	Director	February 24, 2016

EXHIBIT INDEX

Reg. S-K Exhibit Table Item No.	Description of Exhibit
3(i)	Restated Certificate of Incorporation effective February 19, 2016 — Filed with this document.
3(ii)	By-Laws of the Company, as amended effective January 26, 2016 — Incorporated herein by reference to Exhibit 3.1 the Registrant's Form 8-K Current Report filed January 26, 2016.
4(a)	Upon the request of the Securities and Exchange Commission, the Registrant will furnish a copy of all instruments defining the rights of holders of long-term debt of the Registrant.
10(a)	2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 4 of the Registrant's S-8 Registration Statement filed with the Commission on May 10, 2005 (file no. 333-124785).*
10(b)	Form of Restricted Shares to Non-Employee Directors under the 2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 8-K Current Report filed August 25, 2005.*
10(c)	Form of Stock Option Certificate, Restricted Share Unit Certificate and Performance Share Unit Certificate under the 2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.1, 10.2 and 10.3 of the Registrant's Form 8-K Current Report filed January 13, 2012.*
10(d)	2012 Long-Term Incentive Plan — Incorporated herein by reference to Appendix A of the Registrant's Proxy Statement filed with the Commission on March 14, 2012 .*
10(e)	Form of Stock Option Certificate, Restricted Share Unit Certificate and Performance Share Unit Certificate under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.2, 10.3 and 10.4 of the Registrant's Form 10-Q Quarterly Report filed May 7, 2012.*
10(f)	Executive Incentive Plan (as amended) — Incorporated herein by reference to Exhibit 10(f) of the Registrant's Form 10-K Annual Report for the year ended December 31, 2000.*
10(g)	Domestic Deferred Compensation (Certificate of Extra Compensation) Plan — Incorporated herein by reference to Exhibit 10(g) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2003.*
10(h)	Amendments to the Certificate of Extra Compensation Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(i)	2009 Certificates of Long-Term Performance Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 27, 2009.*
10(j)	Amended and Restated Deferred Fee Plan for Directors — Incorporated herein by reference to Exhibit 10(k) of the Registrant's Form 10-K Annual Report for the year ended January 1, 2012.*
10(k)	Executive Income Deferral Plan (Amended and Restated) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*
10(l)	Excess Savings Plan — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the year ended December 29, 1996.*
10(m)	Amendments to the Johnson & Johnson Excess Savings Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(p) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(n)	Excess Benefit Plan (Supplemental Retirement Plan) — Incorporated herein by reference to Exhibit 10(h) of the Registrant's Form 10-K Annual Report for the year ended January 3, 1993.*
10(o)	Amendments to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(r) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(p)	Amendment to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies, effective as of January 1, 2015 — Incorporated herein by reference to Exhibit 10(q) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2014.*
10(q)	Executive Life Plan Agreement — Incorporated herein by reference to Exhibit 10(i) of the Registrant's Form 10-K Annual Report for the year ended January 3, 1993.*
10(r)	Executive Life Plan Agreement Closure Letter — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended March 29, 2015.*
10(s)	Johnson & Johnson Retirement Savings Plan, Johnson & Johnson Savings Plan for Union Represented Employees, and Johnson & Johnson Savings Plan - Incorporated herein by reference to Exhibits 99.1, 99.2 and 99.3 of the Registrant's Form S-8 filed with the Commission on May 6, 2013.*
10(t)	Employment Agreement for Dr. Paulus Stoffels - Incorporated herein by reference to Exhibit 10.2 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*

Reg. S-K Exhibit Table Item No.	Description of Exhibit
10(u)	Summary of Employment Arrangements for Sandra E. Peterson — Incorporated herein by reference to Exhibit 10(t) of the Registrant's Form 10-K Annual Report for the year ended December 30, 2012.*
10(v)	Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies, Amended and Restated as of October 1, 2014 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 28, 2014.*
10(w)	First Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended June 28, 2015.*
10(x)	Second Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Filed with this document.*
12	Statement of Computation of Ratio of Earnings to Fixed Charges — Filed with this document.
21	Subsidiaries - Filed with this document.
23	Consent of Independent Registered Public Accounting Firm — Filed with this document.
31(a)	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
31(b)	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
32(a)	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
32(b)	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
99	Cautionary Statement Pursuant to Private Securities Litigation Reform Act of 1995 — "Safe Harbor" for Forward-Looking Statements — Filed with this document.
101	XBRL (Extensible Business Reporting Language) The following materials from this Report for the fiscal year ended January 3, 2016, formatted in Extensive Business Reporting Language (XBRL): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Earnings, (iii) Consolidated Statements of Comprehensive Income, (iv) Consolidated Statements of Equity, (v) Consolidated Statements of Cash Flows, and (vi) Notes to the Consolidated Financial Statements.

* Management contract or compensatory plan.

A copy of any of the Exhibits listed above will be provided without charge to any shareholder submitting a written request specifying the desired exhibit(s) to the Secretary at the principal executive offices of the Company.

Exhibit “J14”

This is Exhibit “J14” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.
Arash Rouhi

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended January 1, 2017 **Commission file number 1-3215**

JOHNSON & JOHNSON

(Exact name of registrant as specified in its charter)

New Jersey	**22-1024240**
(State of incorporation)	(I.R.S. Employer Identification No.)
One Johnson & Johnson Plaza **New Brunswick, New Jersey**	**08933**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(732) 524-0400**

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT

Title of each class	Name of each exchange on which registered
Common Stock, Par Value $1.00	New York Stock Exchange
4.75% Notes Due November 2019	New York Stock Exchange
0.250% Notes Due January 2022	New York Stock Exchange
0.650% Notes Due May 2024	New York Stock Exchange
5.50% Notes Due November 2024	New York Stock Exchange
1.150% Notes Due November 2028	New York Stock Exchange
1.650% Notes Due May 2035	New York Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☑ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $332 billion.

On February 23, 2017, there were 2,713,346,602 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Parts I and III:	Portions of registrant's proxy statement for its 2017 annual meeting of shareholders filed within 120 days after the close of the registrant's fiscal year (the "Proxy Statement"), are incorporated by reference to this report on Form 10-K (this "Report").

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and Johnson & Johnson's other publicly available documents contain "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Management and representatives of Johnson & Johnson and its subsidiaries (the "Company") also may from time to time make forward-looking statements. Forward-looking statements do not relate strictly to historical or current facts and reflect management's assumptions, views, plans, objectives and projections about the future. Forward-looking statements may be identified by the use of words such as "plans," "expects," "will," "anticipates," "estimates" and other words of similar meaning in conjunction with, among other things: discussions of future operations; expected operating results and financial performance; impact of planned acquisitions and dispositions; the Company's strategy for growth; product development; regulatory approvals; market position and expenditures.

Because forward-looking statements are based on current beliefs, expectations and assumptions regarding future events, they are subject to uncertainties, risks and changes that are difficult to predict and many of which are outside of the Company's control. Investors should realize that if underlying assumptions prove inaccurate, or known or unknown risks or uncertainties materialize, the Company's actual results and financial condition could vary materially from expectations and projections expressed or implied in its forward-looking statements. Investors are therefore cautioned not to rely on these forward-looking statements. Risks and uncertainties include, but are not limited to:

Risks Related to Product Development, Market Success and Competition

- Challenges and uncertainties inherent in innovation and development of new and improved products and technologies on which the Company's continued growth and success depend, including uncertainty of clinical outcomes, obtaining regulatory approvals, health plan coverage and customer access, and initial and continued commercial success;
- Challenges to the Company's ability to obtain and protect adequate patent and other intellectual property rights for new and existing products and technologies in the U.S. and other important markets;
- The impact of patent expirations, typically followed by the introduction of competing biosimilars and generics and resulting revenue and market share losses;
- Increasingly aggressive and frequent challenges to the Company's patents by competitors and others seeking to launch competing generic, biosimilar or other products, potentially resulting in loss of market exclusivity and rapid decline in sales for the relevant product;
- Competition in research and development of new and improved products, processes and technologies, which can result in product and process obsolescence;
- Competition to reach agreement with third parties for collaboration, licensing, development and marketing agreements for products and technologies;
- Competition on the basis of cost-effectiveness, product performance, technological advances and patents attained by competitors; and
- Allegations that the Company's products infringe the patents and other intellectual property rights of third parties, which could adversely affect the Company's ability to sell the products in question and require the payment of money damages and future royalties.

Risks Related to Product Liability, Litigation and Regulatory Activity

- Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the U.S. Food and Drug Administration (or international counterparts), declining sales and reputational damage;
- Impact of significant litigation or government action adverse to the Company, including product liability claims;
- Increased scrutiny of the health care industry by government agencies and state attorneys general resulting in investigations and prosecutions, which carry the risk of significant civil and criminal penalties, including, but not limited to, debarment from government business;
- Failure to meet compliance obligations in the McNEIL-PPC, Inc. Consent Decree or the Corporate Integrity Agreements of the Johnson & Johnson Pharmaceutical Affiliates, or any other compliance agreements with governments or government agencies, which could result in significant sanctions;

- Potential changes to applicable laws and regulations affecting U.S. and international operations, including relating to: approval of new products; licensing and patent rights; sales and promotion of health care products; access to, and reimbursement and pricing for, health care products and services; environmental protection and sourcing of raw materials;
- Changes in tax laws and regulations, increasing audit scrutiny by tax authorities around the world and exposures to additional tax liabilities potentially in excess of reserves; and
- Issuance of new or revised accounting standards by the Financial Accounting Standards Board and the Securities and Exchange Commission.

Risks Related to the Company's Strategic Initiatives and Health Care Market Trends

- Pricing pressures resulting from trends toward health care cost containment, including the continued consolidation among health care providers, trends toward managed care and the shift toward governments increasingly becoming the primary payers of health care expenses;
- Restricted spending patterns of individual, institutional and governmental purchasers of health care products and services due to economic hardship and budgetary constraints;
- Challenges to the Company's ability to realize its strategy for growth including through externally sourced innovations, such as development collaborations, strategic acquisitions, licensing and marketing agreements, and the potential heightened costs of any such external arrangements due to competitive pressures;
- The potential that the expected strategic benefits and opportunities from any planned or completed acquisition or divestiture by the Company, including the planned acquisition of Actelion Ltd., may not be realized or may take longer to realize than expected;
- The potential that the expected benefits and opportunities related to the planned restructuring actions in the Medical Device segment may not be realized or may take longer to realize than expected, including due to any required consultation procedures relating to restructuring of workforce; and
- Market conditions and the possibility that the Company's share repurchase program may be delayed, suspended or discontinued.

Risks Related to Economic Conditions, Financial Markets and Operating Internationally

- Impact of inflation and fluctuations in interest rates and currency exchange rates and the potential effect of such fluctuations on revenues, expenses and resulting margins;
- Potential changes in export/import and trade laws, regulations and policies of the U.S., U.K. and other countries, including any increased trade restrictions and potential drug reimportation legislation;
- The impact on international operations from financial instability in international economies, sovereign risk, possible imposition of governmental controls and restrictive economic policies, and unstable international governments and legal systems;
- Changes to global climate, extreme weather and natural disasters that could affect demand for the Company's products and services, cause disruptions in manufacturing and distribution networks, alter the availability of goods and services within the supply chain, and affect the overall design and integrity of the Company's products and operations; and
- The impact of armed conflicts and terrorist attacks in the U.S. and other parts of the world including social and economic disruptions and instability of financial and other markets.

Risks Related to Supply Chain and Operations

- Difficulties and delays in manufacturing, internally or within the supply chain, that may lead to voluntary or involuntary business interruptions or shutdowns, product shortages, withdrawals or suspensions of products from the market, and potential regulatory action;
- Interruptions and breaches of the Company's information technology systems, and those of the Company's vendors, could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action; and
- Reliance on global supply chains and production and distribution processes that are complex and subject to increasing regulatory requirements that may adversely affect supply, sourcing and pricing of materials used in the Company's products.

Investors also should carefully read the Risk Factors described in Item 1A of this Annual Report on Form 10-K for a description of certain risks that could, among other things, cause the Company's actual results to differ materially from those expressed in its forward-looking statements. Investors should understand that it is not possible to predict or identify all such factors and should not consider the risks described above and in Item 1A to be a complete statement of all potential risks and

uncertainties. The Company does not undertake to publicly update any forward-looking statement that may be made from time to time, whether as a result of new information or future events or developments.

PART I

Item 1. BUSINESS

General

Johnson & Johnson and its subsidiaries (the "Company") have approximately 126,400 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. Johnson & Johnson is a holding company, which has more than 230 operating companies conducting business in virtually all countries of the world. The Company's primary focus is products related to human health and well-being. Johnson & Johnson was incorporated in the State of New Jersey in 1887.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Company's three business segments: Consumer, Pharmaceutical and Medical Devices. Within the strategic parameters provided by the Committee, senior management groups at U.S. and international operating companies are each responsible for their own strategic plans and the day-to-day operations of those companies. Each subsidiary within the business segments is, with limited exceptions, managed by residents of the country where located.

Segments of Business

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. Additional information required by this item is incorporated herein by reference to the narrative and tabular descriptions of segments and operating results under: "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition" of this Report; and Note 18 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Consumer

The Consumer segment includes a broad range of products used in the baby care, oral care, beauty (previously referred to as skin care), over-the-counter pharmaceutical, women's health and wound care markets. Baby Care includes the JOHNSON'S® line of products. Oral Care includes the LISTERINE® product line. Major brands in Beauty include the AVEENO®; CLEAN & CLEAR®; DABAO™; JOHNSON'S® Adult; LE PETITE MARSEILLAIS®; NEUTROGENA®; RoC® and OGX® product lines. Over-the-counter medicines include the broad family of TYLENOL® acetaminophen products; SUDAFED® cold, flu and allergy products; BENADRYL® and ZYRTEC® allergy products; MOTRIN® IB ibuprofen products; and the PEPCID® line of acid reflux products. Major brands in Women's Health outside of North America are STAYFREE® and CAREFREE® sanitary pads and o.b.® tampon brands. Wound Care brands include the BAND-AID® Brand Adhesive Bandages and NEOSPORIN® First Aid product lines. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world.

Pharmaceutical

The Pharmaceutical segment is focused on five therapeutic areas: immunology (e.g., rheumatoid arthritis, inflammatory bowel disease and psoriasis), infectious diseases and vaccines (e.g., HIV, hepatitis, respiratory infections and tuberculosis), neuroscience (e.g., Alzheimer's disease, mood disorders and schizophrenia), oncology (e.g., prostate cancer, hematologic malignancies and lung cancer), and cardiovascular and metabolic diseases (e.g., thrombosis and diabetes). Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. Key products in the Pharmaceutical segment include: REMICADE® (infliximab), a treatment for a number of immune-mediated inflammatory diseases; SIMPONI® (golimumab), a subcutaneous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis and moderately active to severely active ulcerative colitis; SIMPONI ARIA® (golimumab), an intravenous treatment for adults with moderate to severe rheumatoid arthritis; STELARA® (ustekinumab), a treatment for adults with moderate to severe plaque psoriasis and active psoriatic arthritis, and for adults with moderately to severely active Crohn's disease; PREZISTA® (darunavir), EDURANT® (rilpivirine), and PREZCOBIX®/REZOLSTA® (darunavir/cobicistat), antiretroviral medicines for the treatment of human immunodeficiency virus (HIV-1) in combination with other antiretroviral products; CONCERTA® (methylphenidate HCl) extended-release tablets CII, a treatment for attention deficit hyperactivity disorder; INVEGA® (paliperidone) extended-release tablets, for the treatment of schizophrenia and schizoaffective disorder; INVEGA SUSTENNA®/XEPLION® (paliperidone palmitate), for the treatment of schizophrenia and schizoaffective disorder in adults; INVEGA TRINZA®/TREVICTA® (paliperidone palmitate), for the treatment of schizophrenia in patients after they have been adequately treated with INVEGA SUSTENNA® for at least four months; RISPERDAL CONSTA® (risperidone long-acting injection), for the treatment of schizophrenia and the maintenance treatment of Bipolar 1 Disorder in adults; VELCADE® (bortezomib), a treatment for multiple myeloma and for use in combination with rituximab, cyclophosphamide, doxorubicin and prednisone for the treatment of adult patients with previously

untreated mantle cell lymphoma; ZYTIGA® (abiraterone acetate), used in combination with prednisone as a treatment for metastatic castration-resistant prostate cancer; IMBRUVICA® (ibrutinib), an oral, once-daily therapy approved for use in treating certain B-cell malignancies, or blood cancers, and Waldenstrom's Macroglobulinemia; DARZALEX® (daratumumab), for the treatment of relapsed/refractory multiple myeloma; PROCRIT® (epoetin alfa, sold outside the U.S. as EPREX®), to stimulate red blood cell production; XARELTO® (rivaroxaban), an oral anticoagulant for the prevention of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery, to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, for the treatment and reduction of risk of recurrence of DVT and PE; INVOKANA® (canagliflozin), for the treatment of adults with type 2 diabetes; INVOKAMET®/VOKANAMET® (canagliflozin/metformin HCl), a combination therapy of fixed doses of canagliflozin and metformin hydrochloride for the treatment of adults with type 2 diabetes; and INVOKAMET® XR (canagliflozin/metformin hydrochloride extended-release), a once-daily, fixed-dose combination therapy of canagliflozin and metformin hydrochloride extended-release, for the treatment of adults with type 2 diabetes. Many of these medicines were developed in collaboration with strategic partners or are licensed from other companies and maintain active lifecycle development programs.

Medical Devices

The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, cardiovascular, diabetes care and vision care fields. These products are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics. They include orthopaedic products; general surgery, biosurgical, endomechanical and energy products; electrophysiology products to treat cardiovascular disease; sterilization and disinfection products to reduce surgical infection; diabetes care products, such as blood glucose monitoring and insulin delivery products; and disposable contact lenses.

For details regarding acquisitions and divestitures see Note 20 to the Consolidated Financial Statements included in Item 8.

Geographic Areas

The business of Johnson & Johnson is conducted by more than 230 operating companies located in 60 countries, including the U.S., in virtually all countries throughout the world. The products made and sold in the international business include many of those described above under "– Segments of Business – Consumer," "– Pharmaceutical" and "– Medical Devices." However, the principal markets, products and methods of distribution in the international business vary with the country and the culture. The products sold in international business include those developed in the U.S. and by subsidiaries abroad.

Investments and activities in some countries outside the U.S. are subject to higher risks than comparable U.S. activities because the investment and commercial climate may be influenced by financial instability in international economies, restrictive economic policies and political and legal system uncertainties.

Raw Materials

Raw materials essential to the Company's business are generally readily available from multiple sources. Where there are exceptions, the temporary unavailability of those raw materials would not likely have a material adverse effect on the financial results of the Company.

Patents

The Company's subsidiaries have made a practice of obtaining patent protection on their products and processes where possible. They own, or are licensed under, a significant number of patents in the U.S. and other countries relating to their products, product uses, formulations and manufacturing processes, which in the aggregate are believed to be of material importance to the Company in the operation of its businesses. The Company's subsidiaries face patent challenges from third parties, including challenges seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. Significant legal proceedings and claims involving the Company's patent and other intellectual property are described in Note 21, "Legal Proceedings—Intellectual Property" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Sales of the Company's largest product, REMICADE® (infliximab), accounted for approximately 9.7% of the Company's total revenues for fiscal 2016. Accordingly, the patents related to this product are believed to be material to the Company.

There are two sets of patents related specifically to REMICADE®. The first set of patents is co-owned by Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson, and NYU Langone Medical Center (NYU). Janssen Biotech, Inc. has an exclusive license to NYU's interests in the patents. These patents have expired in all countries outside the United States. In the United States, the one remaining patent, which expires in September 2018, stands rejected following

reexamination proceedings instituted by a third party in the United States Patent and Trademark Office (USPTO). The patent has also been held invalid by the Federal District Court in the District of Massachusetts. The decisions by the USPTO and the Federal District Court have been appealed to the U.S. Court of Appeals for the Federal Circuit. The appeals are pending.

The second set of patents specifically related to REMICADE® was granted to The Kennedy Institute of Rheumatology in Europe, Canada, Australia and the United States. Janssen Biotech, Inc. has licenses (exclusive for human anti-TNF antibodies and semi-exclusive for non-human anti-TNF antibodies) to these patents, which expire in 2017 outside of the United States and 2018 in the United States. Certain of these patents have been successfully challenged and invalidated, and others are under review in various patent offices around the world and are also subject to litigation in Canada.

The Company does not expect that any extensions will be available for the above described patents specifically related to REMICADE®. In 2016, a third party received approval from the Food and Drug Administration for sale of its infliximab biosimilar in the United States and introduced its biosimilar to the U.S. market in late 2016. For a more extensive description of legal matters regarding the patents related to REMICADE®, see Note 21 "Legal Proceedings – Intellectual Property – Pharmaceutical – REMICADE® Related Cases" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

In addition to competing in the immunology market with REMICADE®, the Company is currently marketing STELARA® (ustekinumab), SIMPONI® (golimumab) and SIMPONI ARIA® (golimumab), next generation immunology products with remaining patent lives of up to seven years.

Trademarks

The Company's subsidiaries have made a practice of selling their products under trademarks and of obtaining protection for these trademarks by all available means. These trademarks are protected by registration in the U.S. and other countries where such products are marketed. The Company considers these trademarks in the aggregate to be of material importance in the operation of its businesses.

Seasonality

Worldwide sales do not reflect any significant degree of seasonality; however, spending has been heavier in the fourth quarter of each year than in other quarters. This reflects increased spending decisions, principally for advertising and research and development activity.

Competition

In all of their product lines, the Company's subsidiaries compete with companies both locally and globally. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, both internally and externally sourced, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products, as well as protecting the underlying intellectual property of the Company's product portfolio, is important to the Company's success in all areas of its business. The competitive environment requires substantial investments in continuing research. In addition, the development and maintenance of customer demand for the Company's consumer products involve significant expenditures for advertising and promotion.

Research and Development

Research activities represent a significant part of the Company's businesses. Research and development expenditures relate to the processes of discovering, testing and developing new products, improving existing products, as well as demonstrating product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products. Worldwide costs of research and development activities amounted to $9.1 billion, $9.0 billion and $8.5 billion for fiscal years 2016, 2015 and 2014, respectively. Research facilities are located in the United States, Belgium, Brazil, Canada, China, France, Germany, India, Israel, Japan, the Netherlands, Singapore, Switzerland and the United Kingdom.

Environment

The Company is subject to a variety of U.S. and international environmental protection measures. The Company believes that its operations comply in all material respects with applicable environmental laws and regulations. The Company's compliance with these requirements did not change during the past year, and is not expected to have a material effect upon its capital expenditures, cash flows, earnings or competitive position.

Regulation

The Company's businesses are subject to varying degrees of governmental regulation in the countries in which operations are conducted, and the general trend is toward increasingly stringent regulation. In the U.S., the drug, device and cosmetic industries have long been subject to regulation by various federal and state agencies, primarily as to product safety, efficacy, manufacturing, advertising, labeling and safety reporting. The exercise of broad regulatory powers by the U.S. Food and Drug Administration (the "FDA") continues to result in increases in the amounts of testing and documentation required for FDA approval of new drugs and devices and a corresponding increase in the expense of product introduction. Similar trends are also evident in major markets outside of the U.S.

The costs of human health care have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. In the U.S., attention has been focused on drug prices and profits and programs that encourage doctors to write prescriptions for particular drugs, or to recommend, use or purchase particular medical devices. Payers have become a more potent force in the market place and increased attention is being paid to drug and medical device pricing, appropriate drug and medical device utilization and the quality and costs of health care generally.

U.S. government agencies continue to implement the extensive requirements of the Patient Protection and Affordable Care Act (the "ACA"). These have both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of the ACA, and potential modification or repeal of ACA provisions, will ultimately affect the industry.

The regulatory agencies under whose purview the Company operates have administrative powers that may subject it to actions such as product withdrawals, recalls, seizure of products and other civil and criminal sanctions. In some cases, the Company's subsidiaries may deem it advisable to initiate product recalls.

In addition, business practices in the health care industry have come under increased scrutiny, particularly in the United States, by government agencies and state attorneys general, and resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Further, the Company relies on global supply chains, and production and distribution processes, that are complex, are subject to increasing regulatory requirements that may affect sourcing, supply and pricing of materials used in the Company's products. These processes also are subject to lengthy regulatory approvals.

Available Information

The Company's main corporate website address is *www.jnj.com.* Copies of the Company's Quarterly Reports on Form 10-Q, Annual Report on Form 10-K and Current Reports on Form 8-K filed or furnished to the U.S. Securities and Exchange Commission (the "SEC"), and any amendments to the foregoing, will be provided without charge to any shareholder submitting a written request to the Secretary at the principal executive offices of the Company or by calling 1-800-950-5089. All of the Company's SEC filings are also available on the Company's website at *www.investor.jnj.com/sec.cfm*, as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*. In addition, the written charters of the Audit Committee, the Compensation & Benefits Committee, the Nominating & Corporate Governance Committee, the Regulatory, Compliance & Government Affairs Committee and the Science, Technology & Sustainability Committee of the Board of Directors and the Company's Principles of Corporate Governance, Code of Business Conduct (for employees), Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers, and other corporate governance materials, are available at *www.investor.jnj.com/gov.cfm* on the Company's website and will be provided without charge to any shareholder submitting a written request, as provided above. The information on the Company's website is not, and will not be deemed, a part of this Report or incorporated into any other filings the Company makes with the SEC.

Item 1A. RISK FACTORS

The Company faces a number of uncertainties and risks that are difficult to predict and many of which are outside of the Company's control. In addition to the other information in this report and the Company's other filings with the SEC, investors should consider carefully the factors set forth below. Investors should be aware that it is not possible to predict or identify all such factors and that the following is not meant to be a complete discussion of all potential risks or uncertainties. If known or unknown risks or uncertainties materialize, the Company's business, results of operations or financial condition could be adversely affected, potentially in a material way.

One of the Company's key products, REMICADE® (infliximab), is experiencing biosimilar competition, which will result in a reduction in U.S. sales of REMICADE®.

The Company has experienced significant challenges to patents covering its largest product, REMICADE® (infliximab) (accounting for approximately 9.7% of the Company's total revenues for fiscal 2016), and continues to assert certain patents related to the product. In April 2016, the FDA approved for sale in the United States an infliximab biosimilar to be marketed by a subsidiary of Pfizer Inc. In October 2016, the notice of launch period under the U.S. Biologics Price Competition and Innovation Act (the BPCIA) passed and in November 2016 Pfizer began shipment of an infliximab biosimilar to wholesalers in the United States. Sales of an infliximab biosimilar in the U.S. market will result in a reduction in U.S. sales of REMICADE®.

Global sales in the Company's pharmaceutical and medical devices segments may be negatively impacted by healthcare reforms and increasing pricing pressures.

Sales of the Company's pharmaceutical and medical device products are significantly affected by reimbursements by third-party payers such as government healthcare programs, private insurance plans and managed care organizations. As part of various efforts to contain healthcare costs, these payers are putting downward pressure on prices at which products will be reimbursed. In the United States, increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, in part due to continued consolidation among health care providers, could result in further pricing pressures. Outside the United States, numerous major markets, including the EU and Japan, have pervasive government involvement in funding healthcare and, in that regard, directly or indirectly impose price controls, limit access to, or reimbursement for, the Company's products, or reduce the value of its intellectual property protection.

The Company is subject to significant legal proceedings that can result in significant expenses, fines and reputational damage.

In the ordinary course of business, Johnson & Johnson and its subsidiaries are subject to numerous claims and lawsuits involving various issues such as patent disputes, product liability and claims that their product sales, marketing and pricing practices violate various antitrust, unfair trade practices and/or consumer protection laws. The most significant of these proceedings are described in Note 21, "Legal Proceedings" under Notes to the Consolidated Financial Statements included in Item 8 of this Report. While the Company believes it has substantial defenses in these matters, it is not feasible to predict the ultimate outcome of litigation. The Company could in the future be required to pay significant amounts as a result of settlements or judgments in these matters, potentially in excess of accruals. The resolution of, or increase in accruals for, one or more of these matters in any reporting period could have a material adverse effect on the Company's results of operations and cash flows for that period. Furthermore, as a result of cost and availability factors, effective November 1, 2005, the Company ceased purchasing third-party product liability insurance.

Product reliability, safety and effectiveness concerns can have significant negative impacts on sales and results of operations, lead to litigation and cause reputational damage.

Concerns about product safety, whether raised internally or by regulators or consumer advocates, and whether or not based on scientific evidence, can result in safety alerts, product recalls, governmental investigations, regulatory action on the part of the FDA (or its counterpart in other countries), private claims and lawsuits, payment of fines and settlements, declining sales and reputational damage. These circumstances can also result in damage to brand image, brand equity and consumer trust in the Company's products. Product recalls have in the past, and could in the future, prompt government investigations and inspections, the shutdown of manufacturing facilities, continued product shortages and related sales declines, significant remediation costs, reputational damage, possible civil penalties and criminal prosecution.

Changes in tax laws or exposures to additional tax liabilities could negatively impact the Company's operating results.

Changes in tax laws or regulations, including tax reform proposals in the U.S., Belgium and Switzerland, could negatively impact the Company's effective tax rate and results of operations. A change in statutory tax rate may result in the revaluation of the Company's deferred tax assets and liabilities related to the relevant jurisdiction in the period in which the new tax law is enacted, potentially resulting in a material expense or benefit recorded to the Company's Consolidated Statement of Earnings for that period. For a discussion of risks of changes in tax rates in other countries, including Belgium, please see "Management's Discussion and Analysis of Results of Operations and Financial Condition—Other Information—Economic and Market Factors" in Item 7 of this Report.

The Company conducts business and files tax returns in numerous countries and currently has tax audits in progress with many tax authorities. In connection with the Organization for Economic Cooperation and Development Base Erosion and Profit Shifting (BEPS) project, starting in 2017, companies are required to disclose more information to tax authorities on operations around the world, which may lead to greater audit scrutiny of profits earned in other countries. The Company regularly assesses the likely outcomes of its tax audits to determine the appropriateness of its tax reserves. However, any tax authority

could take a position on tax treatment that is contrary to the Company's expectations, which could result in tax liabilities in excess of reserves.

The Company may not be able to successfully secure and defend intellectual property rights essential to the Company's businesses.

The Company owns or licenses a significant number of patents and other proprietary rights, determined by patent offices, courts and lawmakers in various countries, relating to its products and manufacturing processes. These rights are essential to the Company's businesses and materially important to the Company's results of operations. Public policy, both within and outside the U.S., has become increasingly unfavorable toward intellectual property rights. The Company cannot be certain that it will obtain adequate patent protection for new products and technologies in the U.S. and other important markets or that such protections, once granted, will last as long as originally anticipated.

Competitors routinely challenge the validity or extent of the Company's owned or licensed patents and proprietary rights through litigation, interferences, oppositions and other proceedings. These proceedings absorb resources and can be protracted as well as unpredictable. In addition, challenges that the Company's products infringe the patents of third parties could result in the need to pay past damages and future royalties and adversely affect the competitive position and sales of the products in question.

The Company has faced increasing patent challenges from third parties seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the United States, manufacturers of generic versions of innovative human pharmaceutical products may challenge the validity, or claim non-infringement, of innovator products through the Abbreviated New Drug Application, or ANDA, process with the FDA. The BPCIA, enacted in 2010, which created a new regulatory pathway for the approval by the FDA of biosimilar alternatives to innovator-developed biological products, also created mechanisms for biosimilar applicants to challenge the patents on the innovator biologics. The inter partes review (IPR) process with the USPTO, created under the 2011 America Invents Act, is also being used by competitors to challenge patents held by the Company's subsidiaries. For example, a key patent for ZYTIGA® is currently subject to patent litigation and several IPR proceedings brought by generic companies seeking to invalidate the patent.

In the event the Company is not successful in defending its patents against such challenges, or upon the "at-risk" launch (despite pending patent infringement litigation) by the generic or biosimilar firm of its product, the Company can lose a major portion of revenues for the referenced product in a very short period of time. Current legal proceedings involving the Company's patents and other intellectual property rights are described in Note 21, "Legal Proceedings—Intellectual Property" of the Notes to the Consolidated Financial Statements included in Item 8 of this Report.

The Company's businesses operate in highly competitive product markets and competitive pressures could adversely affect the Company's earnings.

The Company faces substantial competition in all three operating segments and in all geographic markets. The Company's businesses compete with companies of all sizes on the basis of cost-effectiveness, technological innovations, intellectual property rights, product performance, real or perceived product advantages, pricing and availability and rate of reimbursement. The Company also competes with other market participants in securing rights to acquisitions, collaborations and licensing agreements with third parties. Competition for rights to product candidates and technologies may result in significant investment and acquisition costs and onerous agreement terms for the Company. Competitors' development of more effective or less costly products, and/or their ability to secure patent and other intellectual property rights and successfully market products ahead of us, could negatively impact sales of the Company's existing products as well as its ability to bring new products to market despite significant prior investment in the related product development.

For the Company's pharmaceutical businesses, loss of patent exclusivity for a product often is followed by a substantial reduction in sales as competitors gain regulatory approval for generic and other competing products and enter the market. Similar competition can be triggered by the loss of exclusivity for a biological product. For the Company's medical device businesses, technological innovation, product quality, reputation and customer service are especially important to competitiveness. Development by other companies of new or improved products, processes and technologies could threaten to make the Company's products or technologies less desirable, less economical or obsolete. The Company's consumer businesses face intense competition from other branded products and retailers' private-label brands. If the Company fails to sufficiently differentiate and market its brand name consumer products, this could adversely affect revenues and profitability of those products.

Significant challenges or delays in the Company's innovation and development of new products, technologies and indications could have an adverse impact on the Company's long-term success.

The Company's continued growth and success depends on its ability to innovate and develop new and differentiated products and services that address the evolving health care needs of patients, providers and consumers. Development of successful products and technologies is also necessary to offset revenue losses when the Company's existing products lose market share due to various factors such as competition and loss of patent exclusivity. New products introduced within the past five years accounted for approximately 22% of 2016 sales. The Company cannot be certain when or whether it will be able to develop, license or otherwise acquire companies, products and technologies, whether particular product candidates will be granted regulatory approval, and, if approved, whether the products will be commercially successful.

The Company pursues product development through internal research and development as well as through collaborations, acquisitions, joint ventures and licensing or other arrangements with third parties. In all of these contexts, developing new products, particularly pharmaceutical and biotechnology products and medical devices, requires significant investment of resources over many years. Only a very few biopharmaceutical research and development programs result in commercially viable products. The process depends on many factors including the ability to discern patients' and health care providers' future needs; develop promising new compounds, strategies and technologies; achieve successful clinical trial results; secure effective intellectual property protection; obtain regulatory approvals on a timely basis; and, if and when they reach the market, successfully differentiate the Company's products from competing products and approaches to treatment. New products or enhancements to existing products may not be accepted quickly or significantly in the marketplace due to product and price competition, changes in customer preferences or healthcare purchasing patterns, resistance by healthcare providers or uncertainty over third-party reimbursement. Even following initial regulatory approval, the success of a product can be adversely impacted by safety and efficacy findings in larger real world patient populations, as well as market entry of competitive products.

The Company faces increasing regulatory scrutiny which imposes significant compliance costs and exposes the Company to government investigations, legal actions and penalties.

Like other companies in the healthcare industry, the Company is subject to extensive regulation, investigations and legal action, by national, state and local government agencies in the United States and other countries in which they operate. Regulatory issues regarding compliance with Good Manufacturing Practices (cGMP) (and comparable quality regulations in foreign countries) by manufacturers of drugs, devices and consumer products can lead to fines and penalties, product recalls, product shortages, interruptions in production, delays in new product approvals and litigation. In addition, the marketing, pricing and sale of the Company's products are subject to regulation, investigations and legal actions including under the Federal Food, Drug, and Cosmetic Act, the Medicaid Rebate Program, federal and state false claims acts, state unfair trade practices acts and consumer protection laws. Increased scrutiny of health care industry business practices in recent years by government agencies and state attorneys general in the U.S., and any resulting investigations and prosecutions, carry risk of significant civil and criminal penalties including, but not limited to, debarment from participation in government healthcare programs. Any such debarment could have a material adverse effect on the Company's business and results of operations. The most significant current investigations and litigation brought by government agencies are described in Note 21, "Legal Proceedings-Government Proceedings" under Notes to the Consolidated Financial Statements included in Item 8 of this Report.

The Company faces a variety of risks associated with conducting business internationally.

The Company's extensive operations and business activity outside the U.S. are accompanied by certain financial, economic and political risks, including those listed below.

Foreign Currency Exchange: In fiscal 2016, approximately 47% of the Company's sales occurred outside of the U.S., with approximately 22% in Europe, 8% in the Western Hemisphere, excluding the U.S., and 17% in the Asia-Pacific and Africa region. Changes in non-U.S. currencies relative to the U.S. dollar impact the Company's revenues and expenses. While the Company uses financial instruments to mitigate the impact of fluctuations in currency exchange rates on its cash flows, unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the U.S. dollar may result in significant favorable or unfavorable translation effects when the operating results of the Company's non-U.S. business activity are translated into U.S. dollars.

Inflation and Currency Devaluation Risks: The Company faces challenges in maintaining profitability of operations in economies experiencing high inflation rates. The Company has accounted for operations in Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. While the Company strives to maintain profit margins in these areas through cost reduction programs, productivity improvements and periodic price increases, it might experience operating losses as a result of continued inflation. In addition, the impact of currency devaluations in countries experiencing high inflation rates or significant currency exchange fluctuations could negatively impact the Company's operating results.

Illegal Importation of Pharmaceutical Products: The illegal importation of pharmaceutical products from countries where government price controls or other market dynamics result in lower prices may adversely affect the Company's sales and profitability in the U.S. and other countries in which the Company operates. With the exception of limited quantities of prescription drugs for personal use, foreign imports of pharmaceutical products are illegal under current U.S. law. However, the volume of illegal imports continues to rise as the ability of patients and other customers to obtain the lower-priced imports has grown significantly.

Anti-Bribery and Other Regulations: The Company is subject to various federal and foreign laws that govern its international business practices with respect to payments to government officials. Those laws include the U.S. Foreign Corrupt Practices Act (FCPA), which prohibits U.S. publicly traded companies, from promising, offering, or giving anything of value to foreign officials with the corrupt intent of influencing the foreign official for the purpose of helping the Company obtain or retain business or gain any improper advantage. The Company's business is heavily regulated and therefore involves significant interaction with foreign officials. Also, in many countries outside the U.S., the health care providers who prescribe human pharmaceuticals are employed by the government and the purchasers of human pharmaceuticals are government entities; therefore, the Company's interactions with these prescribers and purchasers are subject to regulation under the FCPA. In addition to the U.S. application and enforcement of the FCPA, various jurisdictions in which the Company operates have laws and regulations, including the U.K Bribery Act 2010, aimed at preventing and penalizing corrupt and anticompetitive behavior. Enforcement activities under these laws could subject the Company to additional administrative and legal proceedings and actions, which could include claims for civil penalties, criminal sanctions, and administrative remedies, including exclusion from health care programs.

Other Legal, Social and Political Risks. Other risks inherent in conducting business globally include:

- protective economic policies taken by governments such as trade protection measures and import/export licensing requirements;
- compliance with local regulations and laws including, in some countries, regulatory requirements restricting the Company's ability to manufacture or sell its products in the relevant market;
- diminished protection of intellectual property and contractual rights in certain jurisdictions;
- potential nationalization or expropriation of the Company's foreign assets; and
- disruptions to markets due to war, armed conflict, terrorism, social upheavals or pandemics.

Interruptions and delays in manufacturing operations could adversely affect the Company's business, sales and reputation.

The Company's manufacture of products requires the timely delivery of sufficient amounts of complex, high-quality components and materials. These subsidiaries operate 119 manufacturing facilities as well as sourcing from hundreds of suppliers around the world. The Company has in the past, and may in the future, face unanticipated interruptions and delays in manufacturing through its internal or external supply chain. Manufacturing disruptions can occur for many reasons including regulatory action, production quality deviations or safety issues, labor disputes, site-specific incidents (such as fires), natural disasters, raw material shortages, political unrest and terrorist attacks. Such delays and difficulties in manufacturing can result in product shortages, declines in sales and reputational impact as well as significant remediation and related costs associated with addressing the shortage.

An information security incident, including a cybersecurity breach, could have a negative impact to the Company's business or reputation

To meet business objectives, the Company relies on both internal information technology (IT) systems and networks, and those of third parties and their vendors, to process and store sensitive data, including confidential research, business plans, financial information, intellectual property, and personal data. The extensive information security and cybersecurity threats, which affect companies globally, pose a risk to the security and availability of these IT systems and networks, and the confidentiality, integrity, and availability of the Company's sensitive data. The Company continually assesses these threats and makes investments to increase internal protection, detection, and response capabilities, as well as ensure the Company's third party providers have required capabilities and controls, to address this risk. To date, the Company has not experienced any material impact to our business or operations resulting from information or cybersecurity attacks; however, because of the frequently changing attack techniques, along with the increased volume and sophistication of the attacks, there is the potential for the Company to be adversely impacted. This impact could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

The Company's subsidiaries operate 119 manufacturing facilities occupying approximately 21.5 million square feet of floor space. The manufacturing facilities are used by the industry segments of the Company's business approximately as follows:

Segment	Square Feet (in thousands)
Consumer	6,928
Pharmaceutical	7,463
Medical Devices	7,087
Worldwide Total	21,478

Within the United States, seven facilities are used by the Consumer segment, seven by the Pharmaceutical segment and 21 by the Medical Devices segment. Outside of the United States, 30 facilities are used by the Consumer segment, 17 by the Pharmaceutical segment and 37 by the Medical Devices segment.

The locations of the manufacturing facilities by major geographic areas of the world are as follows:

Geographic Area	Number of Facilities	Square Feet (in thousands)
United States	35	6,015
Europe	37	7,770
Western Hemisphere, excluding U.S.	14	2,862
Africa, Asia and Pacific	33	4,831
Worldwide Total	119	21,478

In addition to the manufacturing facilities discussed above, the Company maintains numerous office and warehouse facilities throughout the world. Research facilities are also discussed in Item 1 of this Report under "Business – Research and Development."

The Company's subsidiaries generally seek to own their manufacturing facilities, although some, principally in non-U.S. locations, are leased. Office and warehouse facilities are often leased. The Company also engages contract manufacturers.

The Company is committed to maintaining all of its properties in good operating condition and repair, and the facilities are well utilized.

McNEIL-PPC, Inc. (now Johnson & Johnson Consumer Inc.) (McNEIL-PPC) continues to operate under a consent decree, signed in 2011 with the FDA, which governs certain McNeil Consumer Healthcare manufacturing operations, and requires McNEIL-PPC to remediate the facilities it operates in Lancaster, Pennsylvania, Fort Washington, Pennsylvania, and Las Piedras, Puerto Rico (the "Consent Decree"). The Fort Washington facility was voluntarily shut down in April 2010, and subsequently many products were transferred to other manufacturing sites and successfully reintroduced to the market. After McNEIL-PPC successfully completed all requirements contained in the Consent Decree Workplans for the Lancaster and Las Piedras manufacturing sites and completed the steps required for third-party certification of the Fort Washington plant, a third-party cGMP expert submitted written certifications to the FDA for all three manufacturing sites. Following FDA inspections in 2015, McNEIL-PPC received notifications from the FDA that all three manufacturing facilities are in conformity with applicable laws and regulations. Commercial production in Fort Washington started as of September 2015.

Under the Consent Decree, after receiving notice from the FDA of being in compliance with applicable laws and regulations, each of the three facilities is subject to a five-year audit period by a third-party cGMP expert. Thus, a third-party expert will continue to reassess the sites at various times for at least five years. A discussion of legal proceedings related to this matter can be found in Note 21 "Legal Proceedings – Government Proceedings – McNeil Consumer Healthcare" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

For information regarding lease obligations, see Note 16 "Rental Expense and Lease Commitments" of the Notes to Consolidated Financial Statements included in Item 8 of this Report. Segment information on additions to property, plant and equipment is contained in Note 18 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 3. LEGAL PROCEEDINGS

The information called for by this item is incorporated herein by reference to the information set forth in Note 21 "Legal Proceedings" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

In addition, Johnson & Johnson and its subsidiaries are from time to time party to government investigations, inspections or other proceedings relating to environmental matters, including their compliance with applicable environmental laws.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

EXECUTIVE OFFICERS OF THE REGISTRANT

Listed below are the executive officers of the Company. There are no family relationships between any of the executive officers, and there is no arrangement or understanding between any executive officer and any other person pursuant to which the executive officer was selected. At the annual meeting of the Board of Directors, the executive officers are elected by the Board to hold office for one year and until their respective successors are elected and qualified, or until earlier resignation or removal.

Information with regard to the directors of the Company, including information for Alex Gorsky, is incorporated herein by reference to the material captioned "Item 1. Election of Directors" in the Proxy Statement.

Name	Age	Position
Dominic J. Caruso	59	Member, Executive Committee; Executive Vice President; Chief Financial Officer(a)
Joaquin Duato	54	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Pharmaceuticals(b)
Peter M. Fasolo	54	Member, Executive Committee; Executive Vice President, Chief Human Resources Officer(c)
Alex Gorsky	56	Chairman, Board of Directors; Chairman, Executive Committee; Chief Executive Officer
Jorge Mesquita	55	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Consumer(d)
Sandra E. Peterson	58	Member, Executive Committee; Executive Vice President, Group Worldwide Chairman(e)
Gary Pruden	55	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Medical Devices(f)
Paulus Stoffels	55	Member, Executive Committee; Executive Vice President, Chief Scientific Officer(g)
Michael H. Ullmann	58	Member, Executive Committee; Executive Vice President, General Counsel(h)

(a) Mr. D. J. Caruso joined the Company in 1999 when the Company acquired Centocor, Inc. At the time of that acquisition, he had been Senior Vice President, Finance of Centocor. Mr. Caruso was named Vice President, Finance of Ortho-McNeil Pharmaceutical, Inc., a subsidiary of the Company, in 2001 and Vice President, Group Finance of the Company's Medical Devices and Diagnostics Group in 2003. In 2005, Mr. Caruso was named Vice President of the Company's Group Finance organization. Mr. Caruso became a member of the Executive Committee and Vice President, Finance and Chief Financial Officer in 2007. In April 2016, he was named Executive Vice President, Chief Financial Officer.

(b) Mr. J. Duato joined the Company in 1989 with Janssen-Farmaceutica S.A. (Spain) and in 1997 became Managing Director of Janssen-Cilag S.p.A. (Italy). In 2000, he led Ortho Biotech Europe before relocating to the United States in 2002 to serve as Vice President, and, in 2005, President of Ortho Biotech Inc. In 2008, he was named Company Group Chairman, Ortho-Clinical Diagnostics, and in 2009 Company Group Chairman, Pharmaceuticals, where he oversaw

pharmaceutical product launches and the major therapeutic franchises in Canada, the United States and Latin America. In 2011, he was named Worldwide Chairman, Pharmaceuticals, responsible for the global commercial businesses of the Janssen Pharmaceutical Companies, including functional support for the research & development organizations. In April 2016. Mr. Duato became a member of the Executive Committee and was named Executive Vice President, Worldwide Chairman, Pharmaceuticals.

(c) Dr. P. M. Fasolo joined the Company in 2004 as Vice President, Worldwide Human Resources for Cordis Corporation, a subsidiary of the Company. He was then named Vice President, Global Talent Management for the Company. He left Johnson & Johnson in 2007 to join Kohlberg Kravis Roberts & Co., as Chief Talent Officer. Dr. Fasolo returned to the Company in 2010 as the Vice President, Global Human Resources, and in 2011, he became a member of the Executive Committee. In April 2016, he was named Executive Vice President, Chief Human Resources Officer.

(d) Mr. J. Mesquita joined the Company in 2014 as Worldwide Chairman, Consumer. Prior to joining the Company, he served in various marketing and leadership capacities across Latin America, including roles in Oral Care and Beauty, at The Procter & Gamble Company from 1984 to 2013. In April 2016, Mr. Mesquita became a member of the Executive Committee and was named as Executive Vice President, Worldwide Chairman, Consumer.

(e) Ms. S. E. Peterson joined the Company in 2012 as Group Worldwide Chairman and a member of the Executive Committee. She oversees the Consumer and Consumer Medical Device businesses; the Company's operating infrastructure — Supply Chain, Information Technology, Global Services; Health & Wellness; Global Design; and Health Technology. Prior to joining the Company, Ms. Peterson was Chairman and Chief Executive Officer of Bayer CropScience AG in Germany, previously serving as President and Chief Executive Officer of Bayer Medical Care and President of Bayer HealthCare AG's Diabetes Care Division. Before joining Bayer in 2005, Ms. Peterson held a number of leadership roles at Medco Health Solutions (previously known as Merck-Medco). In April 2016. Ms. Peterson was named Executive Vice President, Group Worldwide Chairman of Johnson & Johnson. Effective June 1, 2017, Ms. Peterson will assume leadership of the Hospital Medical Device business, in addition to her current responsibilities.

(f) Mr. G. Pruden joined the Company in 1985 with Janssen Pharmaceutica.Inc. and held a number of senior positions in sales, marketing, and strategic account management. In April 2004, he became President of Janssen-Ortho Inc. in Canada. In January 2006, Mr. Pruden was appointed Worldwide President, Ethicon Products, and in 2009 became Company Group Chairman, Ethicon. In 2012, he was named Worldwide Chairman, Global Surgery Group, and in 2015, Worldwide Chairman, Medical Devices. In April 2016. Mr. Pruden became a member of the Executive Committee and was named Executive Vice President, Worldwide Chairman, Medical Devices. Mr. Pruden has announced his intention to retire from the Company effective June 1, 2017.

(g) Dr. P. Stoffels joined the Company in 2002 with the acquisition of Tibotec Virco NV, where he was Chief Executive Officer of Virco NV and Chairman of Tibotec NV. In 2005, he was appointed Company Group Chairman, Global Virology. In 2006, he assumed the role of Company Group Chairman, Pharmaceuticals, with responsibility for worldwide research and development for the Central Nervous System and Internal Medicine Franchises. Dr. Stoffels was appointed Global Head, Research & Development, Pharmaceuticals in 2009, and in 2011, became Worldwide Chairman, Pharmaceuticals, with responsibility for the Company's therapeutic pipeline through global research and development and strategic business development. In 2012, Dr. Stoffels was also appointed Chief Scientific Officer, with responsibility for enterprise-wide innovation and product safety, and a member of the Executive Committee. In April 2016. Dr. Stoffels was named Executive Vice President, Chief Scientific Officer.

(h) Mr. M. H. Ullmann joined the Company in 1989 as a corporate attorney in the Law Department. He was appointed Corporate Secretary in 1999 and served in that role until 2006. During that time, he also held various management positions in the Law Department. In 2006, he was named General Counsel, Medical Devices and Diagnostics and was appointed Vice President, General Counsel and a member of the Executive Committee in 2012. In April 2016, Mr. Ullmann was named Executive Vice President, General Counsel.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

As of February 17, 2017, there were 156,073 record holders of common stock of the Company. Additional information called for by this item is incorporated herein by reference to the following sections of this Report: "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition – Liquidity and Capital Resources – Dividends" and "— Other Information — Common Stock Market Prices"; Note 17 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements included in Item 8; and Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters – Equity Compensation Plan Information".

Issuer Purchases of Equity Securities

On October 13, 2015, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $10.0 billion of the Company's Common Stock. Share repurchases take place on the open market from time to time based on market conditions. The repurchase program has no time limit and may be delayed or suspended for periods or discontinued at any time.

The following table provides information with respect to common stock purchases by the Company during the fiscal fourth quarter of 2016. Common stock purchases on the open market are made as part of a systematic plan to meet the needs of the Company's compensation programs. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal fourth quarter.

Period	Total Number of Shares Purchased[1]	Avg. Price Paid Per Share	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs[2]	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs[3]
October 3, 2016 through October 30, 2016	2,485,016	$ 116.76	-	-
October 31, 2016 through November 27, 2016	9,324,574	116.53	8,775,704	-
November 28, 2016 through January 1, 2017	5,739,190	113.35	3,400,003	-
Total	17,548,780		12,175,707	23,543,007

(1) During the fiscal fourth quarter of 2016, the Company repurchased an aggregate of 17,548,780 shares of Johnson & Johnson Common Stock in open-market transactions, of which 12,175,707 shares were purchased pursuant to the repurchase program that was publicly announced on October 13, 2015, and of which 5,373,073 shares were purchased in open-market transactions as part of a systematic plan to meet the needs of the Company's compensation programs.

(2) As of January 1, 2017, an aggregate of 65,362,675 shares were purchased for a total of $7.3 billion since the inception of the repurchase program announced on October 13, 2015.

(3) As of January 1, 2017, the maximum number of shares that may yet be purchased under the plan is 23,543,007 based on the closing price of Johnson & Johnson Common Stock on the New York Stock Exchange on December 30, 2016 of $115.21 per share.

Item 6. SELECTED FINANCIAL DATA

Summary of Operations and Statistical Data 2006-2016

(Dollars in Millions Except Per Share Amounts)	2016	2015	2014	2013	2012	2011	2010	2009	2008	2007	2006
Sales to customers — U.S.	$37,811	35,687	34,782	31,910	29,830	28,908	29,450	30,889	32,309	32,444	29,775
Sales to customers — International	34,079	34,387	39,549	39,402	37,394	36,122	32,137	31,008	31,438	28,651	23,549
Total sales	71,890	70,074	74,331	71,312	67,224	65,030	61,587	61,897	63,747	61,095	53,324
Cost of products sold	21,685	21,536	22,746	22,342	21,658	20,360	18,792	18,447	18,511	17,751	15,057
Selling, marketing and administrative expenses	19,945	21,203	21,954	21,830	20,869	20,969	19,424	19,801	21,490	20,451	17,433
Research and development expense	9,095	9,046	8,494	8,183	7,665	7,548	6,844	6,986	7,577	7,680	7,125
In-process research and development	29	224	178	580	1,163	—	—	—	181	807	559
Interest income	(368)	(128)	(67)	(74)	(64)	(91)	(107)	(90)	(361)	(452)	(829)
Interest expense, net of portion capitalized	726	552	533	482	532	571	455	451	435	296	63
Other (income) expense, net	484	(2,064)	(70)	2,498	1,626	2,743	(768)	(526)	(1,015)	534	(671)
Restructuring	491	509	—	—	—	569	—	1,073	—	745	—
	52,087	50,878	53,768	55,841	53,449	52,669	44,640	46,142	46,818	47,812	38,737
Earnings before provision for taxes on income	$19,803	19,196	20,563	15,471	13,775	12,361	16,947	15,755	16,929	13,283	14,587
Provision for taxes on income	3,263	3,787	4,240	1,640	3,261	2,689	3,613	3,489	3,980	2,707	3,534
Net earnings	16,540	15,409	16,323	13,831	10,514	9,672	13,334	12,266	12,949	10,576	11,053
Add: Net loss attributable to noncontrolling interest	—	—	—	—	339	—	—	—	—	—	—
Net earnings attributable to Johnson & Johnson	16,540	15,409	16,323	13,831	10,853	9,672	13,334	12,266	12,949	10,576	11,053
Percent of sales to customers	23.0%	22.0	22.0	19.4	16.1	14.9	21.7	19.8	20.3	17.3	20.7
Diluted net earnings per share of common stock [1]	$5.93	5.48	5.70	4.81	3.86	3.49	4.78	4.40	4.57	3.63	3.73
Percent return on average shareholders' equity	23.4%	21.9	22.7	19.9	17.8	17.0	24.9	26.4	30.2	25.6	28.3
Percent increase (decrease) over previous year:											
Sales to customers	2.6%	(5.7)	4.2	6.1	3.4	5.6	(0.5)	(2.9)	4.3	14.6	5.6
Diluted net earnings per share	8.2%	(3.9)	18.5	24.6	10.6	(27.0)	8.6	(3.7)	25.9	(2.7)	11.3
Supplementary balance sheet data:											
Property, plant and equipment, net	15,912	15,905	16,126	16,710	16,097	14,739	14,553	14,759	14,365	14,185	13,044
Additions to property, plant and equipment	3,226	3,463	3,714	3,595	2,934	2,893	2,384	2,365	3,066	2,942	2,666
Total assets	141,208	133,411	130,358	131,754	121,347	113,644	102,908	94,682	84,912	80,954	70,556
Long-term debt	22,442	12,857	15,122	13,328	11,489	12,969	9,156	8,223	8,120	7,074	2,014
Operating cash flow[2]	18,767	19,569	18,710	17,414	15,396	14,298	16,385	16,571	14,972	15,022	14,248
Common stock information											
Dividends paid per share	$3.15	2.95	2.76	2.59	2.40	2.25	2.11	1.93	1.795	1.62	1.455
Shareholders' equity per share	26.02	25.82	25.06	26.25	23.33	20.95	20.66	18.37	15.35	15.25	13.59
Market price per share (year-end close)	$115.21	102.72	105.06	92.35	69.48	65.58	61.85	64.41	58.56	67.38	66.02
Average shares outstanding (millions)											
— basic	2,737.3	2,771.8	2,815.2	2,809.2	2,753.3	2,736.0	2,751.4	2,759.5	2,802.5	2,882.9	2,936.4
— diluted	2,788.9	2,812.9	2,863.9	2,877.0	2,812.6	2,775.3	2,788.8	2,789.1	2,835.6	2,910.7	2,961.0
Employees (thousands)	126.4	127.1	126.5	128.1	127.6	117.9	114.0	115.5	118.7	119.2	122.2

[1] Attributable to Johnson & Johnson. [2] Amounts have been reclassified to conform to current year presentation.

Organization and Business Segments

Description of the Company and Business Segments

Johnson & Johnson and its subsidiaries (the Company) have approximately 126,400 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. The Consumer segment includes a broad range of products used in the baby care, oral care, beauty (previously referred to as skin care), over-the-counter pharmaceutical, women's health and wound care markets. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on five therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, and cardiovascular and metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, cardiovascular, diabetes care and vision care fields which are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Consumer, Pharmaceutical and Medical Devices business segments.

In all of its product lines, the Company competes with companies both locally and globally, throughout the world. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products, as well as protecting the underlying intellectual property of the Company's product portfolio, is important to the Company's success in all areas of its business. The competitive environment requires substantial investments in continuing research. In addition, the development and maintenance of customer demand for the Company's consumer products involves significant expenditures for advertising and promotion.

Management's Objectives

The Company manages within a strategic framework with Our Credo as the foundation. The Company believes that our strategic operating principles: being broadly based in human health care, managing the business for the long term, having a decentralized management approach, and being committed to our people and values, are crucial to successfully meeting the demands of the rapidly evolving markets in which we compete. To this end, management is focused on our long-term strategic growth drivers: creating value through innovation, expanding our global reach with a local focus, excellence in execution and leading with purpose.

The Company is broadly based in human health care, and is committed to creating value by developing accessible, high quality, innovative products and services. New products introduced within the past five years accounted for approximately 22% of 2016 sales. In 2016, $9.1 billion, or 12.7% of sales, was invested in research and development, reflecting management's commitment to delivering new and differentiated products and services to meet evolving health care needs and sustain the Company's long-term growth.

Our diverse businesses with more than 230 operating companies located in 60 countries are the key drivers of the Company's success. Maintaining the Company's decentralized management approach, while at the same time leveraging the extensive resources of the enterprise, positions the Company well to innovate, execute strategic plans and reach markets globally, as well as address the needs and challenges of the local markets.

In order to remain a leader in health care, the Company strives to maintain a purpose-driven organization and is committed to developing global business leaders who can achieve these growth objectives. Businesses are managed for the long-term in order to sustain market leadership positions and enable growth, which provides an enduring source of value to our shareholders.

Our Credo unifies all Johnson & Johnson employees in achieving these objectives, and provides a common set of values that serve as the foundation of the Company's responsibilities to patients, consumers and health care professionals, employees, communities and shareholders. The Company believes that these foundational values, its strategic framework and long-term growth drivers, along with its overall mission of improving the quality of life for people around the world, will enable Johnson & Johnson to continue to be a leader in the health care industry.

Results of Operations

Analysis of Consolidated Sales

In 2016, worldwide sales increased 2.6% to $71.9 billion, compared to a decrease of 5.7% in 2015 and an increase of 4.2% in 2014. These sales changes consisted of the following:

Sales increase/(decrease) due to:	2016	2015	2014
Volume	3.2%	1.2 %	6.3
Price	0.7	0.6	(0.2)
Currency	(1.3)	(7.5)	(1.9)
Total	**2.6%**	**(5.7)%**	**4.2**

In 2016, acquisitions and divestitures had a negative impact of 1.1% on the worldwide operational sales growth and competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a negative impact of 0.8% on the worldwide operational sales growth. Operations in Venezuela negatively impacted the worldwide operational sales growth 0.3%.

In 2015, the introduction of competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a negative impact of 2.7% on the worldwide operational sales growth. In 2015, the impact of acquisitions and divestitures on the worldwide operational sales growth was negative 2.0%.

In 2014, sales of the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a positive impact of 2.8%, and the divestiture of the Ortho-Clinical Diagnostics business had a negative impact of 1.4% on the worldwide operational growth.

Sales by U.S. companies were $37.8 billion in 2016, $35.7 billion in 2015 and $34.8 billion in 2014. This represents increases of 6.0% in 2016, 2.6% in 2015 and 9.0% in 2014. Sales by international companies were $34.1 billion in 2016, $34.4 billion in 2015 and $39.5 billion in 2014. This represents decreases of 0.9% in 2016, and 13.1% in 2015 and an increase of 0.4% in 2014.

The five-year compound annual growth rates for worldwide, U.S. and international sales were 2.0%, 5.5% and (1.2)%, respectively. The ten-year compound annual growth rates for worldwide, U.S. and international sales were 3.0%, 2.4% and 3.8%, respectively.

Sales by companies in Europe experienced a decline of 1.4% as compared to the prior year, including operational growth of 1.4%, offset by a negative currency impact of 2.8%. Sales by companies in the Western Hemisphere (excluding the U.S.) experienced a decline of 5.1% as compared to the prior year, including operational growth of 4.0% offset by a negative currency impact of 9.1%. Sales by companies in the Asia-Pacific, Africa region achieved growth of 1.8% as compared to the prior year, including operational growth of 1.4% and a positive currency impact of 0.4%.

The 2016 sales growth percentage as compared to the prior year was negatively impacted by approximately 1.3% from additional shipping days in 2015. (See Note 1 to the Consolidated Financial Statements for Annual Closing Date details). While the additional week in 2015 added a few days to sales, it also added a full week's worth of operating costs; therefore, the net earnings impact was negligible.

In 2016, the Company had two wholesalers distributing products for all three segments that represented approximately 13.5% and 10.7% of the total consolidated revenues. In 2015 and 2014, the Company had one wholesaler distributing products for all three segments that represented approximately 12.5% and 11.0%, respectively, of the total consolidated revenues.

Analysis of Sales by Business Segments

Consumer Segment

Consumer segment sales in 2016 were $13.3 billion, a decrease of 1.5% from 2015, which included 1.5% operational growth offset by a negative currency impact of 3.0%. U.S. Consumer segment sales were $5.4 billion, an increase of 3.8%. International sales were $7.9 billion, a decrease of 4.8%, which included 0.1% operational growth offset by a negative currency impact of 4.9%. In 2016, the impact of acquisitions and divestitures on the Consumer segment operational sales growth was negative 0.5%. In 2016, the Consumer segment operational sales growth was negatively impacted 1.2% by operations in Venezuela and negatively impacted by 1.1% due to additional shipping days in 2015.

Major Consumer Franchise Sales:*

				% Change	
(Dollars in Millions)	**2016**	**2015**	**2014**	**'16 vs. '15**	**'15 vs. '14**
OTC	$ 3,977	3,895	4,016	2.1 %	(3.0)
Beauty**	3,897	3,633	3,873	7.3	(6.2)
Baby Care	2,001	2,157	2,346	(7.2)	(8.1)
Oral Care	1,568	1,580	1,647	(0.8)	(4.1)
Women's Health	1,067	1,200	1,302	(11.1)	(7.8)
Wound Care/Other	797	1,042	1,312	(23.5)	(20.6)
Total Consumer Sales	**$ 13,307**	**13,507**	**14,496**	**(1.5)%**	**(6.8)**

* Prior year amounts have been reclassified to conform to current year product disclosure.
** Formerly Skin Care

The Over-the-Counter (OTC) franchise sales of $4.0 billion increased 2.1% as compared to the prior year, which included 4.8% operational growth and a negative currency impact of 2.7%. Operational growth was primarily driven by analgesics, anti-smoking aids and digestive health products.

The Beauty franchise sales of $3.9 billion increased 7.3% as compared to the prior year, which included 9.4% operational growth and a negative currency impact of 2.1%. Operational growth was primarily due to sales from the recent acquisitions of Vogue International LLC, which contributed approximately 4.6%, and NeoStrata Company, Inc., as well as sales growth of NEUTROGENA®, AVEENO® adult products and DABAO® products.

The Baby Care franchise sales were $2.0 billion in 2016, a decrease of 7.2% compared to the prior year, primarily due to competitive pressure partially offset by sales growth of AVEENO® baby products.

The Oral Care franchise sales were $1.6 billion in 2016, a decrease of 0.8% as compared to the prior year, which included 2.0% operational growth and a negative currency impact of 2.8%. Operational growth was driven by increased sales of LISTERINE® products, attributable to new product launches and successful marketing campaigns.

The Women's Health franchise sales were $1.1 billion in 2016, a decrease of 11.1% as compared to the prior year, primarily due to operations in Venezuela and the U.S. divestiture of TUCKS®.

The Wound Care/Other franchise sales were $0.8 billion in 2016, a decrease of 23.5% from 2015, primarily due to the SPLENDA® divestiture.

Consumer segment sales in 2015 were $13.5 billion, a decrease of 6.8% from 2014, which included 2.7% operational growth offset by a negative currency impact of 9.5%. U.S. Consumer segment sales were $5.2 billion, an increase of 2.5%. International sales were $8.3 billion, a decrease of 11.9%, which included 2.7% operational growth offset by a negative currency impact of 14.6%. In 2015, divestitures had a negative impact of 1.4% on the worldwide Consumer segment operational growth.

Pharmaceutical Segment
Pharmaceutical segment sales in 2016 were $33.5 billion, an increase of 6.5% from 2015, which included operational growth of 7.4% partially offset by a negative currency impact of 0.9%. U.S. sales were $20.1 billion, an increase of 9.8%. International sales were $13.3 billion, an increase of 1.8%, which included 4.0% operational growth partially offset by a negative currency impact of 2.2%. In 2016, acquisitions, divestitures and competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a negative impact of 2.5% on the operational growth of the Pharmaceutical segment. In 2016, the Pharmaceutical segment operational growth was negatively impacted by 1.5% due to additional shipping days in 2015. The Pharmaceutical segment operational growth for 2016, as compared to the prior year, was not impacted by adjustments to previous reserve estimates as both periods included approximately $0.5 billion of adjustments.

Major Pharmaceutical Therapeutic Area Sales:*

(Dollars in Millions)	2016	2015	2014	% Change '16 vs. '15	% Change '15 vs. '14
Total Immunology	**$ 11,968**	**10,402**	**10,193**	**15.1 %**	**2.1**
REMICADE®	6,966	6,561	6,868	6.2	(4.5)
SIMPONI®/SIMPONI ARIA®	1,745	1,328	1,187	31.4	11.9
STELARA®	3,232	2,474	2,072	30.6	19.4
Other Immunology	25	39	66	(35.9)	(40.9)
Total Infectious Diseases	**3,208**	**3,656**	**5,599**	**(12.3)**	**(34.7)**
EDURANT®/rilpivirine	573	410	365	39.8	12.3
OLYSIO®/SOVRIAD®	106	621	2,302	(82.9)	(73.0)
PREZISTA®/ PREZCOBIX®/REZOLSTA®	1,851	1,810	1,831	2.3	(1.1)
Other Infectious Diseases	678	815	1,101	(16.8)	(26.0)
Total Neuroscience	**6,085**	**6,259**	**6,487**	**(2.8)**	**(3.5)**
CONCERTA®/methylphenidate	863	821	599	5.1	37.1
INVEGA®/paliperidone	311	573	640	(45.7)	(10.5)
INVEGA SUSTENNA®/XEPLION®/TRINZA®	2,214	1,830	1,588	21.0	15.2
RISPERDAL® CONSTA®	893	970	1,190	(7.9)	(18.5)
Other Neuroscience	1,804	2,065	2,470	(12.6)	(16.4)
Total Oncology	**5,807**	**4,695**	**4,457**	**23.7**	**5.3**
DARZALEX®	572	20	—	**	—
IMBRUVICA®	1,251	689	200	81.6	**
VELCADE®	1,224	1,333	1,618	(8.2)	(17.6)
ZYTIGA®	2,260	2,231	2,237	1.3	(0.3)
Other Oncology	500	422	402	18.5	5.0
Cardiovascular / Metabolism / Other	**6,396**	**6,418**	**5,577**	**(0.3)**	**15.1**
XARELTO®	2,288	1,868	1,522	22.5	22.7
INVOKANA®/ INVOKAMET®	1,407	1,308	586	7.6	**
PROCRIT®/EPREX®	1,105	1,068	1,238	3.5	(13.7)
Other	1,596	2,174	2,231	(26.6)	(2.6)
Total Pharmaceutical Sales	**$ 33,464**	**31,430**	**32,313**	**6.5 %**	**(2.7)**

* Prior year amounts have been reclassified to conform to current year presentation.
** Percentage greater than 100%

Immunology products achieved sales of $12.0 billion in 2016, representing an increase of 15.1% as compared to the prior year. Immunology products growth of 15.1% included operational growth of 15.9% and a negative currency impact of 0.8%. The strong growth of REMICADE®(infliximab), STELARA® (ustekinumab) and SIMPONI®/SIMPONI ARIA® (golimumab)was primarily driven by immunology market growth and increased penetration for both STELARA® (ustekinumab) and SIMPONI®/SIMPONI ARIA® (golimumab).

The patents for REMICADE®(infliximab) in certain countries in Europe expired in February 2015. Biosimilar versions of REMICADE® have been introduced in certain markets outside the United States, resulting in a reduction in sales of REMICADE® in those markets. Additional biosimilar competition will likely result in a further reduction in REMICADE® sales in markets outside the United States. The introduction of a biosimilar version of REMICADE® in the United States is subject to enforcement of patent rights, approval by the U.S. Food and Drug Administration (FDA) and compliance with the 180-day notice provisions of the Biologics Price Competition and Innovation Act (the BPCIA). In April 2016, the FDA approved for sale in the United States an infliximab biosimilar to be marketed by a subsidiary of Pfizer Inc. In October 2016, the period for notice of launch under the BPCIA passed and Pfizer Inc., began shipment of an infliximab biosimilar to wholesalers in the United States in late November 2016. Sales of an infliximab biosimilar in the U.S. market will result in a reduction in U.S. sales of REMICADE®. The Company continues to assert REMICADE® related patent rights. See Note 21 to the Consolidated Financial Statements for a description of legal matters regarding the REMICADE® patents.

Infectious disease products sales were $3.2 billion, a decline of 12.3% from 2015, which included an operational decrease of 11.2% and a negative currency impact of 1.1%. Competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a significant negative impact on sales. The decline of Hepatitis C sales was partially offset by sales growth of EDURANT®(rilpivirine) and PREZCOBIX®(darunavir/cobicistat).

Neuroscience products sales were $6.1 billion, a decrease of 2.8% from 2015, which included an operational decrease of 2.3% and a negative currency impact of 0.5%. Strong sales of INVEGA SUSTENNA®/XEPLION®/ TRINZA®(paliperidone palmitate) were offset by lower sales of INVEGA®(paliperidone) due to generic competition, RISPERDAL CONSTA®(risperidone) and the impact of divestitures. Sales growth of CONCERTA®/methylphenidate was primarily due to a therapeutic equivalence reclassification of generic competitors.

Oncology products achieved sales of $5.8 billion in 2016, representing an increase of 23.7% as compared to the prior year. Oncology products growth of 23.7% included operational growth of 25.2% and a negative currency impact of 1.5%. Contributors to the growth of Oncology products were strong sales of IMBRUVICA® (ibrutinib) and DARZALEX® (daratumumab) due to patient uptake, additional country launches and additional indications for IMBRUVICA®. Generic competition negatively impacted the sales growth of VELCADE®(bortezomib). Sales growth of ZYTIGA®(abiraterone acetate) in the Asia Pacific region, primarily due to the launch in China earlier this year, was partially offset by lower sales in Europe due to competition.

Cardiovascular/Metabolism/Other products sales were $6.4 billion, a decline of 0.3% from 2015, which included an operational increase of 0.8% and a negative currency impact of 1.1%. Contributors to the growth were strong sales of XARELTO®(rivaroxaban) due to market share growth and INVOKANA®/INVOKAMET® (canagliflozin) due to market growth and continued uptake in the European Union and Canada. Sales of hormonal contraceptives were negatively impacted by generic competition and a higher adjustment to previous reserve estimates in 2015 as compared to 2016, which negatively impacted Cardiovascular/Metabolism/Other by approximately 2.3%.

During 2016, the Company advanced its pipeline with several regulatory submissions and approvals for new drugs and additional indications for existing drugs as follows:

Product Name (Chemical Name)	Indication	US Approv	EU Approv	US Filing	EU Filing
DARZALEX® (daratumumab)	In combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy	✓			✓
	For the treatment of double refractory multiple myeloma		✓		
darunavir STR	Single tablet regimen for HIV in treatment naive patients and treatment experienced patients				✓
guselkumab	Treatment of adults living with moderate to severe plaque psoriasis			✓	✓
IMBRUVICA® (ibrutinib)	Additional indication for first-line treatment of chronic lymphocytic leukemia	✓	✓		
	Expanded label to include overall survival and combination data in chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL)	✓			
	Expanded label to include treatment for patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma in combination with bendamustine and rituximab	✓	✓		
INVOKAMET® (canagliflozin)	Initial Therapy FDC with Metformin, Immediate Release	✓			
INVOKAMET® XR (canagliflozin)	A once-daily therapy combining fixed doses of canagliflozin and metformin hydrochloride extended release for the treatment of adults with type 2 diabetes	✓			
SIMPONI® (golimumab)	Treatment of polyarticular juvenile idiopathic arthritis		✓		
SIMPONI ARIA® (golimumab)	Treatment of adults living with active psoriatic arthritis and the treatment of adults living with active ankylosing spondylitis			✓	
sirukumab	Treatment of Rheumatoid Arthritis			✓	✓
STELARA® (ustekinumab)	Treatment of adults with moderately to severely active Crohn's disease	✓	✓		
	Treatment of adolescents (12 to 17 years of age) with moderate to severe plaque psoriasis			✓	
TREVICTA® (paliperidone palmitate a 3 monthly injection)	Maintenance treatment of schizophrenia in adult patients		✓		

Pharmaceutical segment sales in 2015 were $31.4 billion, a decrease of 2.7% from 2014, which included operational growth of 4.2% offset by a negative currency impact of 6.9%. U.S. sales were $18.3 billion, an increase of 5.2%. International sales were $13.1 billion, a decrease of 12.0%, which included 3.0% operational growth offset by a negative currency impact of 15.0%. The Pharmaceutical segment operational growth was negatively impacted by 6.5% due to the introduction of competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), and positively impacted by 1.4% due to an adjustment to previous reserve estimates, including Managed Medicaid rebates primarily in the Cardiovascular/Metabolism/Other therapeutic area. In 2015, divestitures had a negative impact of 0.3% on the worldwide Pharmaceutical segment operational growth.

Medical Devices Segment

The Medical Devices segment sales in 2016 were $25.1 billion, a decrease of 0.1% from 2015, which included an operational increase of 0.9% and a negative currency impact of 1.0%. U.S. sales were $12.3 billion, an increase of 1.1% as compared to the prior year. International sales were $12.9 billion, a decrease of 1.2% as compared to the prior year, with an operational increase of 0.7% and a negative currency impact of 1.9%. In 2016, acquisitions and divestitures had a negative impact of 1.8% on the worldwide operational growth of the Medical Devices segment as compared to 2015. In 2016, the Medical Devices segment operational growth was negatively impacted by 0.9% due to additional shipping days in 2015.

Major Medical Devices Franchise Sales:

				% Change	
(Dollars in Millions)	**2016**	**2015**	**2014**	**'16 vs. '15**	**'15 vs. '14**
Orthopaedics	**$ 9,334**	**9,262**	**9,675**	0.8 %	(4.3)
Hips	1,361	1,332	1,368	2.2	(2.6)
Knees	1,524	1,496	1,533	1.9	(2.4)
Trauma	2,569	2,528	2,640	1.6	(4.2)
Spine & Other	3,880	3,906	4,134	(0.7)	(5.5)
Surgery	**9,296**	**9,217**	**9,717**	0.9	(5.1)
Advanced	3,517	3,275	3,237	7.4	1.2
General	4,362	4,482	4,970	(2.7)	(9.8)
Specialty	1,417	1,460	1,510	(2.9)	(3.3)
Vision Care	**2,785**	**2,608**	**2,818**	6.8	(7.5)
Cardiovascular	**1,849**	**2,036**	**2,208**	(9.2)	(7.8)
Diabetes Care	**1,789**	**1,928**	**2,142**	(7.2)	(10.0)
Diagnostics*	**66**	**86**	**962**	(23.3)	(91.1)
Total Medical Devices Sales	**$ 25,119**	**25,137**	**27,522**	**(0.1)%**	**(8.7)**

* On June 30, 2014, the Company divested the Ortho-Clinical Diagnostics business (the Diagnostics Franchise)

The Orthopaedics franchise sales were $9.3 billion in 2016, an increase of 0.8% from 2015, which included operational growth of 1.8% and a negative currency impact of 1.0%. Sales growth was primarily driven by market growth, U.S. sales of the trauma TFNA nailing system, worldwide sales of the hip primary stem platform and the ATTUNE® Knee System. Growth was negatively impacted by continued pricing pressures.

The Surgery franchise sales were $9.3 billion in 2016, an increase of 0.9% from 2015, which included operational growth of 2.3% and a negative currency impact of 1.4%. Operational growth in Advanced Surgery was driven by endocutter, energy and biosurgery products, primarily attributable to market growth, increased penetration in certain markets and new product launches. The acquisition of NeuWave Medical, Inc. also contributed to growth. The operational decline in General Surgery was due to lower sales of women's health and urology products and pricing pressures partially offset by growth of sutures. The operational decline in Specialty Surgery was primarily due to lower sales of Acclarent products and Advanced Sterilization Products outside the U.S., divestitures and competitive pressures in Sterilmed partially offset by growth of Mentor products outside the U.S.

The Vision Care franchise achieved sales of $2.8 billion in 2016, an increase of 6.8% from 2015, which included operational growth of 6.4% and a positive currency impact of 0.4%. Growth in all the major regions was primarily driven by new product launches.

The Cardiovascular franchise sales were $1.8 billion, a decrease of 9.2% from 2015, which represented an operational decline of 9.2%. Strong operational growth in the electrophysiology business driven by market growth, share growth and new product launches was more than offset by the impact of divesting the Cordis business. The Company completed the divestiture of the Cordis business to Cardinal Health on October 4, 2015. For additional details see Note 20 to the Consolidated Financial Statements.

The Diabetes Care franchise sales were $1.8 billion, a decrease of 7.2% from 2015, which represented an operational decline of 5.9% and a negative currency impact of 1.3%. The operational decline was primarily due to price declines and competitive pressures. On January 26, 2017, subsequent to year-end, the Company announced it is engaging in a process to evaluate potential strategic options for the Diabetes Care franchise.

The Medical Devices segment sales in 2015 were $25.1 billion, a decrease of 8.7% from 2014, which included an operational decline of 1.4% and a negative currency impact of 7.3%. U.S. sales were $12.1 billion, a decrease of 1.0% as

compared to the prior year. International sales were $13.0 billion, a decrease of 14.8% as compared to the prior year, with an operational decrease of 1.0% and a negative currency impact of 13.1%. The divestitures of the Ortho-Clinical Diagnostics and the Cordis Businesses had a negative impact of 3.2% and 0.6%, respectively, on the worldwide operational growth of the Medical Devices segment as compared to 2014.

Analysis of Consolidated Earnings Before Provision for Taxes on Income

Consolidated earnings before provision for taxes on income increased to $19.8 billion in 2016, as compared to $19.2 billion in 2015, an increase of 3.2%. The increase was primarily attributable to higher sales volume, favorable mix in the business and lower selling, marketing and administrative costs. This was partially offset by higher net litigation expense of $0.7 billion and a higher restructuring charge of $0.1 billion as compared to 2015. Additionally, the fiscal year 2015 included higher gains on the sale of assets/businesses as compared to 2016. The fiscal year of 2016 included gains of $0.6 billion from the divestitures of the controlled substance raw material and API business, certain anesthetic products in Europe and certain non-strategic Consumer brands versus gains of $2.6 billion recorded in 2015 primarily from the divestiture of the Cordis business, the U.S. divestiture of NUCYNTA® and the SPLENDA® brand. This was partially offset by a $0.3 billion intangible asset write-down related to Acclarent included in 2015.

Consolidated earnings before provision for taxes on income decreased to $19.2 billion in 2015, as compared to $20.6 billion in 2014, a decrease of 6.6%. The decrease was primarily attributable to significantly lower sales of OLYSIO®/SOVRIAD® (simeprevir), negative currency impacts, a restructuring charge of $0.6 billion and higher intangible asset write-downs of $0.1 billion in 2015 as compared to 2014. The decrease was partially offset by lower net litigation expense of $1.1 billion, lower Synthes integration costs of $0.6 billion, a positive adjustment of $0.4 billion to previous reserve estimates including Managed Medicaid rebates, and higher gains of $0.3 billion from divestitures as compared to the prior year. The fiscal year 2015 included higher gains of $0.3 billion primarily from the divestitures of the Cordis business, the SPLENDA® brand and the U.S. divestiture of NUCYNTA® versus the gains recorded in 2014 from the divestitures of the Ortho-Clinical Diagnostics business and the K-Y® brand. Additionally, 2014 included an additional year of the Branded Prescription Drug Fee of $0.2 billion.

As a percent to sales, consolidated earnings before provision for taxes on income in 2016 was 27.5% versus 27.4% in 2015.

Cost of Products Sold and Selling, Marketing and Administrative Expenses: Cost of products sold and selling, marketing and administrative expenses as a percent to sales were as follows:

% of Sales	2016	2015	2014
Cost of products sold	30.2%	30.7	30.6
Percent point increase/(decrease) over the prior year	(0.5)	0.1	(0.7)
Selling, marketing and administrative expenses	27.7%	30.3	29.5
Percent point increase/(decrease) over the prior year	(2.6)	0.8	(1.1)

In 2016, cost of products sold as a percent to sales decreased to 30.2% from 30.7% as compared to the same period a year ago. Favorable mix in the business and cost improvement programs was partially offset by the unfavorable impact of transactional currency. Intangible asset amortization expense of $1.2 billion was included in cost of products sold for 2016 and 2015. There was a decrease in the percent to sales of selling, marketing and administrative expenses in 2016 compared to the prior year, primarily due to cost management in all the segments and favorable mix.

In 2015, cost of products sold as a percent to sales increased slightly as compared to the prior year. Favorable mix between the segments was offset by $81 million associated with the restructuring activity in the Medical Devices segment, negative transactional currency and lower sales of OLYSIO®/SOVRIAD® (simeprevir) in 2015. Intangible asset amortization expense included in cost of products sold for 2015 and 2014 was $1.2 billion and $1.4 billion, respectively. There was an increase in the percent to sales of selling, marketing and administrative expenses in 2015 compared to the prior year, primarily due to incremental investment spending in all the segments and the impact from lower sales of OLYSIO®/SOVRIAD® (simeprevir), partially offset by favorable mix and the inclusion of an additional year of the Branded Prescription Drug Fee of $0.2 billion in 2014.

Research and Development Expense: Research and development expense by segment of business was as follows:

	2016		2015		2014	
(Dollars in Millions)	Amount	% of Sales*	Amount	% of Sales*	Amount	% of Sales*
Consumer	$ 580	4.4%	625	4.6	629	4.3
Pharmaceutical	6,967	20.8	6,821	21.7	6,213	19.2
Medical Devices	1,548	6.2	1,600	6.4	1,652	6.0
Total research and development expense	$ 9,095	12.7%	9,046	12.9	8,494	11.4
Percent increase/(decrease) over the prior year	0.5%		6.5		3.8	

* As a percent to segment sales

Research and development activities represent a significant part of the Company's business. These expenditures relate to the processes of discovering, testing and developing new products, upfront payments and milestones, improving existing products, as well as ensuring product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products. In 2016, worldwide costs of research and development activities increased by 0.5% compared to 2015 but decreased as a percent of sales. The decrease as a percent of sales was attributable to higher overall sales in the Pharmaceutical segment. The increased dollar spend in the Pharmaceutical segment was for investment spending to advance the pipeline. In 2015, worldwide costs of research and development activities increased by 6.5% compared to 2014. The increase as a percent to sales was attributable to increased investment spending primarily in the Pharmaceutical segment, lower overall sales and business mix.

In-Process Research and Development (IPR&D): In 2016, the Company recorded an IPR&D charge of $29 million for the discontinuation of a development program related to Crucell. In 2015, the Company recorded an IPR&D charge of $0.2 billion primarily for the discontinuation of certain development projects related to Covagen. In 2014, the Company recorded an IPR&D charge of $0.2 billion for the impairment of various IPR&D projects related to RespiVert, Crucell, Mentor and Synthes for the delay or discontinuation of certain development projects.

Other (Income) Expense, Net: Other (income) expense, net is the account where the Company records gains and losses related to the sale and write-down of certain investments in equity securities held by Johnson & Johnson Innovation - JJDC, Inc. (JJDC), gains and losses on divestitures, transactional currency gains and losses, acquisition-related costs, litigation accruals and settlements, as well as royalty income. The change in other (income) expense, net for the fiscal year 2016 was an unfavorable change of $2.5 billion as compared to the prior year primarily due to higher gains on the sale of assets/businesses in the fiscal year 2015 as compared to 2016. The fiscal year of 2016 included gains of $0.6 billion from the divestitures of the controlled substance raw material and API business, certain anesthetic products in Europe and certain non-strategic Consumer brands versus gains of $2.6 billion recorded in 2015 primarily from the divestiture of the Cordis business, the U.S. divestiture of NUCYNTA® and the SPLENDA® brand. Additionally, the fiscal year of 2016 included higher litigation expense of $0.7 billion as compared to 2015. This was partially offset by a $0.3 billion intangible asset write-down related to Acclarent included the fiscal year 2015.

The change in other (income) expense, net for the fiscal year 2015 was a favorable change of $2.0 billion as compared to the prior year primarily due to lower litigation expense of $1.1 billion, lower Synthes integration costs of $0.6 billion and higher JJDC portfolio gains of $0.2 billion as compared to the prior year. Additionally, the fiscal year 2015 included higher gains of $0.3 billion primarily from the divestitures of the Cordis business, the SPLENDA® brand and the U.S. divestiture of NUCYNTA® versus the gains recorded in 2014 from the divestitures of the Ortho-Clinical Diagnostics business and the K-Y® brand. This was partially offset by higher intangible asset write-downs of $0.1 billion in 2015.

Interest (Income) Expense: Interest income in 2016 increased by $240 million as compared to 2015 due to a higher average balance of cash, cash equivalents and marketable securities and higher interest rates. Cash, cash equivalents and marketable securities totaled $41.9 billion at the end of 2016, and averaged $40.1 billion as compared to the $35.7 billion average cash balance in 2015.

Interest expense in 2016 was higher as compared to 2015. The average debt balance was $23.5 billion in 2016 versus $19.3 billion in 2015. The total debt balance at the end of 2016 was $27.1 billion as compared to $19.9 billion at the end of 2015. The higher debt balance of approximately $7.2 billion was primarily due to increased borrowings in February and May of 2016. The Company increased borrowings, capitalizing on favorable terms in the capital markets. The proceeds of the borrowings were used for general corporate purposes, primarily the stock repurchase program.

Interest income in 2015 increased by $61 million as compared to 2014 due to a higher average balance of cash, cash equivalents and marketable securities and higher interest rates. Cash, cash equivalents and marketable securities totaled

$38.4 billion at the end of 2015, and averaged $35.7 billion as compared to the $31.1 billion average cash balance in 2014. The increase in the year-end cash balance was primarily due to cash generated from operating activities.

Interest expense in 2015 increased slightly as compared to 2014. The average debt balance was $19.3 billion in 2015 versus $18.5 billion in 2014. The total debt balance at the end of 2015 was $19.9 billion as compared to $18.8 billion at the end of 2014. The higher debt balance of approximately $1.1 billion was an increase in commercial paper for general corporate purposes, primarily the stock repurchase program.

Income Before Tax by Segment

Income before tax by segment of business were as follows:

	Income Before Tax		Segment Sales		Percent of Segment Sales	
(Dollars in Millions)	**2016**	**2015**	**2016**	**2015**	**2016**	**2015**
Consumer	$ 2,441	1,787	$ 13,307	13,507	18.3%	13.2
Pharmaceutical	12,827	11,734	33,464	31,430	38.3	37.3
Medical Devices	5,578	6,826	25,119	25,137	22.2	27.2
Total [1]	20,846	20,347	71,890	70,074	29.0	29.0
Less: Expenses not allocated to segments [2]	1,043	1,151				
Earnings before provision for taxes on income	$ 19,803	19,196	$ 71,890	70,074	27.5%	27.4

(1) See Note 18 to the Consolidated Financial Statements for more details.

(2) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.

Consumer Segment: In 2016, the Consumer segment income before tax as a percent to sales was 18.3%, versus 13.2% in 2015, primarily driven by favorable selling, marketing and administrative expenses due to cost management and higher gross profit margins from cost improvement projects and favorable mix. This was partially offset by higher gains in 2015 related to divestitures, primarily the divestiture of the SPLENDA® brand. Additionally, operations in Venezuela negatively impacted the Consumer segment income before tax in 2016 as compared to 2015.

In 2015, the Consumer segment income before tax as a percent to sales was 13.2%, versus 13.4% in 2014, primarily due to lower divestiture gains in 2015 versus 2014. In 2015, the Consumer segment tax included a gain of $0.3 billion from divestitures, primarily the divestiture of the SPLENDA® brand. In 2014, the Consumer segment included a gain $0.5 billion from divestitures, primarily the divestiture of the K-Y® brand.

Pharmaceutical Segment: In 2016, the Pharmaceutical segment income before tax as a percent to sales was 38.3% versus 37.3% in 2015. The increase in income before tax was primarily due to strong sales volume growth and favorable selling, marketing and administrative expenses due to cost management. Additionally, the fiscal year 2015, had higher gains of $0.7 billion related to divestitures partially offset by a higher IPR&D charge of $0.2 billion as compared to 2016. The fiscal year of 2016 included the gains from the divestitures of the controlled substance raw material and API business and certain anesthetic products in Europe versus the gains recorded in 2015 from the U.S. divestiture of NUCYNTA®.

In 2015, the Pharmaceutical segment income before tax as a percent to sales was 37.3% versus 36.2% in 2014. The favorable income before tax was primarily due to higher gains recognized in 2015 partially offset by a sales decline of OLYSIO®/SOVRIAD®(simeprevir), increased investment spending and negative currency impacts as compared to 2014. Included in 2015 was a gain of $1.0 billion on the U.S. divestiture of NUCYNTA®, as well as receipt of a contingent payment and a positive adjustment to previous reserve estimates, including Managed Medicaid rebates. Additionally, the Pharmaceutical segment income before tax in 2014 was negatively impacted by $0.2 billion for an additional year of the Branded Prescription Drug Fee and higher intangible asset amortization expense of $0.3 billion primarily related to the write-down of INCIVO® (telaprevir).

Medical Devices Segment: In 2016, the Medical Devices segment income before tax as a percent to sales was 22.2% versus 27.2% in 2015. The decrease in the income before tax as a percent to sales was primarily due to lower gains of $1.4 billion related to divestitures, higher litigation expense of $0.8 billion and a higher restructuring charge of $0.1 billion as compared to 2015. This was partially offset by an intangible asset write-down of $0.3 billion related to Acclarent in 2015 and favorable selling, marketing and administrative expenses in 2016.

In 2015, the Medical Devices segment income before tax as a percent to sales was 27.2% versus 28.9% in 2014 primarily due to a restructuring charge of $0.6 billion, an intangible asset write-down of $0.3 billion related to Acclarent, and lower gains of $0.5 billion on divestitures as compared to 2014. In 2015, the Medical Devices segment included gains of $1.4 billion, primarily for the divestiture of the Cordis business versus a gain of $1.9 billion recorded in 2014 for the divestiture of the Ortho-Clinical Diagnostics business. The 2015 income before tax was favorably impacted by lower net litigation expense of

$0.9 billion, which included a gain from the litigation settlement agreement of $0.6 billion with Guidant, and lower Synthes integration costs of $0.6 billion in 2015 as compared to 2014.

Restructuring: The Company announced restructuring actions in its Medical Devices segment that are expected to result in annualized pre-tax cost savings of $800 million to $1.0 billion, the majority of which is expected to be realized by the end of 2018. Approximately $250 million in savings were realized in 2016. The savings will provide the Company with added flexibility and resources to fund investment in new growth opportunities and innovative solutions for customers and patients. The Company estimates that, in connection with its plans, it will record pre-tax restructuring related charges of approximately $2.0 billion to $2.4 billion, most of which are expected to be incurred by the end of 2017. In 2016, the Company recorded a pre-tax charge of $685 million, of which $45 million is included in cost of products sold and $149 million is included in other (income) expense. In 2015, the Company recorded a pre-tax charge of $590 million, of which $81 million was included in cost of products sold. Restructuring charges of $1.275 billion have been recorded since the restructuring was announced. See Note 22 to the Consolidated Financial Statements for additional details related to the restructuring.

Provision for Taxes on Income: The worldwide effective income tax rate was 16.5% in 2016, 19.7% in 2015 and 20.6% in 2014. The 2016 effective tax rate decreased by 3.2% as compared to 2015. As described in Note 1 to the Consolidated Financial Statements, the Company adopted a new accounting standard for the reporting of additional tax benefits on share-based compensation that vested or were exercised during the fiscal year. The adoption of this new standard reduced the effective tax rate for the fiscal 2016 by 1.8% versus 2015. The remainder of the change in the effective tax rate was primarily related to the lower earnings before taxes in the United States and the settlement of several uncertain tax positions in 2016 versus 2015.

The decrease in the 2015 effective tax rate, as compared to 2014 was primarily attributable to the increases in taxable income in lower tax jurisdictions relative to higher tax jurisdictions and a tax benefit resulting from a restructuring of international affiliates. Additionally, the 2014 effective tax rate was affected by the items mentioned below.

The increase in the 2014 effective tax rate, as compared to 2013, was attributable to the following: the divestiture of the Ortho-Clinical Diagnostics business at an approximate 44% effective tax rate, litigation accruals at low tax rates, the mix of earnings into higher tax jurisdictions, primarily the U.S., the accrual of an additional year of the Branded Prescription Drug Fee, which is not tax deductible, and additional U.S. tax expense related to a planned increase in dividends from current year foreign earnings as compared to the prior year. These increases to the 2014 effective tax rate were partially offset by a tax benefit of $0.4 billion associated with the Conor Medsystems divestiture.

The 2014 effective tax rate was also reduced as the Company adjusted its unrecognized tax benefits as a result of (i) the federal appeals court's decision in OMJ Pharmaceuticals, Inc.'s litigation regarding credits under former Section 936 of the Internal Revenue Code and (ii) a settlement of substantially all issues related to the Company's U.S. Internal Revenue Service audit of tax years 2006 - 2009.

Liquidity and Capital Resources

Liquidity & Cash Flows

Cash and cash equivalents were $19.0 billion at the end of 2016 as compared to $13.7 billion at the end of 2015. The primary sources and uses of cash that contributed to the $5.3 billion increase were approximately $18.8 billion of cash generated from operating activities offset by $4.8 billion net cash used by investing activities, and $8.6 billion net cash used by financing activities, and $0.2 billion due to the effect on exchange rate changes on cash and cash equivalents. In addition, the Company had $22.9 billion in marketable securities at the end of 2016 and $24.6 billion at the end of 2015. See Note 1 to the Consolidated Financial Statements for additional details on cash, cash equivalents and marketable securities.

Cash flow from operations of $18.8 billion was the result of $16.5 billion of net earnings and $4.9 billion of non-cash expenses and other adjustments for depreciation and amortization, stock-based compensation and assets write-downs, reduced by $0.6 billion from net gains on sale of assets/businesses, $0.3 billion related to deferred taxes and $2.4 billion related to accounts receivable, inventories and other current and non-current liabilities. Additional sources of operating cash flow of $0.7 billion resulted from an increase in accounts payable and accrued liabilities and a decrease in other current and non-current assets.

Investing activities use of $4.8 billion was primarily for acquisitions, net of cash acquired of $4.5 billion and additions to property, plant and equipment of $3.2 billion. This was partially offset by proceeds from the net sale of investments primarily marketable securities of $1.8 billion and $1.3 billion of proceeds from the disposal of assets/businesses.

Financing activities use of $8.6 billion was primarily for dividends to shareholders of $8.6 billion and $9.0 billion for the repurchase of common stock. Financing activities also included a source of $7.9 billion from net proceeds of short and long-term debt and $1.2 billion of proceeds from stock options exercised/employee withholding tax on stock awards, net.

In 2016, the Company announced a definitive agreement to acquire Abbott Medical Optics Inc. for approximately $4.3 billion and on January 26, 2017, subsequent to year end the Company announced a definitive transaction agreement to acquire Actelion Ltd. for approximately $30.0 billion. Abbott Medical Optics closed on February 27, 2017. The Company will use cash held by the Company's foreign subsidiaries to pay for these acquisitions.

On October 13, 2015, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $10.0 billion of the Company's shares of common stock. As of January 1, 2017, $7.3 billion has been repurchased under the program. The repurchase program has no time limit and may be delayed or suspended for periods or discontinued at any time. Any shares acquired will be available for general corporate purposes. The Company intends to finance the share repurchase program through available cash and access to the capital markets. The previous share repurchase program approved on July 21, 2014, authorizing the Company to purchase up to $5.0 billion of the Company's shares of common stock, was completed on April 28, 2015.

In 2016, the Company continued to have access to liquidity through the commercial paper market. The Company had a shelf registration with the U.S. Securities and Exchange Commission that expired on February 26, 2017. The Company plans to file a new shelf registration on February 27, 2017 which will enable it to issue debt securities on a timely basis. For additional details on borrowings, see Note 7 to the Consolidated Financial Statements.

The Company anticipates that operating cash flows, existing credit facilities and access to the capital markets will provide sufficient resources to fund operating needs in 2017.

Concentration of Credit Risk

Global concentration of credit risk with respect to trade accounts receivables continues to be limited due to the large number of customers globally and adherence to internal credit policies and credit limits. Economic challenges in Italy, Spain, Greece and Portugal (the Southern European Region) have impacted certain payment patterns, which have historically been longer than those experienced in the U.S. and other international markets. The total net trade accounts receivable balance in the Southern European Region was approximately $1.1 billion as of January 1, 2017 and $1.3 billion as of January 3, 2016. Approximately $0.7 billion as of January 1, 2017 and approximately $0.8 billion as of January 3, 2016 of the Southern European Region net trade accounts receivable balance related to the Company's Consumer, Vision Care and Diabetes Care businesses as well as certain Pharmaceutical and Medical Devices customers which are in line with historical collection patterns.

The remaining balance of net trade accounts receivable in the Southern European Region has been negatively impacted by the timing of payments from certain government owned or supported health care customers, as well as certain distributors of the Pharmaceutical and Medical Devices local affiliates. The total net trade accounts receivable balance for these customers were approximately $0.4 billion at January 1, 2017 and $0.5 billion at January 3, 2016. The Company continues to receive payments from these customers and, in some cases, late payments with interest. For customers where payment is expected over periods of time longer than one year, revenue and trade receivables have been discounted over the estimated period of time for collection. Allowances for doubtful accounts have been increased for these customers, but have been immaterial to date. The Company will continue to work closely with these customers on payment plans, monitor the economic situation and take appropriate actions as necessary.

Financing and Market Risk

The Company uses financial instruments to manage the impact of foreign exchange rate changes on cash flows. Accordingly, the Company enters into forward foreign exchange contracts to protect the value of certain foreign currency assets and liabilities and to hedge future foreign currency transactions primarily related to product costs. Gains or losses on these contracts are offset by the gains or losses on the underlying transactions. A 10% appreciation of the U.S. Dollar from the January 1, 2017 market rates would increase the unrealized value of the Company’s forward contracts by $23 million. Conversely, a 10% depreciation of the U.S. Dollar from the January 1, 2017 market rates would decrease the unrealized value of the Company’s forward contracts by $28 million. In either scenario, the gain or loss on the forward contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated earnings and cash flows.

The Company hedges the exposure to fluctuations in currency exchange rates, and the effect on certain assets and liabilities in foreign currency, by entering into currency swap contracts. A 1% change in the spread between U.S. and foreign interest rates on the Company’s interest rate sensitive financial instruments would either increase or decrease the unrealized value of the Company’s swap contracts by approximately $82 million. In either scenario, at maturity, the gain or loss on the swap contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated cash flows.

The Company does not enter into financial instruments for trading or speculative purposes. Further, the Company has a policy of only entering into contracts with parties that have at least an investment grade credit rating. The counter-parties to these contracts are major financial institutions and there is no significant concentration of exposure with any one counter-party. Management believes the risk of loss is remote.

The Company invests in both fixed rate and floating rate interest earning securities which carry a degree of interest rate risk. The fair market value of fixed rate securities may be adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than predicted if interest rates fall. A 1% (100 basis points) change in spread on the Company’s interest rate sensitive investments would either increase or decrease the unrealized value of cash equivalents and current marketable securities by approximately $336 million.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2016, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 14, 2017. Interest charged on borrowings under the credit line agreement is based on either bids provided by banks, the prime rate or London Interbank Offered Rates (LIBOR), plus applicable margins. Commitment fees under the agreement are not material.

Total borrowings at the end of 2016 and 2015 were $27.1 billion and $19.9 billion, respectively. The increase in borrowings between 2016 and 2015 was a result of financing for the Company's share repurchase program and general corporate purposes. In 2016, net cash (cash and current marketable securities, net of debt) was $14.8 billion compared to net cash of $18.5 billion in 2015. Total debt represented 27.8% of total capital (shareholders' equity and total debt) in 2016 and 21.8% of total capital in 2015. Shareholders' equity per share at the end of 2016 was $26.02 compared to $25.82 at year-end 2015, an increase of 0.8%.

A summary of borrowings can be found in Note 7 to the Consolidated Financial Statements.

Contractual Obligations and Commitments

The Company's contractual obligations are primarily for leases, debt and unfunded retirement plans. There are no other significant obligations. To satisfy these obligations, the Company will use cash from operations. The following table summarizes the Company's contractual obligations and their aggregate maturities as of January 1, 2017 (see Notes 7, 10 and 16 to the Consolidated Financial Statements for further details):

(Dollars in Millions)	Debt Obligations	Interest on Debt Obligations	Unfunded Retirement Plans	Operating Leases	Total
2017	$ 1,704	799	83	216	2,802
2018	1,561	735	84	179	2,559
2019	2,538	680	89	134	3,441
2020	629	608	94	105	1,436
2021	1,795	574	100	88	2,557
After 2021	15,919	6,956	610	100	23,585
Total	**$ 24,146**	**10,352**	**1,060**	**822**	**36,380**

For tax matters, see Note 8 to the Consolidated Financial Statements. For other retirement plan and post-employment medical benefit information, see Note 10 to the Consolidated Financial Statements. The table does not include activity related to business combinations.

Dividends

The Company increased its dividend in 2016 for the 54th consecutive year. Cash dividends paid were $3.15 per share in 2016 compared with dividends of $2.95 per share in 2015, and $2.76 per share in 2014. The dividends were distributed as follows:

	2016	2015	2014
First quarter	$ 0.75	0.70	0.66
Second quarter	0.80	0.75	0.70
Third quarter	0.80	0.75	0.70
Fourth quarter	0.80	0.75	0.70
Total	**$ 3.15**	**2.95**	**2.76**

On January 3, 2017, the Board of Directors declared a regular quarterly cash dividend of $0.80 per share, payable on March 14, 2017, to shareholders of record as of February 28, 2017. The Company expects to continue the practice of paying regular cash dividends.

Other Information

Critical Accounting Policies and Estimates

Management's discussion and analysis of results of operations and financial condition are based on the Company's consolidated financial statements that have been prepared in accordance with accounting principles generally accepted in the U.S. (GAAP). The preparation of these financial statements requires that management make estimates and assumptions that affect the amounts reported for revenues, expenses, assets, liabilities and other related disclosures. Actual results may or may

not differ from these estimates. The Company believes that the understanding of certain key accounting policies and estimates are essential in achieving more insight into the Company's operating results and financial condition. These key accounting policies include revenue recognition, income taxes, legal and self-insurance contingencies, valuation of long-lived assets, assumptions used to determine the amounts recorded for pensions and other employee benefit plans and accounting for stock based awards.

Revenue Recognition: The Company recognizes revenue from product sales when goods are shipped or delivered, and title and risk of loss pass to the customer. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns and discounts to customers are accounted for as reductions in sales in the same period the related sales are recorded.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including prices charged by competitors. Rebates, which include the Medicaid rebate provision, are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns are estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales return accruals.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual net trade sales during the fiscal reporting years 2016, 2015 and 2014.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the year incurred. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on estimated sales volumes for the incentive period and are recorded as products are sold. The Company also earns service revenue for co-promotion of certain products. For all years presented, service revenues were 1% or less of the total revenues and are included in sales to customers. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue.

In addition, the Company enters into collaboration arrangements that contain multiple revenue generating activities. Amounts due from collaborative partners for these arrangements are recognized as each activity is performed or delivered, based on the relative selling price. Upfront fees received as part of these arrangements are deferred and recognized over the performance period. See Note 1 to the Consolidated Financial Statements for additional disclosures on collaborations.

Reasonably likely changes to assumptions used to calculate the accruals for rebates, returns and promotions are not anticipated to have a material effect on the financial statements. The Company currently discloses the impact of changes to assumptions in the quarterly or annual filing in which there is a material financial statement impact.

Below are tables that show the progression of accrued rebates, returns, promotions, reserve for doubtful accounts and reserve for cash discounts by segment of business for the fiscal years ended January 1, 2017 and January 3, 2016.

Consumer Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits	Balance at End of Period
2016				
Accrued rebates [1]	$ 139	615	(618)	136
Accrued returns	54	111	(100)	65
Accrued promotions	412	1,908	(1,962)	358
Subtotal	$ 605	2,634	(2,680)	559
Reserve for doubtful accounts	18	12	(6)	24
Reserve for cash discounts	17	209	(201)	25
Total	$ 640	2,855	(2,887)	608
2015				
Accrued rebates[1]	$ 122	581	(564)	139
Accrued returns	77	84	(107)	54
Accrued promotions	241	1,846	(1,675)	412
Subtotal	$ 440	2,511	(2,346)	605
Reserve for doubtful accounts	18	5	(5)	18
Reserve for cash discounts	22	206	(211)	17
Total	$ 480	2,722	(2,562)	640

(1) Includes reserve for customer rebates of $37 million at January 1, 2017 and $31 million at January 3, 2016, recorded as a contra asset.

Pharmaceutical Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits[2]	Balance at End of Period
2016				
Accrued rebates [1]	$ 3,451	12,306	(12,337)	3,420
Accrued returns	404	140	(210)	334
Accrued promotions	11	10	(21)	—
Subtotal	$ 3,866	12,456	(12,568)	3,754
Reserve for doubtful accounts	46	2	(10)	38
Reserve for cash discounts	63	613	(618)	58
Total	$ 3,975	13,071	(13,196)	3,850
2015				
Accrued rebates [1]	$ 2,717	10,449	(9,715)	3,451
Accrued returns	422	52	(70)	404
Accrued promotions	34	127	(150)	11
Subtotal	$ 3,173	10,628	(9,935)	3,866
Reserve for doubtful accounts	41	30	(25)	46
Reserve for cash discounts	51	625	(613)	63
Total	$ 3,265	11,283	(10,573)	3,975

(1) Includes reserve for customer rebates of $102 million at January 1, 2017 and $64 million at January 3, 2016, recorded as a contra asset.

(2) Includes adjustments

Medical Devices Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits	Balance at End of Period
2016				
Accrued rebates[1]	$ 1,189	5,700	(5,389)	1,500
Accrued returns	239	518	(630)	127
Accrued promotions	47	78	(93)	32
Subtotal	$ 1,475	6,296	(6,112)	1,659
Reserve for doubtful accounts	204	21	(35)	190
Reserve for cash discounts	20	430	(434)	16
Total	$ 1,699	6,747	(6,581)	1,865
2015				
Accrued rebates[1]	$ 844	5,216	(4,871)	1,189
Accrued returns	188	556	(505)	239
Accrued promotions	53	95	(101)	47
Subtotal	$ 1,085	5,867	(5,477)	1,475
Reserve for doubtful accounts	216	13	(25)	204
Reserve for cash discounts	16	877	(873)	20
Total	$ 1,317	6,757	(6,375)	1,699

(1) Includes reserve for customer rebates of $430 million at January 1, 2017 and $411 million at January 3, 2016, recorded as a contra asset.

Income Taxes: Income taxes are recorded based on amounts refundable or payable for the current year and include the results of any difference between U.S. GAAP accounting and tax reporting, recorded as deferred tax assets or liabilities. The Company estimates deferred tax assets and liabilities based on enacted tax regulations and rates. Future changes in tax laws and rates may affect recorded deferred tax assets and liabilities.

The Company has unrecognized tax benefits for uncertain tax positions. The Company follows U.S. GAAP, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Management believes that changes in these estimates would not have a material effect on the Company's results of operations, cash flows or financial position.

At January 1, 2017 and January 3, 2016, the cumulative amounts of undistributed international earnings were approximately $66.2 billion and $58.0 billion, respectively. At January 1, 2017 and January 3, 2016, the Company's foreign subsidiaries held balances of cash, cash equivalents and marketable securities in the amounts of $41.3 billion and $38.2 billion, respectively. The Company has not provided deferred taxes on the undistributed earnings from certain international subsidiaries where the earnings are considered to be indefinitely reinvested. The Company intends to continue to reinvest these earnings in international operations. If the Company decided at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company does not determine the deferred tax liability associated with these undistributed earnings, as such determination is not practical.

See Note 8 to the Consolidated Financial Statements for further information regarding income taxes.

Legal and Self Insurance Contingencies: The Company records accruals for various contingencies, including legal proceedings and product liability claims as these arise in the normal course of business. The accruals are based on management’s judgment as to the probability of losses and, where applicable, actuarially determined estimates. The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated. Additionally, the Company records insurance receivable amounts from third-party insurers when recovery is probable. As appropriate, reserves against these receivables are recorded for estimated amounts that may not be collected from third-party insurers.

The Company follows the provisions of U.S. GAAP when recording litigation related contingencies. A liability is recorded when a loss is probable and can be reasonably estimated. The best estimate of a loss within a range is accrued; however, if no estimate in the range is better than any other, the minimum amount is accrued.

See Notes 1 and 21 to the Consolidated Financial Statements for further information regarding product liability and legal proceedings. 711

Long-Lived and Intangible Assets: The Company assesses changes in economic conditions and makes assumptions regarding estimated future cash flows in evaluating the value of the Company's property, plant and equipment, goodwill and intangible assets. As these assumptions and estimates may change over time, it may or may not be necessary for the Company to record impairment charges.

Employee Benefit Plans: The Company sponsors various retirement and pension plans, including defined benefit, defined contribution and termination indemnity plans, which cover most employees worldwide. These plans are based on assumptions for the discount rate, expected return on plan assets, mortality rates, expected salary increases, health care cost trend rates and attrition rates. See Note 10 to the Consolidated Financial Statements for further details on these rates and the effect a rate change to the health care cost trend would have on the Company's results of operations.

Stock Based Compensation: The Company recognizes compensation expense associated with the issuance of equity instruments to employees for their services. Based on the type of equity instrument, the fair value is estimated on the date of grant using either the Black-Scholes option valuation model or a combination of both the Black-Scholes option valuation model and Monte Carlo valuation model, and is expensed in the financial statements over the service period. The input assumptions used in determining fair value are the expected life, expected volatility, risk-free rate and expected dividend yield. For performance share units the fair market value is calculated for each of the three component goals at the date of grant. The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award, discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. See Note 17 to the Consolidated Financial Statements for additional information.

New Accounting Pronouncements

Refer to Note 1 to the Consolidated Financial Statements for recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of January 1, 2017.

Economic and Market Factors

The Company is aware that its products are used in an environment where, for more than a decade, policymakers, consumers and businesses have expressed concerns about the rising cost of health care. In response to these concerns, the Company has a long-standing policy of pricing products responsibly. For the period 2006 - 2016, in the United States, the weighted average compound annual growth rate of the Company's net price increases for health care products (prescription and over-the-counter drugs, hospital and professional products) was below the U.S. Consumer Price Index (CPI).

The Company operates in certain countries where the economic conditions continue to present significant challenges. The Company continues to monitor these situations and take appropriate actions. Inflation rates continue to have an effect on worldwide economies and, consequently, on the way companies operate. The Company has accounted for operations in Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. In the face of increasing costs, the Company strives to maintain its profit margins through cost reduction programs, productivity improvements and periodic price increases.

The Venezuelan government has established alternative systems and offerings of various foreign currency exchanges. Through the fourth quarter of 2015, the number of the Company's transactions conducted at the official rate declined from prior quarters. As a result, the Company determined that it was no longer likely that all outstanding net monetary assets would be settled at the official government rate of 6.3 Bolivares Fuertes to one U.S. Dollar. Therefore in 2015, the Company recorded a charge of $161 million to revalue its net monetary assets in Venezuela at one of the government's alternative exchange rates (SIMADI) and impair its non-monetary assets. After the revaluation, as of January 3, 2016, the Company's Venezuelan subsidiaries represented less than 0.1% of the Company's consolidated assets and liabilities.

While the Company continues to do business in Greece, the Company closely monitors the economic situation. As of January 1, 2017, the Company's Greek subsidiaries represented 0.3% and 0.4% of the Company's consolidated assets and revenues, respectively.

On June 23, 2016, the United Kingdom (U.K.) held a referendum in which voters approved an exit from the European Union (E.U.), commonly referred to as "Brexit." Given the lack of comparable precedent, it is unclear what financial, trade, regulatory and legal implications the withdrawal of the U.K. from the E.U. will have. Brexit creates global political and economic uncertainty, which may cause, among other consequences, volatility in exchange rates and interest rates, additional cost containment by third-party payors and changes in regulations. However, the Company currently does not believe that these and other related effects will have a material impact on the Company's consolidated financial position or operating results. As of January 1, 2017, the business of the Company's U.K. subsidiaries represented less than 3% of both the Company's consolidated assets and fiscal twelve months revenues.

The Company is exposed to fluctuations in currency exchange rates. A 1% change in the value of the U.S. Dollar as compared to all foreign currencies in which the Company had sales, income or expense in 2016 would have increased or decreased the translation of foreign sales by approximately $330 million and income by $105 million.

Governments around the world, including in the United States, consider various proposals to make changes to tax laws, which may include increasing or decreasing existing statutory tax rates. A change in statutory tax rate in any country would result in the revaluation of the Company's deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is enacted. This change would result in an expense or benefit recorded to the Company's Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries where it operates. Changes to the statutory tax rate may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted.

The Belgian government is currently considering a proposed change to its corporate tax code, including a proposal to lower its statutory tax rate. If enacted, the proposed change would result in revaluation of the Company's deferred tax assets, with a corresponding charge to tax expense that may have a material effect on the Company's results of operations for the period. Based on the deferred tax asset balances as of January 1, 2017, the Company estimates for every 1% that the statutory tax is lowered there will be additional one-time tax expense of approximately $60-75 million. A significant portion of the deferred tax asset described as "International R&D capitalized for tax" in Note 8 to the Consolidated Financial Statements is related to the Company's operations in Belgium.

The U.S. government is currently considering various proposals to changes in its corporate tax code. These proposals include but are not limited to lowering the statutory tax rate and the rules on how international income earned by the Company is taxed in the U.S. The impact of these proposals may have a material effect on the Company's results of operations for the period and on future periods.

As the Belgian or U.S. governments are still considering these proposals, it is not certain when or if they will be enacted.

The Company faces various worldwide health care changes that may continue to result in pricing pressures that include health care cost containment and government legislation relating to sales, promotions and reimbursement of health care products.

Changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing health care insurance coverage, as a result of the current global economic downturn, may continue to impact the Company's businesses.

The Company also operates in an environment increasingly hostile to intellectual property rights. Firms have filed Abbreviated New Drug Applications or Biosimilar Biological Product Applications with the FDA or otherwise challenged the coverage and/or validity of the Company's patents, seeking to market generic or biosimilar forms of many of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the event the Company is not successful in defending the patent claims challenged in the resulting lawsuits, generic or biosimilar versions of the products at issue will be introduced to the market, resulting in the potential for substantial market share and revenue losses for those products, and which may result in a non-cash impairment charge in any associated intangible asset. There is also a risk that one or more competitors could launch a generic or biosimilar version of the product at issue following regulatory approval even though one or more valid patents are in place. For further information, see the discussion on "REMICADE® Related Cases" and "Litigation Against Filers of Abbreviated New Drug Applications" in Note 21 to the Consolidated Financial Statements.

Legal Proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability, intellectual property, commercial and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of business.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. The Company has accrued for certain litigation matters and continues to monitor each related legal issue and adjust accruals for new information and further developments in accordance with Accounting Standards Codification (ASC) 450-20-25. For these and other litigation and regulatory matters currently disclosed for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions. The ability to make such estimates and judgments can be affected by various factors, including whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; or there are numerous parties involved.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution of, or increase in accruals for, one or more of these matters in any reporting period may have a material adverse effect on the Company's results of operations and cash flows for that period.

See Note 21 to the Consolidated Financial Statements for further information regarding legal proceedings.

Common Stock Market Prices

The Company's Common Stock is listed on the New York Stock Exchange under the symbol JNJ. As of February 17, 2017, there were 156,073 record holders of Common Stock of the Company. The composite market price ranges for Johnson & Johnson Common Stock during 2016 and 2015 were:

	2016		2015	
	High	Low	High	Low
First quarter	$ 109.56	94.28	$ 106.50	97.15
Second quarter	121.54	107.88	104.48	97.01
Third quarter	126.07	117.04	101.36	81.79
Fourth quarter	122.50	109.32	105.49	89.90
Year-end close	$115.21		$102.72	

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK 714

The information called for by this item is incorporated herein by reference to "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition - Liquidity and Capital Resources - Financing and Market Risk" of this Report; and Note 1 "Summary of Significant Accounting Policies - Financial Instruments" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Audited Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
At January 1, 2017 and January 3, 2016
(Dollars in Millions Except Share and Per Share Amounts) (Note 1)

		2016	2015
Assets			
Current assets			
Cash and cash equivalents (Notes 1 and 2)	$	18,972	13,732
Marketable securities (Notes 1 and 2)		22,935	24,644
Accounts receivable trade, less allowances for doubtful accounts $252 (2015, $268)		11,699	10,734
Inventories (Notes 1 and 3)		8,144	8,053
Prepaid expenses and other receivables		3,282	3,047
Total current assets		**65,032**	**60,210**
Property, plant and equipment, net (Notes 1 and 4)		15,912	15,905
Intangible assets, net (Notes 1 and 5)		26,876	25,764
Goodwill (Notes 1 and 5)		22,805	21,629
Deferred taxes on income (Note 8)		6,148	5,490
Other assets		4,435	4,413
Total assets	**$**	**141,208**	**133,411**
Liabilities and Shareholders' Equity			
Current liabilities			
Loans and notes payable (Note 7)	$	4,684	7,004
Accounts payable		6,918	6,668
Accrued liabilities		5,635	5,411
Accrued rebates, returns and promotions		5,403	5,440
Accrued compensation and employee related obligations		2,676	2,474
Accrued taxes on income (Note 8)		971	750
Total current liabilities		**26,287**	**27,747**
Long-term debt (Note 7)		22,442	12,857
Deferred taxes on income (Note 8)		2,910	2,562
Employee related obligations (Notes 9 and 10)		9,615	8,854
Other liabilities		9,536	10,241
Total liabilities		**70,790**	**62,261**
Shareholders' equity			
Preferred stock — without par value (authorized and unissued 2,000,000 shares)		—	—
Common stock — par value $1.00 per share (Note 12) (authorized 4,320,000,000 shares; issued 3,119,843,000 shares)		3,120	3,120
Accumulated other comprehensive income (Note 13)		(14,901)	(13,165)
Retained earnings		110,551	103,879
		98,770	93,834
Less: common stock held in treasury, at cost (Note 12) (413,332,000 shares and 364,681,000 shares)		28,352	22,684
Total shareholders' equity		**70,418**	**71,150**
Total liabilities and shareholders' equity	**$**	**141,208**	**133,411**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EARNINGS
(Dollars and Shares in Millions Except Per Share Amounts) (Note 1)

		2016	2015	2014
Sales to customers	$	71,890	70,074	74,331
Cost of products sold		21,685	21,536	22,746
Gross profit		50,205	48,538	51,585
Selling, marketing and administrative expenses		19,945	21,203	21,954
Research and development expense		9,095	9,046	8,494
In-process research and development		29	224	178
Interest income		(368)	(128)	(67)
Interest expense, net of portion capitalized (Note 4)		726	552	533
Other (income) expense, net		484	(2,064)	(70)
Restructuring (Note 22)		491	509	—
Earnings before provision for taxes on income		19,803	19,196	20,563
Provision for taxes on income (Note 8)		3,263	3,787	4,240
Net earnings	**$**	**16,540**	**15,409**	**16,323**
Net earnings per share (Notes 1 and 15)				
Basic	**$**	**6.04**	**5.56**	**5.80**
Diluted	**$**	**5.93**	**5.48**	**5.70**
Cash dividends per share	**$**	**3.15**	**2.95**	**2.76**
Average shares outstanding (Notes 1 and 15)				
Basic		**2,737.3**	**2,771.8**	**2,815.2**
Diluted		**2,788.9**	**2,812.9**	**2,863.9**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Dollars in Millions) (Note 1)

	2016	2015	2014
Net earnings	$ 16,540	15,409	16,323
Other comprehensive income (loss), net of tax			
Foreign currency translation	(612)	(3,632)	(4,601)
Securities:			
Unrealized holding gain (loss) arising during period	(52)	471	156
Reclassifications to earnings	(141)	(124)	(5)
Net change	(193)	347	151
Employee benefit plans:			
Prior service credit (cost), net of amortization	21	(60)	193
Gain (loss), net of amortization	(862)	931	(3,698)
Effect of exchange rates	159	148	197
Net change	(682)	1,019	(3,308)
Derivatives & hedges:			
Unrealized gain (loss) arising during period	(359)	(115)	92
Reclassifications to earnings	110	(62)	(196)
Net change	(249)	(177)	(104)
Other comprehensive income (loss)	(1,736)	(2,443)	(7,862)
Comprehensive income	$ 14,804	12,966	8,461

The tax effects in other comprehensive income for the fiscal years ended 2016, 2015 and 2014 respectively: Securities; $104 million, $187 million and $81 million, Employee Benefit Plans; $346 million, $519 million and $1,556 million, Derivatives & Hedges; $134 million, $95 million and $56 million.

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY
(Dollars in Millions) (Note 1)

	Total	Retained Earnings	Accumulated Other Comprehensive Income	Common Stock Issued Amount	Treasury Stock Amount
Balance, December 29, 2013	**$ 74,053**	**89,493**	**(2,860)**	**3,120**	**(15,700)**
Net earnings	16,323	16,323			
Cash dividends paid	(7,768)	(7,768)			
Employee compensation and stock option plans	2,164	(769)			2,933
Repurchase of common stock	(7,124)				(7,124)
Other	(34)	(34)			
Other comprehensive income (loss), net of tax	(7,862)		(7,862)		
Balance, December 28, 2014	**69,752**	**97,245**	**(10,722)**	**3,120**	**(19,891)**
Net earnings	15,409	15,409			
Cash dividends paid	(8,173)	(8,173)			
Employee compensation and stock option plans	1,920	(577)			2,497
Repurchase of common stock	(5,290)				(5,290)
Other	(25)	(25)			
Other comprehensive income (loss), net of tax	(2,443)		(2,443)		
Balance, January 3, 2016	**71,150**	**103,879**	**(13,165)**	**3,120**	**(22,684)**
Net earnings	16,540	16,540			
Cash dividends paid	(8,621)	(8,621)			
Employee compensation and stock option plans	2,130	(1,181)			3,311
Repurchase of common stock	(8,979)				(8,979)
Other	(66)	(66)			
Other comprehensive income (loss), net of tax	(1,736)		(1,736)		
Balance, January 1, 2017	**$ 70,418**	**110,551**	**(14,901)**	**3,120**	**(28,352)**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Dollars in Millions) (Note 1)

		2016	2015	2014
Cash flows from operating activities				
Net earnings	$	16,540	15,409	16,323
Adjustments to reconcile net earnings to cash flows from operating activities:				
Depreciation and amortization of property and intangibles		3,754	3,746	3,895
Stock based compensation		878	874	792
Venezuela adjustments		—	122	87
Asset write-downs		283	624	410
Net gain on sale of assets/businesses		(563)	(2,583)	(2,383)
Deferred tax provision		(341)	(270)	441
Accounts receivable allowances		(11)	18	(28)
Changes in assets and liabilities, net of effects from acquisitions and divestitures:				
Increase in accounts receivable		(1,065)	(433)	(247)
Increase in inventories		(249)	(449)	(1,120)
Increase in accounts payable and accrued liabilities		656	287	1,194
Decrease in other current and non-current assets		18	65	442
(Decrease)/Increase in other current and non-current liabilities		(1,133)	2,159	(1,096)
Net cash flows from operating activities		**18,767**	**19,569**	**18,710**
Cash flows from investing activities				
Additions to property, plant and equipment		(3,226)	(3,463)	(3,714)
Proceeds from the disposal of assets/businesses, net		1,267	3,464	4,631
Acquisitions, net of cash acquired (Note 20)		(4,509)	(954)	(2,129)
Purchases of investments		(33,950)	(40,828)	(34,913)
Sales of investments		35,780	34,149	24,119
Other (primarily intangibles)		(123)	(103)	(299)
Net cash used by investing activities		**(4,761)**	**(7,735)**	**(12,305)**
Cash flows from financing activities				
Dividends to shareholders		(8,621)	(8,173)	(7,768)
Repurchase of common stock		(8,979)	(5,290)	(7,124)
Proceeds from short-term debt		111	2,416	1,863
Retirement of short-term debt		(2,017)	(1,044)	(1,267)
Proceeds from long-term debt		12,004	75	2,098
Retirement of long-term debt		(2,223)	(68)	(1,844)
Proceeds from the exercise of stock options/employee withholding tax on stock awards, net		1,189	1,005	1,543
Other		(15)	(57)	—
Net cash used by financing activities		**(8,551)**	**(11,136)**	**(12,499)**
Effect of exchange rate changes on cash and cash equivalents		(215)	(1,489)	(310)
Increase/(Decrease) in cash and cash equivalents		5,240	(791)	(6,404)
Cash and cash equivalents, beginning of year (Note 1)		13,732	14,523	20,927
Cash and cash equivalents, end of year (Note 1)	**$**	**18,972**	**13,732**	**14,523**

Supplemental cash flow data				
Cash paid during the year for:				
Interest	$	730	617	603
Interest, net of amount capitalized		628	515	488
Income taxes		2,843	2,865	3,536

Supplemental schedule of non-cash investing and financing activities			
Treasury stock issued for employee compensation and stock option plans, net of cash proceeds/ employee withholding tax on stock awards	2,043	1,486	1,409
Conversion of debt	35	16	17

Acquisitions			
Fair value of assets acquired	$ 4,586	1,174	2,167
Fair value of liabilities assumed and noncontrolling interests	(77)	(220)	(38)
Net cash paid for acquisitions	**$ 4,509**	**954**	**2,129**

See Notes to Consolidated Financial Statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Johnson & Johnson and its subsidiaries (the Company). Intercompany accounts and transactions are eliminated.

Description of the Company and Business Segments

The Company has approximately 126,400 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world and its primary focus is on products related to human health and well-being.

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. The Consumer segment includes a broad range of products used in the baby care, oral care, beauty (previously referred to as skin care), over-the-counter pharmaceutical, women's health and wound care markets. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on five therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, and cardiovascular and metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, cardiovascular, diabetes care and vision care fields, which are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

New Accounting Pronouncements

Recently Adopted Accounting Pronouncements

During the fiscal first quarter of 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update 2016-09 Compensation - Stock Compensation: Improvements to Employee Share Based Payment Accounting. The amendments in the update are effective for annual periods beginning after December 15, 2016 and interim periods within those annual periods. Early adoption is permitted for any entity in any interim or annual period. During the fiscal second quarter of 2016, the Company elected to early adopt this standard. The update requires the following changes to presentation of the financial statements:

- All excess tax benefits and deficiencies to be recognized as a reduction or an increase to the provision for taxes on income. Previously, the Company recorded these benefits directly to Retained Earnings. The tax benefit for the Company was $353 million for the fiscal year 2016. The standard does not permit retroactive presentation of this benefit to prior fiscal years on the Consolidated Statement of Earnings.
- The tax benefit or deficiency is required to be classified and presented as a cash flow to/from operating activities. It was previously required to be presented as a cash flow to/from financing activities on the Consolidated Statement of Cash Flows. As permitted in the standard, the Company has elected to adopt this reclassification on a prospective basis and therefore prior fiscal years for the Consolidated Statement of Cash Flows have not been recast for this provision.
- Clarifies that all cash payments made to taxing authorities on employees' share-based compensation should be classified as a cash outflow from financing activities. This reclassification is required to be recast retrospectively. As a result, for the fiscal year 2016, $269 million was classified as a cash outflow from financing activities and $290 million and $239 million, of cash outflow was reclassified from an operating activity to a financing activity (Proceeds from the exercise of stock options/employee withholding tax on stock awards, net) in the fiscal years 2015 and 2014, respectively.
- In the diluted net earnings per share calculation, when applying the treasury stock method for shares that could be repurchased, the assumed proceeds no longer include the amount of excess tax benefit. This did not have a material impact on the Company's diluted net earnings per share calculation.

During the fiscal second quarter of 2015, the FASB issued Accounting Standards Update 2015-03: Simplifying the Presentation of Debt Issuance Costs. This update requires capitalized debt issuance costs to be presented as a reduction to the carrying value of debt instead of being classified as a deferred charge. This update is effective for the Company for all annual and interim periods beginning after December 15, 2015 and is required to be applied retroactively for all periods presented. This update did not have a material impact on the presentation of the Company's financial position.

During the fiscal third quarter of 2015, the FASB issued Accounting Standards Update 2015-16 Business Combinations: Simplifying the Accounting for Measurement-Period Adjustments. The amendments in this update require that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. This update is effective for the Company for all annual and interim periods beginning after December 15, 2015. The amendments in this update should be applied prospectively to adjustments to provisional amounts that occur after the effective date of this update with earlier application permitted for financial statements that have not been issued. This update did not have a material impact on the Company's consolidated financial statements.

During the fiscal third quarter of 2014, the FASB issued Accounting Standards Update No. 2014-15: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. This standard requires management to evaluate, for each annual and interim reporting period, whether there are conditions and events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date the financial statements are issued or are available to be issued. If substantial doubt is raised, additional disclosures around management's plan to alleviate these doubts are required. This update becomes effective for all annual periods and interim reporting periods ending after December 15, 2016. The adoption of this standard did not have any impact on the Company's current disclosures in the financial statements.

Recently Issued Accounting Pronouncements
Not Adopted as of January 1, 2017

During the fiscal first quarter of 2017, the FASB issued Accounting Standard Update 2017-01: Clarifying the Definition of a Business. This update narrows the definition of a business by providing a screen to determine when an integrated set of assets and activities is not a business. The screen specifies that an integrated set of assets and activities is not a business if substantially all of the fair value of the gross assets acquired or disposed of is concentrated in a single or a group of similar identifiable assets. This update will be effective for the Company for annual periods beginning after December 15, 2017, including interim periods within those annual periods. Early adoption is permitted. This update should be applied prospectively. The Company is currently assessing the impact of the future adoption of this standard on its financial statements.

During the fiscal first quarter of 2017, the FASB issued Accounting Standard Update 2017-04: Simplifying the Test for Goodwill Impairment. This update simplifies how an entity is required to test goodwill for impairment. A goodwill impairment will now be measured by the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. This update will be effective for the Company for its annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. Early adoption is permitted. This update should be applied prospectively. The Company is currently assessing the impact of the future adoption of this standard on its financial statements.

During the fiscal first quarter of 2017, the FASB issued Accounting Standard Update 2017-05: Other Income-Gains and Losses from the Derecognition of Nonfinancial Assets. This update clarifies the scope of asset derecognition guidance, adds guidance for partial sales of nonfinancial assets and clarifies recognizing gains and losses from the transfer of nonfinancial assets in contracts with noncustomers. This update will be effective for the Company for its annual and interim reporting periods beginning after December 15, 2017, the same time as the amendments in Update 2014-09 Revenue from Contracts with Customers. This update allows the Company to choose either a full retrospective method or modified retrospective method upon adoption. The Company is currently assessing the impact of the future adoption of this standard on its financial statements.

During the fiscal first quarter of 2016, the FASB issued Accounting Standards Update 2016-01 Financial Instruments: Recognition and Measurement of Financial Assets and Financial Liabilities. The amendments in this update supersede the guidance to classify equity securities with readily determinable fair values into different categories (that is, trading or available-for-sale) and require equity securities to be measured at fair value with changes in the fair value recognized through net income. The standard amends financial reporting by providing relevant information about an entity's equity investments and reducing the number of items that are recognized in other comprehensive income. This update will be effective for the Company for annual periods beginning after December 15, 2017, and interim periods within those annual periods. The Company is unable to estimate the impact of the future adoption of this standard on its financial statements as it will depend on the equity investments as of the adoption date.

During the fiscal first quarter of 2016, the FASB issued Accounting Standards Update 2016-02 Leases (Topic 842). This update requires the recognition of lease assets and lease liabilities on the balance sheet for all lease obligations and disclosing key information about leasing arrangements. This update requires the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under current generally accepted accounting principles. This update will be effective for the Company for all annual and interim periods beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. The update is required to be adopted using a modified retrospective approach. The Company anticipates that most of its operating leases will result in the recognition of additional assets and the corresponding liabilities on its Consolidated Balance Sheets, however does not expect to have a material impact on the financial position. The actual impact will depend on the Company's lease portfolio at the time of adoption. The Company continues to assess all implications of the standard and related financial disclosures.

During the fiscal first quarter of 2016, the FASB issued Accounting Standards Update 2016-07 Investments - Equity Method and Joint Ventures (Topic 323): Simplifying the Transition to the Equity Method of Accounting. The amendments in the update eliminate the requirement that when an investment qualifies for the use of the equity method as a result of an increase in the level of ownership interest or degree of influence, an investor must adjust the investment, results of operations, and retained earnings retroactively on a step by step basis as if the equity method had been in effect during all previous periods that the investment had been held. The amendments in this update are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. The amendments should be applied prospectively upon their effective date to increases in the level of ownership interest or degree of influence that result in the application of the equity method. Earlier adoption is permitted for any entity in any interim or annual period. The adoption of this standard is not expected to have a material impact on the presentation of the Company's consolidated financial statements.

During the fiscal third quarter of 2016, the FASB issued Accounting Standards Update 2016-15 Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. This update addresses whether to present certain specific cash flow items as operating, investing or financing activities. The amendments in this update are effective for public entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. Early adoption is permitted, including adoption in an interim period. The Company is currently assessing the impact of the future adoption of this standard on its consolidated Statements of Cash Flows.

During the fiscal fourth quarter of 2016, the FASB issued Accounting Standards Update 2016-16 Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory. This update removes the current exception in US GAAP prohibiting entities from recognizing current and deferred income tax expenses or benefits related to transfer of assets, other than inventory, within the consolidated entity. The current exception to defer the recognition of any tax impact on the transfer of inventory within the consolidated entity until it is sold to a third party remains unaffected. The amendments in this update are effective for public entities for annual reporting periods beginning after December 15, 2017. Early adoption is permitted and should be in the first interim period if an entity issues interim financial statements. The Company is currently assessing the impact of the future adoption of this standard on its consolidated financial statements.

During the fiscal second quarter of 2015, the FASB issued Accounting Standards Update 2015-11: Simplifying the Measurement of Inventory. This update requires inventory to be measured at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. This update will be effective for the Company for all annual and interim periods beginning after December 15, 2016. The amendments in this update should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. This update will not have a material impact on the presentation of the Company’s financial position.

During the fiscal second quarter of 2014, the FASB issued Accounting Standards Update 2014-09: Revenue from Contracts with Customers, which, along with amendments issued in 2015 and 2016, will replace substantially all current U.S. GAAP guidance on this topic and eliminate industry-specific guidance. Early adoption of this standard is permitted but not before the original effective date for all annual periods and interim reporting periods beginning after December 15, 2017. The guidance permits two methods of adoption: full retrospective method (retrospective application to each prior reporting period presented) or modified retrospective method (retrospective application with the cumulative effect of initially applying the guidance recognized at the date of initial application and providing certain additional disclosures). While the Company continues to evaluate the effect of the standard, preliminarily, it does not anticipate a material impact on its financial statements. To complete the assessment of the impact of the standard to the financial statements, the Company continues to assess all implications of the standard, method of adoption and related financial disclosures. Additionally, the Company continues to monitor modifications, clarifications and interpretations issued by the FASB that may affect current conclusions.

Cash Equivalents

The Company classifies all highly liquid investments with stated maturities of three months or less from date of purchase as cash equivalents and all highly liquid investments with stated maturities of greater than three months from the date of purchase as current marketable securities. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating. The Company invests its cash primarily in government securities and obligations, corporate debt securities, money market funds and reverse repurchase agreements (RRAs).

RRAs are collateralized by deposits in the form of Government Securities and Obligations for an amount not less than 102% of their value. The Company does not record an asset or liability as the Company is not permitted to sell or repledge the associated collateral. The Company has a policy that the collateral has at least an A (or equivalent) credit rating. The Company utilizes a third party custodian to manage the exchange of funds and ensure that collateral received is maintained at 102% of the value of the RRAs on a daily basis. RRAs with stated maturities of greater than three months from the date of purchase are classified as marketable securities.

Investments

Investments classified as held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings. Investments classified as available-for-sale are carried at estimated fair value with unrealized gains and losses

recorded as a component of accumulated other comprehensive income. Available-for-sale securities available for current operations are classified as current assets otherwise, they are classified as long term. Management determines the appropriate classification of its investment in debt and equity securities at the time of purchase and re-evaluates such determination at each balance sheet date. The Company periodically reviews its investments in equity securities for impairment and adjusts these investments to their fair value when a decline in market value is deemed to be other than temporary. If losses on these securities are considered to be other than temporary, the loss is recognized in earnings.

Property, Plant and Equipment and Depreciation
Property, plant and equipment are stated at cost. The Company utilizes the straight-line method of depreciation over the estimated useful lives of the assets:

Building and building equipment	20 - 30 years
Land and leasehold improvements	10 - 20 years
Machinery and equipment	2 - 13 years

The Company capitalizes certain computer software and development costs, included in machinery and equipment, when incurred in connection with developing or obtaining computer software for internal use. Capitalized software costs are amortized over the estimated useful lives of the software, which generally range from 3 to 8 years.

The Company reviews long-lived assets to assess recoverability using undiscounted cash flows. When certain events or changes in operating or economic conditions occur, an impairment assessment may be performed on the recoverability of the carrying value of these assets. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows.

Revenue Recognition
The Company recognizes revenue from product sales when the goods are shipped or delivered and title and risk of loss pass to the customer. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns and discounts to customers are accounted for as reductions in sales in the same period the related sales are recorded.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including prices charged by competitors. Rebates, which include Medicaid, are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns are generally estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales returns accruals.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual sales to customers during the fiscal reporting years 2016, 2015 and 2014.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the year incurred. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. The Company also earns service revenue for co-promotion of certain products and includes it in sales to customers. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue.

Shipping and Handling
Shipping and handling costs incurred were $974 million, $996 million and $1,068 million in 2016, 2015 and 2014, respectively, and are included in selling, marketing and administrative expense. The amount of revenue received for shipping and handling is less than 0.5% of sales to customers for all periods presented.

Inventories
Inventories are stated at the lower of cost or market determined by the first-in, first-out method.

Intangible Assets and Goodwill

The authoritative literature on U.S. GAAP requires that goodwill and intangible assets with indefinite lives be assessed annually for impairment. The Company completed the annual impairment test for 2016 in the fiscal fourth quarter. Future impairment tests will be performed annually in the fiscal fourth quarter, or sooner if warranted. Purchased in-process research and development is accounted for as an indefinite lived intangible asset until the underlying project is completed, at which point the intangible asset will be accounted for as a definite lived intangible asset, or abandoned, at which point the intangible asset will be written off or partially impaired.

Intangible assets that have finite useful lives continue to be amortized over their useful lives, and are reviewed for impairment when warranted by economic conditions. See Note 5 for further details on Intangible Assets and Goodwill.

Financial Instruments

As required by U.S. GAAP, all derivative instruments are recorded on the balance sheet at fair value. Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value, with Level 1 having the highest priority and Level 3 having the lowest. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The Company documents all relationships between hedged items and derivatives. The overall risk management strategy includes reasons for undertaking hedge transactions and entering into derivatives. The objectives of this strategy are: (1) minimize foreign currency exposure's impact on the Company's financial performance; (2) protect the Company's cash flow from adverse movements in foreign exchange rates; (3) ensure the appropriateness of financial instruments; and (4) manage the enterprise risk associated with financial institutions. See Note 6 for additional information on Financial Instruments.

Product Liability

Accruals for product liability claims are recorded, on an undiscounted basis, when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated based on existing information and actuarially determined estimates where applicable. The accruals are adjusted periodically as additional information becomes available. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated.

As a result of cost and availability factors, effective November 1, 2005, the Company ceased purchasing third-party product liability insurance. The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated. Based on the availability of prior coverage, receivables for insurance recoveries related to product liability claims are recorded on an undiscounted basis, when it is probable that a recovery will be realized. As appropriate, reserves against these receivables are recorded for estimated amounts that may not be collected from third-party insurers.

Concentration of Credit Risk

Global concentration of credit risk with respect to trade accounts receivables continues to be limited due to the large number of customers globally and adherence to internal credit policies and credit limits. Economic challenges in Italy, Spain, Greece and Portugal (the Southern European Region) have impacted certain payment patterns, which have historically been longer than those experienced in the U.S. and other international markets. The total net trade accounts receivable balance in the Southern European Region was approximately $1.1 billion as of January 1, 2017 and approximately $1.3 billion as of January 3, 2016. Approximately $0.7 billion as of January 1, 2017 and approximately $0.8 billion as of January 3, 2016 of the Southern European Region net trade accounts receivable balance related to the Company's Consumer, Vision Care and Diabetes Care businesses as well as certain Pharmaceutical and Medical Devices customers which are in line with historical collection patterns.

The remaining balance of net trade accounts receivable in the Southern European Region has been negatively impacted by the timing of payments from certain government owned or supported health care customers, as well as certain distributors of the Pharmaceutical and Medical Devices local affiliates. The total net trade accounts receivable balance for these customers were approximately $0.4 billion at January 1, 2017 and $0.5 billion at January 3, 2016. The Company continues to receive payments from these customers and, in some cases, late payments with interest. For customers where payment is expected over periods of time longer than one year, revenue and trade receivables have been discounted over the estimated period of time for collection. Allowances for doubtful accounts have been increased for these customers, but have been immaterial to date. The Company will continue to work closely with these customers on payment plans, monitor the economic situation and take appropriate actions as necessary.

Research and Development

Research and development expenses are expensed as incurred. Upfront and milestone payments made to third parties in connection with research and development collaborations are expensed as incurred up to the point of regulatory approval. Payments made to third parties subsequent to regulatory approval are capitalized and amortized over the remaining useful life of the related product. Amounts capitalized for such payments are included in other intangibles, net of accumulated amortization.

The Company enters into collaborative arrangements, typically with other pharmaceutical or biotechnology companies, to develop and commercialize drug candidates or intellectual property. These arrangements typically involve two (or more) parties who are active participants in the collaboration and are exposed to significant risks and rewards dependent on the commercial success of the activities. These collaborations usually involve various activities by one or more parties, including research and development, marketing and selling and distribution. Often, these collaborations require upfront, milestone and royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development. Amounts due from collaborative partners related to development activities are generally reflected as a reduction of research and development expense because the performance of contract development services is not central to the Company's operations. In general, the income statement presentation for these collaborations is as follows:

Nature/Type of Collaboration	Statement of Earnings Presentation
Third-party sale of product	Sales to customers
Royalties/milestones paid to collaborative partner (post-regulatory approval)*	Cost of products sold
Royalties received from collaborative partner	Other income (expense), net
Upfront payments & milestones paid to collaborative partner (pre-regulatory approval)	Research and development expense
Research and development payments to collaborative partner	Research and development expense
Research and development payments received from collaborative partner	Reduction of Research and development expense

* Milestones are capitalized as intangible assets and amortized to cost of goods sold over the useful life.

For all years presented, there was no individual project that represented greater than 5% of the total annual consolidated research and development expense.

The Company has a number of products and compounds developed in collaboration with strategic partners including XARELTO®, co-developed with Bayer HealthCare AG and IMBRUVICA®, developed in collaboration and co-marketed with Pharmacyclics LLC, an AbbVie company.

Advertising

Costs associated with advertising are expensed in the year incurred and are included in selling, marketing and administrative expenses. Advertising expenses worldwide, which comprised television, radio, print media and Internet advertising, were $2.4 billion, $2.5 billion and $2.6 billion in 2016, 2015 and 2014, respectively.

Income Taxes

Income taxes are recorded based on amounts refundable or payable for the current year and include the results of any difference between U.S. GAAP accounting and tax reporting, recorded as deferred tax assets or liabilities. The Company estimates deferred tax assets and liabilities based on enacted tax regulations and rates. Future changes in tax laws and rates may affect recorded deferred tax assets and liabilities in the future.

The Company has unrecognized tax benefits for uncertain tax positions. The Company follows U.S. GAAP which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Management believes that changes in these estimates would not have a material effect on the Company's results of operations, cash flows or financial position.

At January 1, 2017 and January 3, 2016, the cumulative amounts of undistributed international earnings were approximately $66.2 billion and $58.0 billion, respectively. At January 1, 2017 and January 3, 2016, the Company's foreign subsidiaries held balances of cash, cash equivalents and marketable securities in the amounts of $41.3 billion and $38.2 billion, respectively. The Company has not provided deferred taxes on the undistributed earnings from certain international subsidiaries where the earnings are considered to be indefinitely reinvested. The Company intends to continue to reinvest these earnings in international operations. If the Company decided at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company does not determine the deferred tax liability associated with these undistributed earnings, as such determination is not practical.

See Note 8 to the Consolidated Financial Statements for further information regarding income taxes.

Net Earnings Per Share
Basic earnings per share is computed by dividing net earnings available to common shareholders by the weighted average number of common shares outstanding for the period. Diluted earnings per share reflects the potential dilution that could occur if securities were exercised or converted into common stock using the treasury stock method.

Use of Estimates
The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the amounts reported. Estimates are used when accounting for sales discounts, rebates, allowances and incentives, product liabilities, income taxes, depreciation, amortization, employee benefits, contingencies and intangible asset and liability valuations. Actual results may or may not differ from those estimates.

The Company follows the provisions of U.S. GAAP when recording litigation related contingencies. A liability is recorded when a loss is probable and can be reasonably estimated. The best estimate of a loss within a range is accrued; however, if no estimate in the range is better than any other, the minimum amount is accrued.

Annual Closing Date
The Company follows the concept of a fiscal year, which ends on the Sunday nearest to the end of the month of December. Normally each fiscal year consists of 52 weeks, but every five or six years the fiscal year consists of 53 weeks, and therefore includes additional shipping days, as was the case in 2015, and will be the case again in 2020.

Reclassification
Certain prior period amounts have been reclassified to conform to current year presentation.

2. Cash, Cash Equivalents and Current Marketable Securities

At the end of 2016 and 2015, cash, cash equivalents and current marketable securities were comprised of:

(Dollars in Millions)	2016					
	Carrying Amount	Unrecognized Gain	Unrecognized Loss	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	$ 1,979	—	—	1,979	$ 1,979	—
U.S. Gov't Securities[1]	10,832	—	(1)	10,831	2,249	8,583
Other Sovereign Securities[1]	1,299	—	—	1,299	120	1,179
U.S. Reverse repurchase agreements	6,103	—	—	6,103	6,103	—
Other Reverse repurchase agreements	240	—	—	240	240	—
Corporate debt securities[1]	754	—	—	754	—	754
Money market funds	7,187	—	—	7,187	7,187	—
Time deposits[1]	1,094	—	—	1,094	1,094	—
Subtotal	$ 29,488	—	(1)	29,487	18,972	10,516
		Unrealized Gain	Unrealized Loss			
Gov't Securities	$ 10,277	5	(51)	10,231	—	10,231
Other Sovereign Securities	90	—	—	90		90
Corporate debt securities	1,777	1	(12)	1,766	—	1,766
Equity investments	34	298		332		332
Subtotal available for sale[2]	$ 12,178	304	(63)	12,419	—	12,419
Total cash, cash equivalents and current marketable securities					$ 18,972	22,935

(Dollars in Millions)	2015					
	Carrying Amount	Unrecognized Gain	Unrecognized Loss	Estimated Fair Value	Cash Equivalents	Current Marketable Securities
Cash	$ 1,832	—	—	1,832	1,832	—
U.S. Gov't Securities[1]	14,641	1	(2)	14,640	650	13,991
Other Sovereign Securities[1]	2,122	—	—	2,122	933	1,189
U.S. Reverse repurchase agreements	1,579	—	—	1,579	1,579	—
Other Reverse repurchase agreements	2,200	—	—	2,200	2,200	—
Corporate debt securities[1]	2,941	—	—	2,941	1,793	1,148
Money market funds	3,855	—	—	3,855	3,855	—
Time deposits[1]	890	—	—	890	890	—
Subtotal	$ 30,060	1	(2)	30,059	13,732	16,328
		Unrealized Gain	Unrealized Loss			
Gov't Securities	$ 7,307	1	(34)	7,274	—	7,274
Other Sovereign Securities	—	—	—	—		—
Corporate debt securities	1,046	1	(5)	1,042	—	1,042
Subtotal available for sale[2]	$ 8,353	2	(39)	8,316	—	8,316
Total cash, cash equivalents and current marketable securities					$ 13,732	24,644

[1] Held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings.
[2] Available for sale securities are reported at fair value with unrealized gains and losses reported net of taxes in other comprehensive income.

Fair value of government securities and obligations and corporate debt securities were estimated using quoted broker prices and significant other observable inputs.

The contractual maturities of the available for sale debt securities at January 1, 2017 are as follows:

(Dollars in Millions)	Cost Basis	Fair Value
Due within one year	$ 474	474
Due after one year through five years	11,430	11,381
Due after five years through ten years	240	232
Total debt securities	$ 12,144	12,087

The Company invests its excess cash in both deposits with major banks throughout the world and other high-quality money market instruments. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating.

3. Inventories

At the end of 2016 and 2015, inventories were comprised of:

(Dollars in Millions)	2016	2015
Raw materials and supplies	$ 952	936
Goods in process	2,185	2,241
Finished goods	5,007	4,876
Total inventories	**$ 8,144**	**8,053**

4. Property, Plant and Equipment

At the end of 2016 and 2015, property, plant and equipment at cost and accumulated depreciation were:

(Dollars in Millions)		2016	2015
Land and land improvements	$	753	780
Buildings and building equipment		10,112	9,829
Machinery and equipment		23,554	22,511
Construction in progress		3,354	3,528
Total property, plant and equipment, gross	$	37,773	36,648
Less accumulated depreciation		21,861	20,743
Total property, plant and equipment, net	**$**	**15,912**	**15,905**

The Company capitalizes interest expense as part of the cost of construction of facilities and equipment. Interest expense capitalized in 2016, 2015 and 2014 was $102 million, $102 million and $115 million, respectively.

Depreciation expense, including the amortization of capitalized interest was $2.5 billion in 2016, 2015 and 2014.

Upon retirement or other disposal of property, plant and equipment, the costs and related amounts of accumulated depreciation or amortization are eliminated from the asset and accumulated depreciation accounts, respectively. The difference, if any, between the net asset value and the proceeds are recorded in earnings.

5. Intangible Assets and Goodwill

At the end of 2016 and 2015, the gross and net amounts of intangible assets were:

(Dollars in Millions)		2016	2015
Intangible assets with definite lives:			
Patents and trademarks — gross	$	10,521	8,299
Less accumulated amortization		5,076	4,745
Patents and trademarks — net	**$**	**5,445**	**3,554**
Customer relationships and other intangibles — gross	$	17,615	17,583
Less accumulated amortization		6,515	5,816
Customer relationships and other intangibles — net	**$**	**11,100**	**11,767**
Intangible assets with indefinite lives:			
Trademarks	$	6,888	7,023
Purchased in-process research and development		3,443	3,420
Total intangible assets with indefinite lives	**$**	**10,331**	**10,443**
Total intangible assets — net	**$**	**26,876**	**25,764**

Goodwill as of January 1, 2017 and January 3, 2016, as allocated by segment of business, was as follows:

(Dollars in Millions)		Consumer	Pharmaceutical	Med Devices	Total
Goodwill at December 28, 2014	$	7,675	2,626	11,531	21,832
Goodwill, related to acquisitions		110	366	34	510
Goodwill, related to divestitures		(119)	(17)	(57)	(193)
Currency translation/other		(426)	(86)	(8)	(520)
Goodwill at January 3, 2016	$	7,240	2,889	11,500	21,629
Goodwill, related to acquisitions		1,362	—	210	1,572
Goodwill, related to divestitures		(63)	(12)	—	(75)
Currency translation/other		(276)	(37)	(8)	(321)
Goodwill at January 1, 2017	**$**	**8,263**	**2,840**	**11,702**	**22,805**

The weighted average amortization periods for patents and trademarks and customer relationships and other intangible assets are 19 years and 24 years, respectively. The amortization expense of amortizable assets included in cost of products sold was $1.2 billion, $1.2 billion and $1.4 billion before tax, for the fiscal years ended January 1, 2017, January 3, 2016 and December 28, 2014, respectively. The estimated amortization expense, including Abbott Medical Optics (AMO), for the five succeeding years approximates $1.5 billion before tax, per year. Intangible asset write-downs are included in Other (income) expense, net.

See Note 20 to the Consolidated Financial Statements for additional details related to acquisitions and divestitures.

6. Fair Value Measurements

The Company uses forward foreign exchange contracts to manage its exposure to the variability of cash flows, primarily related to the foreign exchange rate changes of future intercompany products and third-party purchases of materials denominated in a foreign currency. The Company uses cross currency interest rate swaps to manage currency risk primarily related to borrowings. The Company also uses equity collar contracts to manage exposure to market risk associated with certain equity investments. All three types of derivatives are designated as cash flow hedges.

Additionally, the Company uses interest rate swaps as an instrument to manage interest rate risk related to fixed rate borrowings. These derivatives are treated as fair value hedges. The Company uses forward foreign exchange contracts designated as net investment hedges. Additionally, the Company uses forward foreign exchange contracts to offset its exposure to certain foreign currency assets and liabilities. These forward foreign exchange contracts are not designated as hedges and therefore, changes in the fair values of these derivatives are recognized in earnings, thereby offsetting the current earnings effect of the related foreign currency assets and liabilities.

The Company does not enter into derivative financial instruments for trading or speculative purposes, or that contain credit risk related contingent features or requirements to post collateral (excluding equity collar contract) by either the Company or the counter-party. For equity collar contracts, the Company pledged the underlying hedged marketable equity securities to the counter-party as collateral. On an ongoing basis, the Company monitors counterparty credit ratings. The Company considers credit non-performance risk to be low, because the Company primarily enters into agreements with commercial institutions that have at least an investment grade credit rating. Refer to the table on significant financial assets and liabilities measured at fair value contained in this footnote for receivables and payables with these commercial institutions. As of January 1, 2017, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps, interest rate swaps and equity collar contracts of $36.0 billion, $2.3 billion, $1.8 billion and $0.3 billion respectively.

All derivative instruments are recorded on the balance sheet at fair value. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The designation as a cash flow hedge is made at the entrance date of the derivative contract. At inception, all derivatives are expected to be highly effective. Changes in the fair value of a derivative that is designated as a cash flow hedge and is highly effective are recorded in accumulated other comprehensive income until the underlying transaction affects earnings, and are then reclassified to earnings in the same account as the hedged transaction. Gains and losses associated with interest rate swaps and changes in fair value of hedged debt attributable to changes in interest rates are recorded to interest expense in the period in which they occur. Gains and losses on net investment hedges are accounted for through the currency translation account. On an ongoing basis, the Company assesses whether each derivative continues to be highly effective in offsetting changes of hedged items. If and when a derivative is no longer expected to be highly effective, hedge accounting is discontinued. Hedge ineffectiveness, if any, is included in current period earnings in Other (income) expense, net for forward foreign exchange contracts, cross currency interest rate swaps, net investment hedges and equity collar contracts. For interest rate swaps designated as fair value hedges, hedge ineffectiveness, if any, is included in current period earnings within interest expense. For the current reporting period, hedge ineffectiveness associated with interest rate swaps was not material.

During the fiscal second quarter of 2016, the Company designated its Euro denominated notes issued in May 2016 with due dates ranging from 2022 to 2035 as a net investment hedge of the Company's investments in certain of its international subsidiaries that use the Euro as their functional currency in order to reduce the volatility caused by changes in exchange rates.

During 2016, the change in the carrying value due to remeasurement of these Euro notes resulted in a $375 million pretax gain reflected in foreign currency translation adjustment, within the Consolidated Statements of Comprehensive Income.

As of January 1, 2017, the balance of deferred net losses on derivatives included in accumulated other comprehensive income was $285 million after-tax. For additional information, see the Consolidated Statements of Comprehensive Income and Note 13. The Company expects that substantially all of the amounts related to forward foreign exchange contracts will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months, excluding interest rate contracts, net investment hedges and equity collar contracts. The amount ultimately realized in earnings may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity of the derivative.

The following table is a summary of the activity related to derivatives designated as cash flow hedges for the fiscal years ended January 1, 2017 and January 3, 2016:

(Dollars in Millions)	Gain/(Loss) Recognized In Accumulated OCI[1]		Gain/(Loss) Reclassified From Accumulated OCI Into Income[1]		Gain/(Loss) Recognized In Other Income/Expense[2]	
Cash Flow Hedges by Income Statement Caption	**2016**	**2015**	**2016**	**2015**	**2016**	**2015**
Sales to customers [3]	$ (65)	(83)	(47)	(126)	(1)	(5)
Cost of products sold [3]	(212)	(22)	(3)	122	(15)	14
Research and development expense [3]	(76)	(3)	(90)	6	—	1
Interest (income)/Interest expense, net [4]	66	(40)	37	—	—	—
Other (income) expense, net [3][5]	(72)	33	(7)	60	2	1
Total	**$ (359)**	**(115)**	**(110)**	**62**	**(14)**	**11**

All amounts shown in the table above are net of tax.

(1) Effective portion

(2) Ineffective portion

(3) Forward foreign exchange contracts

(4) Cross currency interest rate swaps

(5) Includes equity collar contracts

For the fiscal years ended January 1, 2017 and January 3, 2016, a loss of $56 million and a loss of $34 million, respectively, was recognized in Other (income) expense, net, relating to forward foreign exchange contracts not designated as hedging instruments.

Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described below with Level 1 having the highest priority and Level 3 having the lowest.

The fair value of a derivative financial instrument (i.e. forward foreign exchange contracts, interest rate contracts) is the aggregation by currency of all future cash flows discounted to its present value at the prevailing market interest rates and subsequently converted to the U.S. Dollar at the current spot foreign exchange rate. The Company does not believe that fair values of these derivative instruments materially differ from the amounts that could be realized upon settlement or maturity, or that the changes in fair value will have a material effect on the Company's results of operations, cash flows or financial position. The Company also holds equity investments which are classified as Level 1 and debt securities which are classified as Level 2. The Company did not have any other significant financial assets or liabilities which would require revised valuations under this standard that are recognized at fair value.

The following three levels of inputs are used to measure fair value:

Level 1 — Quoted prices in active markets for identical assets and liabilities.

Level 2 — Significant other observable inputs.

Level 3 — Significant unobservable inputs.

The Company's significant financial assets and liabilities measured at fair value as of January 1, 2017 and January 3, 2016 were as follows:

(Dollars in Millions)	2016 Level 1	2016 Level 2	2016 Level 3	2016 Total	2015 Total [1]
Derivatives designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts [7]	$ —	747	—	747	452
Interest rate contracts [2][4][7]	—	31	—	31	28
Total	—	**778**	—	**778**	**480**
Liabilities:					
Forward foreign exchange contracts [8]	—	723	—	723	358
Interest rate contracts [3][4][8]	—	382	—	382	241
Equity collar contracts [8]	—	57	—	57	—
Total	—	**1,162**	—	**1,162**	**599**
Derivatives not designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts [7]	—	34	—	34	33
Liabilities:					
Forward foreign exchange contracts [8]	—	57	—	57	41
Available For Sale Other Investments:					
Equity investments [5]	1,209	—	—	1,209	1,494
Debt securities [6]	$ —	12,087	—	12,087	8,316

(1) 2015 assets and liabilities are all classified as Level 2 with the exception of equity investments of $1,494 million, which are classified as Level 1.
(2) Includes $23 million and $20 million of non-current assets for the fiscal years ending January 1, 2017 and January 3, 2016, respectively.
(3) Includes $382 million and $239 million of non-current liabilities for the fiscal years ending January 1, 2017 and January 3, 2016, respectively.
(4) Includes cross currency interest rate swaps and interest rate swaps.
(5) Classified as non-current other assets with the exception of $332 million of current assets for January 1, 2017. The carrying amount of the equity investments were $520 million and $528 million as of January 1, 2017 and January 3, 2016, respectively. The unrealized gains were $757 million and $979 million as of January 1, 2017 and January 3, 2016, respectively. The unrealized losses were $68 million and $13 million as of January 1, 2017 and January 3, 2016, respectively.
(6) Classified as current marketable securities.
(7) Classified as other current assets.
(8) Classified as accounts payable.

See Notes 2 and 7 for financial assets and liabilities held at carrying amount on the Consolidated Balance Sheet.

7. Borrowings

The components of long-term debt are as follows:

(Dollars in Millions)	2016	Effective Rate %	2015	Effective Rate %
2.15% Notes due 2016	$ —	—	900	2.22
3 month LIBOR+0.07% FRN due 2016	—	—	800	0.48
0.70% Notes due 2016	—	—	398	0.74
5.55% Debentures due 2017	1,000	5.55	1,000	5.55
1.125% Notes due 2017	699	1.15	700	1.15
5.15% Debentures due 2018	899	5.18	899	5.15
1.65% Notes due 2018	600	1.70	602	1.70
4.75% Notes due 2019 (1B Euro 1.0449)[2]/(1B Euro 1.0882)[3]	1,041 [2]	5.83	1,085 [3]	5.83
1.875% Notes due 2019	499	1.93	502	1.93
0.89% Notes due 2019	299	1.20	—	—
1.125% Notes due 2019	699	1.13	—	—
3% Zero Coupon Convertible Subordinated Debentures due 2020	84	3.00	137	3.00
2.95% Debentures due 2020	546	3.15	545	3.15
3.55% Notes due 2021	447	3.67	448	3.67
2.45% Notes due 2021	348	2.48	349	2.48
1.65% Notes due 2021	997	1.65	—	—
0.250% Notes due 2022 (1B Euro 1.0449)[2]	1,041 [2]	0.26	—	—
6.73% Debentures due 2023	249	6.73	250	6.73
3.375% Notes due 2023	807	3.17	811	3.17
2.05% Notes due 2023	497	2.09	—	—
0.650% Notes due 2024(750MM Euro 1.0449)[2]	779 [2]	0.68	—	—
5.50% Notes due 2024 (500MM GBP 1.2237)[2]/(500MM GBP 1.4818)[3]	605 [2]	6.75	737 [3]	6.75
2.45% Notes due 2026	1,989	2.47	—	—
1.150% Notes due 2028(750MM Euro 1.0449)[2]	775 [2]	1.21	—	—
6.95% Notes due 2029	296	7.14	297	7.14
4.95% Debentures due 2033	497	4.95	500	4.95
4.375% Notes due 2033	857	4.24	864	4.24
1.650% Notes due 2035 (1.5B Euro 1.0449)[2]	1,549 [2]	1.68	—	—
3.55% Notes due 2036	987	3.59	—	—
5.95% Notes due 2037	990	5.99	996	5.99
5.85% Debentures due 2038	695	5.85	700	5.86
4.50% Debentures due 2040	537	4.63	540	4.63
4.85% Notes due 2041	296	4.89	298	4.89
4.50% Notes due 2043	495	4.52	499	4.52
3.70% Notes due 2046	1,970	3.74	—	—
Other	77	—	104	—
Subtotal	**24,146** [4]	**3.33%** [1]	**14,961** [4]	**4.06** [1]
Less current portion	1,704		2,104	
Total long-term debt	**$ 22,442**		**12,857**	

(1) Weighted average effective rate.
(2) Translation rate at January 1, 2017.

(3) Translation rate at January 3, 2016.
(4) The excess of the fair value over the carrying value of debt was $1.6 billion in 2016 and $1.7 billion in 2015.

Fair value of the long-term debt was estimated using market prices, which were corroborated by quoted broker prices and significant other observable inputs.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2016, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 14, 2017. Interest charged on borrowings under the credit line agreements is based on either bids provided by banks, the prime rate or London Interbank Offered Rates (LIBOR), plus applicable margins. Commitment fees under the agreements are not material.

Throughout 2016, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $4.7 billion at the end of 2016, of which $2.7 billion was borrowed under the Commercial Paper Program. The remainder principally represents local borrowing by international subsidiaries.

Throughout 2015, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $7.0 billion at the end of 2015, of which $4.6 billion was borrowed under the Commercial Paper Program. The remainder principally represents local borrowing by international subsidiaries.

Aggregate maturities of long-term obligations commencing in 2017 are:

(Dollars in Millions)					
2017	**2018**	**2019**	**2020**	**2021**	**After 2021**
$1,704	1,561	2,538	629	1,795	15,919

8. Income Taxes

The provision for taxes on income consists of:

(Dollars in Millions)	2016	2015	2014
Currently payable:			
U.S. taxes	$ 1,896	2,748	2,625
International taxes	1,708	1,309	1,174
Total currently payable	3,604	4,057	3,799
Deferred:			
U.S. taxes	294	37	(258)
International taxes	(635)	(307)	699
Total deferred	(341)	(270)	441
Provision for taxes on income	**$ 3,263**	**3,787**	**4,240**

A comparison of income tax expense at the U.S. statutory rate of 35% in 2016, 2015 and 2014, to the Company's effective tax rate is as follows:

(Dollars in Millions)	2016	2015	2014
U.S.	$ 7,457	8,179	8,001
International	12,346	11,017	12,562
Earnings before taxes on income:	$ 19,803	19,196	20,563
Tax rates:			
U.S. statutory rate	35.0 %	35.0	35.0
International operations excluding Ireland	(9.4)	(6.7)	(7.0)
Ireland and Puerto Rico operations[1]	(7.8)	(8.7)	(6.9)
Research and orphan drug tax credits	(0.4)	(0.2)	(0.3)
U.S. state and local	(0.1)	0.4	1.0
U.S. manufacturing deduction	(0.6)	(0.6)	(0.6)
U.S. tax on international income	1.3	0.2	1.4
Additional tax benefits on share based compensation	(1.8)	—	—
U.S. tax benefit on asset/business disposals	—	—	(1.9)
All other	0.3	0.3	(0.1)
Effective tax rate	16.5 %	19.7	20.6

[1]The Company has subsidiaries operating in Puerto Rico under various tax incentives.

The 2016 effective tax rate decreased by 3.2% as compared to 2015. As described in Note 1, the Company adopted a new accounting standard for the reporting of additional tax benefits on share-based compensation that vested or were exercised during the fiscal year. The adoption of this new standard reduced the effective tax rate of fiscal 2016 by 1.8% versus 2015.
The remainder of the change in the effective tax rate was primarily related to the lower earnings before taxes in the United States and the settlement of several uncertain tax positions in 2016 versus 2015.

The decrease in the 2015 effective tax rate, as compared to 2014, was primarily attributable to the increases in taxable income in lower tax jurisdictions relative to higher tax jurisdictions and a tax benefit resulting from a restructuring of international affiliates. Additionally, the 2014 effective tax rate was affected by the items mentioned below.

The increase in the 2014 effective tax rate, as compared to 2013, was attributable to the following: the divestiture of the Ortho-Clinical Diagnostics business at an approximate 44% effective tax rate, litigation accruals at low tax rates, the mix of earnings into higher tax jurisdictions, primarily the U.S., the accrual of an additional year of the Branded Prescription Drug Fee, which is not tax deductible, and additional U.S. tax expense related to a planned increase in dividends from current year foreign earnings as compared to the prior year. These increases to the 2014 effective tax rate were partially offset by a tax benefit of $0.4 billion associated with the Conor Medsystems divestiture.

The 2014 effective tax rate was also reduced as the Company adjusted its unrecognized tax benefits as a result of (i) the federal appeals court's decision in OMJ Pharmaceuticals, Inc.'s litigation regarding credits under former Section 936 of the Internal Revenue Code and (ii) a settlement of substantially all issues related to the Company's U.S. Internal Revenue Service audit of tax years 2006 - 2009. The impact of the settlement is reflected in the U.S. tax on international income and the All other line items within the above reconciliation.

The items noted above reflect the key drivers of the rate reconciliation.

Temporary differences and carryforwards for 2016 and 2015 were as follows:

	2016 Deferred Tax		2015 Deferred Tax	
(Dollars in Millions)	**Asset**	**Liability**	**Asset**	**Liability**
Employee related obligations	$ 2,958		2,863	
Stock based compensation	749		790	
Depreciation		(219)		(247)
Non-deductible intangibles		(6,672)		(6,663)
International R&D capitalized for tax	1,264		1,318	
Reserves & liabilities	1,857		1,801	
Income reported for tax purposes	1,309		960	
Net operating loss carryforward international	717		997	
Miscellaneous international	1,135	(15)	922 (1)	(249)
Miscellaneous U.S.	155		436	
Total deferred income taxes	**$ 10,144**	**(6,906)**	**10,087**	**(7,159)**

(1) Net of a valuation allowance related to Belgium of $196 million. In 2016, this allowance was reversed and the related deferred tax asset was utilized to reduce current tax expense.

The Company has wholly-owned international subsidiaries that have cumulative net losses. The Company believes that it is more likely than not that these subsidiaries will realize future taxable income sufficient to utilize these deferred tax assets.

The following table summarizes the activity related to unrecognized tax benefits:

(Dollars in Millions)	**2016**	**2015**	**2014**
Beginning of year	$ 3,080	2,465	2,729
Increases related to current year tax positions	348	570	281
Increases related to prior period tax positions	11	182	295
Decreases related to prior period tax positions	(338)	(79)	(288)
Settlements	(37)	(4)	(477)
Lapse of statute of limitations	(23)	(54)	(75)
End of year	**$ 3,041**	**3,080**	**2,465**

The unrecognized tax benefits of $3.0 billion at January 1, 2017, if recognized, would affect the Company's annual effective tax rate. The Company conducts business and files tax returns in numerous countries and currently has tax audits in progress with a number of tax authorities. The IRS has completed its audit for the tax years through 2009 and is currently auditing the tax years 2010-2012. In other major jurisdictions where the Company conducts business, the years remain open generally back to the year 2004. The Company believes it is possible that audits may be completed by tax authorities in some jurisdictions over the next twelve months. However, the Company is not able to provide a reasonably reliable estimate of the timing of any other future tax payments relating to uncertain tax positions.

The Company classifies liabilities for unrecognized tax benefits and related interest and penalties as long-term liabilities. Interest expense and penalties related to unrecognized tax benefits are classified as income tax expense. The Company recognized after tax interest expense of $7 million, $44 million and $12 million in 2016, 2015 and 2014, respectively. The total amount of accrued interest was $344 million and $366 million in 2016 and 2015, respectively.

9. Employee Related Obligations

At the end of 2016 and 2015, employee related obligations recorded on the Consolidated Balance Sheets were:

(Dollars in Millions)	2016	2015
Pension benefits	$ 4,710	3,857
Postretirement benefits	2,733	2,738
Postemployment benefits	2,050	2,092
Deferred compensation	534	584
Total employee obligations	10,027	9,271
Less current benefits payable	412	417
Employee related obligations — non-current	**$ 9,615**	**8,854**

Prepaid employee related obligations of $227 million and $256 million for 2016 and 2015, respectively, are included in Other assets on the Consolidated Balance Sheets.

10. Pensions and Other Benefit Plans

The Company sponsors various retirement and pension plans, including defined benefit, defined contribution and termination indemnity plans, which cover most employees worldwide. The Company also provides post-retirement benefits, primarily health care, to all eligible U.S. retired employees and their dependents.

Many international employees are covered by government-sponsored programs and the cost to the Company is not significant.

Retirement plan benefits for employees hired before January 1, 2015 are primarily based on the employee's compensation during the last three to five years before retirement and the number of years of service. In 2014, the Company announced that the U.S. Defined Benefit plan was amended to adopt a new benefit formula, effective for employees hired on or after January 1, 2015. The benefits are calculated using a new formula based on employee compensation over total years of service.

International subsidiaries have plans under which funds are deposited with trustees, annuities are purchased under group contracts, or reserves are provided.

The Company does not fund retiree health care benefits in advance and has the right to modify these plans in the future.

In 2016 and 2015 the Company used December 31, 2016 and December 31, 2015, respectively, as the measurement date for all U.S. and international retirement and other benefit plans.

Net periodic benefit costs for the Company's defined benefit retirement plans and other benefit plans for 2016, 2015 and 2014 include the following components:

	Retirement Plans			Other Benefit Plans		
(Dollars in Millions)	2016	2015	2014	2016	2015	2014
Service cost	$ 949	1,037	882	224	257	211
Interest cost	927	988	1,018	158	186	197
Expected return on plan assets	(1,962)	(1,809)	(1,607)	(6)	(7)	(7)
Amortization of prior service cost (credit)	1	2	6	(34)	(33)	(34)
Amortization of net transition obligation	—	—	1	—	—	—
Recognized actuarial losses	496	745	460	135	201	136
Curtailments and settlements	11	8	(17)	—	—	—
Net periodic benefit cost	**$ 422**	**971**	**743**	**477**	**604**	**503**

Amounts expected to be recognized in net periodic benefit cost in the coming year for the Company's defined benefit retirement plans and other post-retirement plans:

(Dollars in Millions)	
Amortization of net transition obligation	$ —
Amortization of net actuarial losses	715
Amortization of prior service credit	28

Unrecognized gains and losses for the U.S. pension plans are amortized over the average remaining future service for each plan. For plans with no active employees, they are amortized over the average life expectancy. The amortization of gains and

losses for the other U.S. benefit plans is determined by using a 10% corridor of the greater of the market value of assets or the accumulated postretirement benefit obligation. Total unamortized gains and losses in excess of the corridor are amortized over the average remaining future service.

Prior service costs/benefits for the U.S. pension plans are amortized over the average remaining future service of plan participants at the time of the plan amendment. Prior service cost/benefit for the other U.S. benefit plans is amortized over the average remaining service to full eligibility age of plan participants at the time of the plan amendment.

The following table represents the weighted-average actuarial assumptions:

	Retirement Plans			Other Benefit Plans		
Worldwide Benefit Plans	**2016**	**2015**	**2014**	**2016**	**2015**	**2014**
Net Periodic Benefit Cost						
Service cost discount rate	3.98%	3.78	4.78	4.77	4.31	5.25
Interest cost discount rate	4.24%	3.78	4.78	4.10	4.31	5.25
Rate of increase in compensation levels	4.02%	4.05	4.08	4.32	4.11	4.29
Expected long-term rate of return on plan assets	8.55%	8.53	8.46			
Benefit Obligation						
Discount rate	3.78%	4.11	3.78	4.42	4.63	4.31
Rate of increase in compensation levels	4.02%	4.01	4.05	4.29	4.28	4.11

The Company's discount rates are determined by considering current yield curves representing high quality, long-term fixed income instruments. The resulting discount rates are consistent with the duration of plan liabilities. For the fiscal year 2016, the Company changed its methodology in determining service and interest cost from the single weighted average discount rate approach to duration specific spot rates along that yield curve to the plans' liability cash flows, which management has concluded is a more precise estimate. Prior to this change in methodology, the Company measured service and interest costs utilizing a single weighted-average discount rate derived from the yield curve used to measure the plan obligations. The Company has accounted for this change as a change in accounting estimate and, accordingly, has accounted for it on a prospective basis. This change does not impact the benefit obligation and did not have a material impact to the 2016 full year results.

The expected rates of return on plan asset assumptions represent the Company's assessment of long-term returns on diversified investment portfolios globally. The assessment is determined using projections from external financial sources, long-term historical averages, actual returns by asset class and the various asset class allocations by market.

The following table displays the assumed health care cost trend rates, for all individuals:

Health Care Plans	**2016**	**2015**
Health care cost trend rate assumed for next year	6.32%	6.60%
Rate to which the cost trend rate is assumed to decline (ultimate trend)	4.50%	4.50%
Year the rate reaches the ultimate trend rate	2038	2038

A one-percentage-point change in assumed health care cost trend rates would have the following effect:

(Dollars in Millions)	**One-Percentage-Point Increase**	**One-Percentage-Point Decrease**
Health Care Plans		
Total interest and service cost	$ 30	(23)
Post-retirement benefit obligation	$ 401	(325)

The following table sets forth information related to the benefit obligation and the fair value of plan assets at year-end 2016 and 2015 for the Company's defined benefit retirement plans and other post-retirement plans:

	Retirement Plans		Other Benefit Plans	
(Dollars in Millions)	**2016**	**2015**	**2016**	**2015**
Change in Benefit Obligation				
Projected benefit obligation — beginning of year	$ 25,855	26,889	4,669	5,081
Service cost	949	1,037	224	257
Interest cost	927	988	158	186
Plan participant contributions	54	48	—	—
Amendments	(48)	60	—	—
Actuarial (gains) losses	2,302	(1,578)	(73)	(400)
Divestitures & acquisitions	(24)	(5)	—	—
Curtailments, settlements & restructuring	(25)	(20)	—	(3)
Benefits paid from plan*	(1,210)	(773)	(378)	(420)
Effect of exchange rates	(664)	(791)	5	(32)
Projected benefit obligation — end of year	**$ 28,116**	**25,855**	**4,605**	**4,669**
Change in Plan Assets				
Plan assets at fair value — beginning of year	$ 22,254	22,575	74	79
Actual return on plan assets	2,286	298	7	1
Company contributions	838	752	372	414
Plan participant contributions	54	48	—	—
Settlements	(25)	(20)	—	—
Divestitures & acquisitions	(24)	(5)	—	—
Benefits paid from plan assets*	(1,210)	(773)	(378)	(420)
Effect of exchange rates	(540)	(621)	—	—
Plan assets at fair value — end of year	**$ 23,633**	**22,254**	**75**	**74**
Funded status — end of year	**$ (4,483)**	**(3,601)**	**(4,530)**	**(4,595)**
Amounts Recognized in the Company's Balance Sheet consist of the following:				
Non-current assets	$ 227	256	—	—
Current liabilities	(86)	(77)	(315)	(324)
Non-current liabilities	(4,624)	(3,780)	(4,215)	(4,271)
Total recognized in the consolidated balance sheet — end of year	**$ (4,483)**	**(3,601)**	**(4,530)**	**(4,595)**
Amounts Recognized in Accumulated Other Comprehensive Income consist of the following:				
Net actuarial loss	$ 7,749	6,501	1,804	2,013
Prior service cost (credit)	(12)	34	(150)	(185)
Unrecognized net transition obligation	—	—	—	—
Total before tax effects	**$ 7,737**	**6,535**	**1,654**	**1,828**
Accumulated Benefit Obligations — end of year	**$ 25,319**	**23,262**		

*In 2016, the Company offered a voluntary lump-sum payment option below a pre-determined threshold for certain eligible former employees who are vested participants of the U.S. Qualified Defined Benefit Pension Plan. The distribution of the lump-sums was substantially completed by the end of fiscal 2016. The amount distributed in 2016 was approximately $420 million. These distributions from the plan did not have a material impact on the Company's financial position.

(Dollars in Millions)	Retirement Plans 2016	Retirement Plans 2015	Other Benefit Plans 2016	Other Benefit Plans 2015
Amounts Recognized in Net Periodic Benefit Cost and Other Comprehensive Income				
Net periodic benefit cost	**$ 422**	**971**	**477**	**604**
Net actuarial (gain) loss	1,965	(75)	(72)	(389)
Amortization of net actuarial loss	(496)	(745)	(135)	(201)
Prior service cost (credit)	(48)	60	—	—
Amortization of prior service (cost) credit	(1)	(2)	34	33
Effect of exchange rates	(218)	(218)	(1)	(1)
Total recognized in other comprehensive income, before tax	**$ 1,202**	**(980)**	**(174)**	**(558)**
Total recognized in net periodic benefit cost and other comprehensive income	**$ 1,624**	**(9)**	**303**	**46**

The Company plans to continue to fund its U.S. Qualified Plans to comply with the Pension Protection Act of 2006. International Plans are funded in accordance with local regulations. Additional discretionary contributions are made when deemed appropriate to meet the long-term obligations of the plans. For certain plans, funding is not a common practice, as funding provides no economic benefit. Consequently, the Company has several pension plans that are not funded.

In 2016, the Company contributed $501 million and $337 million to its U.S. and international pension plans, respectively.

The following table displays the funded status of the Company's U.S. Qualified & Non-Qualified pension plans and international funded and unfunded pension plans at December 31, 2016 and December 31, 2015, respectively:

	U.S. Plans				International Plans			
	Qualified Plans		Non-Qualified Plans		Funded Plans		Unfunded Plans	
(Dollars in Millions)	2016	2015	2016	2015	2016	2015	2016	2015
Plan Assets	$ 16,057	15,113	—	—	7,576	7,141	—	—
Projected Benefit Obligation	16,336	15,280	1,905	1,675	9,502	8,542	373	358
Accumulated Benefit Obligation	14,759	13,876	1,568	1,411	8,663	7,661	329	314
Over (Under) Funded Status								
Projected Benefit Obligation	$ (279)	(167)	(1,905)	(1,675)	(1,926)	(1,401)	(373)	(358)
Accumulated Benefit Obligation	1,298	1,237	(1,568)	(1,411)	(1,087)	(520)	(329)	(314)

Plans with accumulated benefit obligations in excess of plan assets have an accumulated benefit obligation, projected benefit obligation and plan assets of $8.8 billion, $9.9 billion and $5.6 billion, respectively, at the end of 2016, and $4.5 billion, $5.3 billion and $1.9 billion, respectively, at the end of 2015.

The following table displays the projected future benefit payments from the Company’s retirement and other benefit plans:

(Dollars in Millions)	2017	2018	2019	2020	2021	2022-2026
Projected future benefit payments						
Retirement plans	$ 897	908	958	1,010	1,081	6,416
Other benefit plans	$ 325	315	311	307	304	1,465

The following table displays the projected future minimum contributions to the unfunded retirement plans. These amounts do not include any discretionary contributions that the Company may elect to make in the future.

(Dollars in Millions)	2017	2018	2019	2020	2021	2022-2026
Projected future contributions	$ 83	84	89	94	100	610

Each pension plan is overseen by a local committee or board that is responsible for the overall administration and investment of the pension plans. In determining investment policies, strategies and goals, each committee or board considers factors including, local pension rules and regulations; local tax regulations; availability of investment vehicles (separate accounts, commingled accounts, insurance funds, etc.); funded status of the plans; ratio of actives to retirees; duration of liabilities; and other relevant factors including: diversification, liquidity of local markets and liquidity of base currency. A majority of the Company's pension funds are open to new entrants and are expected to be on-going plans. Permitted investments are primarily liquid and/or listed, with little reliance on illiquid and non-traditional investments such as hedge funds.

The Company's retirement plan asset allocation at the end of 2016 and 2015 and target allocations for 2017 are as follows:

	Percent of Plan Assets		Target Allocation
	2016	2015	2017
Worldwide Retirement Plans			
Equity securities	75%	79%	73%
Debt securities	25	21	27
Total plan assets	**100%**	**100%**	**100%**

Determination of Fair Value of Plan Assets

The Plan has an established and well-documented process for determining fair values. Fair value is based upon quoted market prices, where available. If listed prices or quotes are not available, fair value is based upon models that primarily use, as inputs, market-based or independently sourced market parameters, including yield curves, interest rates, volatilities, equity or debt prices, foreign exchange rates and credit curves.

While the Plan believes its valuation methods are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

Valuation Hierarchy

The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described in the table below with Level 1 having the highest priority and Level 3 having the lowest.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Following is a description of the valuation methodologies used for the investments measured at fair value.

- *Short-term investments* — Cash and quoted short-term instruments are valued at the closing price or the amount held on deposit by the custodian bank. Other investments are through investment vehicles valued using the Net Asset Value (NAV) provided by the administrator of the fund. The NAV is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding. The NAV is a quoted price in a market that is not active and classified as Level 2.
- *Government and agency securities* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified within Level 1 of the valuation hierarchy. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows. When quoted market prices for a security are not available in an active market, they are classified as Level 2.
- *Debt instruments* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified as Level 1. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows and are classified as Level 2. Level 3 debt instruments are priced based on unobservable inputs.
- *Equity securities* — Common stocks are valued at the closing price reported on the major market on which the individual securities are traded. Substantially all common stock is classified within Level 1 of the valuation hierarchy.
- *Commingled funds* — These investment vehicles are valued using the NAV provided by the fund administrator. The NAV is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding. Assets in the Level 2 category have a quoted market price.

- *Insurance contracts* — The instruments are issued by insurance companies. The fair value is based on negotiated value and the underlying investments held in separate account portfolios as well as considering the credit worthiness of the issuer. The underlying investments are government, asset-backed and fixed income securities. In general, insurance contracts are classified as Level 3 as there are no quoted prices nor other observable inputs for pricing.
- *Other assets* — Other assets are represented primarily by limited partnerships and real estate investments, as well as commercial loans and commercial mortgages that are not classified as corporate debt. Other assets that are exchange listed and actively traded are classified as Level 1, while inactively traded assets are classified as Level 2.

The following table sets forth the Retirement Plans' investments measured at fair value as of December 31, 2016 and December 31, 2015:

	Quoted Prices in Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs[a] (Level 3)		Investments Measured at Net Asset Value[b]		Total Assets	
(Dollars in Millions)	**2016**	**2015**	**2016**	**2015**	**2016**	**2015**	**2016**	**2015**	**2016**	**2015**
Short-term investment funds	$ 145	184	652	312	—	—	—	—	797	496
Government and agency securities	—	—	2,655	1,767	—	—	—	—	2,655	1,767
Debt instruments	—	—	1,237	1,050	—	1	—	—	1,237	1,051
Equity securities	11,433	11,317	12	11	—	—	—	—	11,445	11,328
Commingled funds	—	—	1,316	1,100	—	—	5,767	6,122	7,083	7,222
Insurance contracts	—	—	—	—	24	23	—	—	24	23
Other assets	—	—	—	107	—	—	392	260	392	367
Investments at fair value	**$ 11,578**	**11,501**	**5,872**	**4,347**	**24**	**24**	**6,159**	**6,382**	**23,633**	**22,254**

[a] The activity for the Level 3 assets is not significant for all years presented.
[b] Per adoption of ASU 2015-07, certain investments that are measured at fair value using the net asset value per share (or its equivalent) practical expedient have not been classified in the fair value hierarchy. As per ASU 2015-7 prior year amounts have been reclassified to conform to the current year presentation. The fair value amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the total retirement plan assets.

The Company's Other Benefit Plans are unfunded except for U.S. commingled funds (Level 2) of $75 million and $74 million at December 31, 2016 and December 31, 2015, respectively.

The fair value of Johnson & Johnson Common Stock directly held in plan assets was $847 million (3.6% of total plan assets) at December 31, 2016 and $751 million (3.4% of total plan assets) at December 31, 2015.

11. Savings Plan

The Company has voluntary 401(k) savings plans designed to enhance the existing retirement programs covering eligible employees. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which he/she is eligible. Total Company matching contributions to the plans were $191 million, $187 million and $172 million in 2016, 2015 and 2014, respectively.

12. Capital and Treasury Stock
Changes in treasury stock were:

(Amounts in Millions Except Treasury Stock Shares in Thousands)	Treasury Stock Shares	Treasury Stock Amount
Balance at December 29, 2013	299,215	$ 15,700
Employee compensation and stock option plans	(32,302)	(2,933)
Repurchase of common stock	69,707	7,124
Balance at December 28, 2014	336,620	19,891
Employee compensation and stock option plans	(24,413)	(2,497)
Repurchase of common stock	52,474	5,290
Balance at January 3, 2016	364,681	22,684
Employee compensation and stock option plans	(30,839)	(3,311)
Repurchase of common stock	79,490	8,979
Balance at January 1, 2017	413,332	$ 28,352

Aggregate shares of common stock issued were approximately 3,119,843,000 shares at the end of 2016, 2015 and 2014.

Cash dividends paid were $3.15 per share in 2016, compared with dividends of $2.95 per share in 2015, and $2.76 per share in 2014.

On October 13, 2015, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $10.0 billion of the Company's shares of common stock. The repurchase program has no time limit and may be suspended for periods or discontinued at any time. Any shares acquired will be available for general corporate purposes. The Company intends to finance the share repurchase program through available cash and access to the capital markets. As of January 1, 2017, $7.3 billion has been repurchased under the program.

On July 21, 2014, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's shares of common stock. This share repurchase program was completed on April 28, 2015.

13. Accumulated Other Comprehensive Income
Components of other comprehensive income (loss) consist of the following:

(Dollars in Millions)	Foreign Currency Translation	Gain/(Loss) On Securities	Employee Benefit Plans	Gain/ (Loss) On Derivatives & Hedges	Total Accumulated Other Comprehensive Income (Loss)
December 29, 2013	$ (202)	106	(3,009)	245	(2,860)
Net 2014 changes	(4,601)	151	(3,308)	(104)	(7,862)
December 28, 2014	(4,803)	257	(6,317)	141	(10,722)
Net 2015 changes	(3,632)	347	1,019	(177)	(2,443)
January 3, 2016	(8,435)	604	(5,298)	(36)	(13,165)
Net 2016 changes	(612)	(193)	(682)	(249)	(1,736)
January 1, 2017	$ (9,047)	411	(5,980)	(285)	(14,901)

Amounts in accumulated other comprehensive income are presented net of the related tax impact. Foreign currency translation is not adjusted for income taxes where it relates to permanent investments in international subsidiaries. For additional details on comprehensive income see the Consolidated Statements of Comprehensive Income.

Details on reclassifications out of Accumulated Other Comprehensive Income:
Gain/(Loss) On Securities - reclassifications released to Other (income) expense, net.
Employee Benefit Plans - reclassifications are included in net periodic benefit cost. See Note 10 for additional details.
Gain/(Loss) On Derivatives & Hedges - reclassifications to earnings are recorded in the same account as the hedged transaction. See Note 6 for additional details.

14. International Currency Translation

For translation of its subsidiaries operating in non-U.S. Dollar currencies, the Company has determined that the local currencies of its international subsidiaries are the functional currencies except those in highly inflationary economies, which are defined as those which have had compound cumulative rates of inflation of 100% or more during the past three years, or where a substantial portion of its cash flows are not in the local currency.

In consolidating international subsidiaries, balance sheet currency effects are recorded as a component of accumulated other comprehensive income. This equity account includes the results of translating certain balance sheet assets and liabilities at current exchange rates and some accounts at historical rates, except for those located in highly inflationary economies. The translation of balance sheet accounts for highly inflationary economies are reflected in the operating results.

A rollforward of the changes during 2016, 2015 and 2014 for foreign currency translation adjustments is included in Note 13.

Net currency transaction gains and losses included in Other (income) expense were losses of $289 million, $104 million and $156 million in 2016, 2015 and 2014, respectively.

15. Earnings Per Share

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal years ended January 1, 2017, January 3, 2016 and December 28, 2014:

(In Millions Except Per Share Amounts)	2016	2015	2014
Basic net earnings per share	$ 6.04	5.56	5.80
Average shares outstanding — basic	2,737.3	2,771.8	2,815.2
Potential shares exercisable under stock option plans	142.4	141.5	142.6
Less: shares repurchased under treasury stock method	(92.1)	(102.6)	(96.5)
Convertible debt shares	1.3	2.2	2.6
Adjusted average shares outstanding — diluted	2,788.9	2,812.9	2,863.9
Diluted net earnings per share	$ 5.93	5.48	5.70

The diluted net earnings per share calculation included the dilutive effect of convertible debt that is offset by the related reduction in interest expense of $2 million after-tax for year 2016, and $3 million for years 2015 and 2014.

The diluted net earnings per share calculation for 2016, 2015 and 2014 included all shares related to stock options, as the exercise price of all options was less than the average market value of the Company's stock.

16. Rental Expense and Lease Commitments

Rentals of space, vehicles, manufacturing equipment and office and data processing equipment under operating leases were approximately $330 million, $316 million and $341 million in 2016, 2015 and 2014, respectively.

The approximate minimum rental payments required under operating leases that have initial or remaining non-cancelable lease terms in excess of one year at January 1, 2017 are:

(Dollars in Millions)

2017	2018	2019	2020	2021	After 2021	Total
$216	179	134	105	88	100	822

Commitments under capital leases are not significant.

17. Common Stock, Stock Option Plans and Stock Compensation Agreements

At January 1, 2017, the Company had 2 stock-based compensation plans. The shares outstanding are for contracts under the Company's 2005 Long-Term Incentive Plan and the 2012 Long-Term Incentive Plan. The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan. Under the 2012 Long-Term Incentive Plan, the Company may issue up to 650 million shares of common stock, plus any shares canceled, expired, forfeited, or not issued from the 2005 Long-Term Incentive Plan subsequent to April 26, 2012. Shares available for future grants under the 2012 Long-Term Incentive Plan were 439 million at the end of 2016.

The compensation cost that has been charged against income for these plans was $878 million, $874 million and $792 million for 2016, 2015 and 2014, respectively. The total income tax benefit recognized in the income statement for share-based compensation costs was $256 million, $253 million and $259 million for 2016, 2015 and 2014, respectively. An additional tax benefit of $353 million was recognized in 2016 due to the adoption of a new accounting standard for the reporting of additional

tax benefits on share-based compensation as described in Note 1. The total unrecognized compensation cost was $749 million, $744 million and $722 million for 2016, 2015 and 2014, respectively. The weighted average period for this cost to be recognized was 1.09 years, 0.98 years and 1.18 years for 2016, 2015, and 2014, respectively. Share-based compensation costs capitalized as part of inventory were insignificant in all periods.

The Company settles employee benefit equity issuances with treasury shares. Treasury shares are replenished throughout the year for the number of shares used to settle employee benefit equity issuances.

Stock Options

Stock options expire 10 years from the date of grant and vest over service periods that range from 6 months to 4 years. All options are granted at the average of the high and low prices of the Company's Common Stock on the New York Stock Exchange on the date of grant.

The fair value of each option award was estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the following table. For 2014 grants, expected volatility represents a blended rate of 4-year daily historical average volatility rate, and a 5-week average implied volatility rate based on at-the-money traded Johnson & Johnson options with a life of 2 years. For 2016 and 2015 grants, expected volatility represents a blended rate of 10-year weekly historical overall volatility rate, and a 5-week average implied volatility rate based on at-the-money traded Johnson & Johnson options with a life of 2 years. For all grants, historical data is used to determine the expected life of the option. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant.

The average fair value of options granted was $10.01, $10.68 and $8.42, in 2016, 2015 and 2014, respectively. The fair value was estimated based on the weighted average assumptions of:

	2016	2015	2014
Risk-free rate	1.51%	1.77%	1.87%
Expected volatility	15.76%	15.48%	14.60%
Expected life (in years)	7.0	7.0	6.0
Expected dividend yield	3.10%	2.90%	3.10%

A summary of option activity under the Plan as of January 1, 2017, January 3, 2016 and December 28, 2014, and changes during the years ending on those dates is presented below:

(Shares in Thousands)	Outstanding Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (Dollars in Millions)
Shares at December 29, 2013	119,556	$ 64.70	$ 3,306
Options granted	24,356	90.44	
Options exercised	(25,319)	62.31	
Options canceled/forfeited	(2,881)	75.48	
Shares at December 28, 2014	115,712	70.37	4,014
Options granted	20,484	100.06	
Options exercised	(16,683)	62.53	
Options canceled/forfeited	(2,996)	82.22	
Shares at January 3, 2016	116,517	76.41	3,065
Options granted	22,491	101.87	
Options exercised	(22,547)	65.66	
Options canceled/forfeited	(3,006)	92.83	
Shares at January 1, 2017	**113,455**	**$ 83.16**	**$ 3,636**

The total intrinsic value of options exercised was $980 million, $644 million and $954 million in 2016, 2015 and 2014, respectively.

The following table summarizes stock options outstanding and exercisable at January 1, 2017:

(Shares in Thousands)	Outstanding			Exercisable	
Exercise Price Range	Options	Average Life[1]	Average Exercise Price	Options	Average Exercise Price
$52.13-$58.33	7,361	2.1	$58.32	7,361	$58.32
$58.34-$62.20	11,297	2.4	$61.95	11,297	$61.95
$62.62-$65.62	14,380	3.1	$64.24	14,380	$64.24
$66.07-$72.54	18,127	6.0	$72.52	17,241	$72.52
$90.44-$101.87	62,290	8.1	$97.40	135	$93.73
	113,455	**6.2**	**$83.16**	**50,414**	**$65.77**

[1] Average contractual life remaining in years.

Stock options outstanding at January 3, 2016 and December 28, 2014 were 116,517 and an average life of 5.9 years and 115,712 and an average life of 5.7 years, respectively. Stock options exercisable at January 3, 2016 and December 28, 2014 were 48,345 at an average price of $62.26 and 57,846 at an average price of $61.94, respectively.

Restricted Share Units and Performance Share Units

The Company grants restricted share units which vest over service periods that range from 6 months to 3 years. The Company also grants performance share units, which are paid in shares of Johnson & Johnson Common Stock after the end of a three-year performance period. Whether any performance share units vest, and the amount that does vest, is tied to the completion of service periods that range from 6 months to 3 years and the achievement, over a three-year period, of three equally-weighted goals that directly align with or help drive long-term total shareholder return: operational sales, adjusted operational earnings per share, and relative total shareholder return. The number of shares actually earned at the end of the three-year period will vary, based only on actual performance, from 0% to 200% of the target number of performance share units granted.

A summary of the restricted share units and performance share units activity under the Plans as of January 1, 2017 is presented below:

(Shares in Thousands)	Outstanding Restricted Share Units	Outstanding Performance Share Units
Shares at December 29, 2013	30,617	1,535
Granted	8,487	1,113
Issued	(9,685)	(19)
Canceled/forfeited	(1,726)	(98)
Shares at December 28, 2014	27,693	2,531
Granted	7,637	931
Issued	(10,164)	(285)
Canceled/forfeited	(1,281)	(99)
Shares at January 3, 2016	23,885	3,078
Granted	7,173	958
Issued	(8,913)	(1,437)
Canceled/forfeited	(1,084)	(184)
Shares at January 1, 2017	21,061	2,415

The average fair value of the restricted share units granted was $92.45, $91.65 and $83.01 in 2016, 2015 and 2014, respectively, using the fair market value at the date of grant. The fair value of restricted share units was discounted for dividends, which are not paid on the restricted share units during the vesting period. The fair value of restricted share units issued was $587.7 million, $597.6 million and $541.0 million in 2016, 2015 and 2014, respectively.

The weighted average fair value of the performance share units granted was $105.30, $93.54 and $85.94 in 2016, 2015 and 2014, calculated using the weighted average fair market value for each of the three component goals at the date of grant.

The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. The fair value of performance share units issued was $127.7 million, $16.7 million and $1.4 million in 2016, 2015 and 2014, respectively.

18. Segments of Business and Geographic Areas

	Sales to Customers		
(Dollars in Millions)	**2016**	**2015**	**2014**
Consumer —			
United States	$ 5,420	5,222	5,096
International	7,887	8,285	9,400
Total	**13,307**	**13,507**	**14,496**
Pharmaceutical —			
United States	20,125	18,333	17,432
International	13,339	13,097	14,881
Total	**33,464**	**31,430**	**32,313**
Medical Devices —			
United States	12,266	12,132	12,254
International	12,853	13,005	15,268
Total	**25,119**	**25,137**	**27,522**
Worldwide total	**$ 71,890**	**70,074**	**74,331**

	Income Before Tax			Identifiable Assets	
(Dollars in Millions)	**2016 [3]**	**2015 [4]**	**2014 [5]**	**2016**	**2015**
Consumer	$ 2,441	1,787	1,941	$ 23,971	20,772
Pharmaceutical	12,827	11,734	11,696	27,477	26,144
Medical Devices	5,578	6,826	7,953	39,773	40,979
Total	20,846	20,347	21,590	91,221	87,895
Less: Expense not allocated to segments [1]	1,043	1,151	1,027		
General corporate [2]				49,987	45,516
Worldwide total	**$ 19,803**	**19,196**	**20,563**	**$ 141,208**	**133,411**

	Additions to Property, Plant & Equipment			Depreciation and Amortization		
(Dollars in Millions)	**2016**	**2015**	**2014**	**2016**	**2015**	**2014**
Consumer	$ 486	544	581	$ 608	559	577
Pharmaceutical	927	1,063	977	886	929	1,053
Medical Devices	1,472	1,631	1,807	1,928	1,945	1,974
Segments total	2,885	3,238	3,365	3,422	3,433	3,604
General corporate	341	225	349	332	313	291
Worldwide total	**$ 3,226**	**3,463**	**3,714**	**$ 3,754**	**3,746**	**3,895**

(Dollars in Millions)	Sales to Customers 2016	2015	2014	Long-Lived Assets (6) 2016	2015
United States	$ 37,811	35,687	34,782	$ 36,934	36,609
Europe	15,770	15,995	18,947	21,996	20,167
Western Hemisphere excluding U.S.	5,734	6,045	7,160	2,961	2,881
Asia-Pacific, Africa	12,575	12,347	13,442	2,512	2,493
Segments total	71,890	70,074	74,331	64,403	62,150
General corporate				1,190	1,148
Other non long-lived assets				75,615	70,113
Worldwide total	**$ 71,890**	**70,074**	**74,331**	**$ 141,208**	**133,411**

See Note 1 for a description of the segments in which the Company operates.

Export sales are not significant. In 2016, the Company had two wholesalers distributing products for all three segments that represented approximately 13.5% and 10.7% of the total consolidated revenues. In 2015 and 2014, the Company had one wholesaler distributing products for all three segments that represented approximately 12.5% and 11.0%, respectively, of the total consolidated revenues.

(1) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.

(2) General corporate includes cash, cash equivalents and marketable securities.

(3) Includes net litigation expense of $806 million and a restructuring related charge of $685 million in the Medical Devices segment. The Pharmaceutical segment includes a positive adjustment of $0.5 billion to previous reserve estimates, an in-process research and development expense of $29 million, and gains from the divestitures of the controlled substance raw material and active pharmaceutical ingredient (API) business and certain anesthetic products in Europe.

(4) The Medical Devices segment includes a restructuring related charge of $590 million, an intangible asset write-down of $346 million related to Acclarent, Synthes integration costs of $196 million and $148 million expense for the cost associated with the DePuy ASR™ Hip program. Includes $224 million of in-process research and development expense, comprised of $214 million and $10 million in the Pharmaceutical and Medical Devices segments, respectively. Includes net litigation expense of $141 million comprised of $136 million in the Pharmaceutical segment and $5 million in the Medical Devices segment, which included the gain from the litigation settlement agreement with Guidant for $600 million. The Medical Devices Segment includes a gain of $1.3 billion from the divestiture of the Cordis business. The Pharmaceutical segment includes a gain of $981 million from the U.S. divestiture of NUCYNTA® and a positive adjustment of $0.5 billion to previous reserve estimates, including Managed Medicaid rebates. The Consumer segment includes a gain of $229 million from the divestiture of SPLENDA® brand.

(5) Includes net litigation expense of $1,253 million comprised of $907 million, $259 million and $87 million in the Medical Devices, Pharmaceutical and Consumer segments, respectively. Includes $178 million of in-process research and development expense, comprised of $147 million and $31 million in the Pharmaceutical and Medical Devices segments, respectively. The Medical Devices segment includes a net gain of $1,899 million from the divestiture of the Ortho-Clinical Diagnostics business, Synthes integration costs of $754 million and $126 million expense for the cost associated with the DePuy ASR™ Hip program. The Pharmaceutical segment includes an additional year of the Branded Prescription Drug Fee of $220 million and a positive adjustment of $0.1 billion to previous reserve estimates.

(6) Long-lived assets include property, plant and equipment, net for 2016, and 2015 of $15,912 and $15,905, respectively, and intangible assets and goodwill, net for 2016 and 2015 of $49,681 and $47,393, respectively.

19. Selected Quarterly Financial Data (unaudited)

Selected unaudited quarterly financial data for the years 2016 and 2015 are summarized below:

	2016				2015			
(Dollars in Millions Except Per Share Data)	First Quarter [1]	Second Quarter [2]	Third Quarter [3]	Fourth Quarter [4]	First Quarter [5]	Second Quarter [6]	Third Quarter [7]	Fourth Quarter [8]
Segment sales to customers								
Consumer	$ 3,195	3,419	3,261	3,432	3,390	3,483	3,314	3,320
Pharmaceutical	8,178	8,654	8,400	8,232	7,726	7,946	7,694	8,064
Medical Devices	6,109	6,409	6,159	6,442	6,258	6,358	6,094	6,427
Total sales	17,482	18,482	17,820	18,106	17,374	17,787	17,102	17,811
Gross profit	12,153	13,146	12,334	12,572	12,092	12,430	11,878	12,138
Earnings before provision for taxes on income	5,294	4,904	5,281	4,324	5,575	5,741	4,122	3,758
Net earnings	4,457	3,997	4,272	3,814	4,320	4,516	3,358	3,215
Basic net earnings per share	$ 1.62	1.46	1.56	1.41	1.55	1.63	1.21	1.16
Diluted net earnings per share	$ 1.59	1.43	1.53	1.38	1.53	1.61	1.20	1.15

(1) The first quarter has been recast to reflect the adoption of ASU 2016-09. See Note 1 to the Consolidated Financial Statements for more details. The first quarter of 2016 includes a restructuring charge of $120 million after-tax ($137 million before-tax) and net litigation expense of $56 million after-tax ($66 million before-tax).

(2) The second quarter of 2016 includes a restructuring charge of $97 million after-tax ($141 million before-tax) and net litigation expense of $493 million after-tax ($600 million before-tax).

(3) The third quarter of 2016 includes a restructuring charge of $76 million after-tax ($109 million before-tax) and net litigation expense of $46 million after-tax ($55 million before-tax).

(4) The fourth quarter of 2016 includes a restructuring charge of $251 million after-tax ($298 million before-tax) and net litigation expense of $80 million after-tax ($96 million before-tax).

(5) The first quarter of 2015 includes a net litigation gain of $253 million after-tax ($402 million before-tax) and $122 million after-tax ($139 million before-tax) for costs associated with the DePuy ASR™ Hip program.

(6) The second quarter of 2015 includes net litigation expense of $23 million after-tax ($134 million before-tax).

(7) The third quarter of 2015 includes net litigation expense of $348 million after-tax ($409 million before-tax).

(8) The fourth quarter of 2015 includes a restructuring charge of $415 million after-tax ($590 million before-tax), $156 million after-tax ($214 million before-tax) from impairment of in-process research and development and Synthes integration costs of $59 million after-tax ($83 million before-tax). Additionally, the fourth quarter of 2015 includes the gain on the Cordis divestiture.

20. Business Combinations and Divestitures

Certain businesses were acquired for $4,509 million in cash and $77 million of liabilities assumed during 2016. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2016 acquisitions primarily included: Vogue International LLC, a privately-held company focused on the marketing, development and distribution of salon-influenced and nature inspired hair care and other personal products; NeuWave Medical, Inc., a privately-held medical device company that manufactures and markets minimally invasive soft tissue microwave ablation systems; NeoStrata Company, Inc., a global leader in dermocosmetics, and the global rights for the commercialization of RHINOCORT® allergy spray outside the United States.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $4,077 million and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

The net purchase price for Vogue International LLC of $3.3 billion was primarily recorded as amortizable intangible assets for $2.3 billion and goodwill for $1.1 billion. The weighted average life for the $2.3 billion of total amortizable intangibles is approximately 22 years. The trademark asset values were determined to have definite lives ranging from 10 to 22 years, with the majority being 22 years. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is expected to be deductible for tax purposes. The assets acquired were recorded in the Consumer segment.

During the fiscal third quarter of 2016, the Company announced a definitive agreement to acquire Abbott Medical Optics (AMO), a wholly-owned subsidiary of Abbott Laboratories, for $4.325 billion in cash. The acquisition will include ophthalmic products related to: cataract surgery, laser refractive surgery and consumer eye health. The transaction closed on February 27, 2017. The purchase price allocation is in progress and is expected to result in an allocation of significant value to the amortizable intangible assets with any residual recorded as goodwill.

On January 26, 2017, subsequent to year end, the Company announced a definitive transaction agreement under which the company will launch an all-cash tender offer in Switzerland to acquire all of the outstanding shares of Actelion Ltd. for $280 per share, payable in U.S. dollars, for approximately $30.0 billion. As part of the transaction, immediately prior to the completion of the acquisition, Actelion will spin out its drug discovery operations and early-stage clinical development assets into a newly created Swiss biopharmaceutical company ("R&D NewCo"). The shares of R&D NewCo, which will be listed on the SIX Swiss Exchange (SIX), will be distributed to Actelion's shareholders as a stock dividend upon closing of the tender. The Company will initially hold 16% of the shares of R&D NewCo and have rights to an additional 16% of R&D NewCo equity through a convertible note. Actelion has established a leading franchise of differentiated, innovative products for pulmonary arterial hypertension (PAH) that is highly complementary to the existing portfolio of the Company. The addition of Actelion’s specialty in-market medicines and late-stage products is consistent with the Company's efforts to grow in attractive and complementary therapeutic areas and serve patients with serious illnesses and significant unmet medical need. The closing is subject to the demerger, antitrust clearance and other customary closing conditions.

On February 15, 2017, subsequent to year end, the Company received a binding offer from Integra LifeSciences Holdings Corporation to purchase the Codman Neurosurgery business for approximately $1.0 billion.

Subsequent to year end, the Company announced it is engaging in a process to evaluate potential strategic options for the Johnson & Johnson Diabetes Care Companies, specifically LifeScan, Inc., Animas Corporation, and Calibra Medical, Inc. Strategic options may include the formation of operating partnerships, joint ventures or strategic alliances, a sale of the businesses, or other alternatives either separately or together. All options will be evaluated to determine the best opportunity to drive future growth and maximize shareholder value. There can be no assurance that this process will result in any transaction or other strategic alternative of any kind therefore, there were no assets held for sale as of January 1, 2017 related to the announcement.

Certain businesses were acquired for $954 million in cash and $220 million of liabilities assumed during 2015. The assumed liabilities primarily represent the fair value of the contingent consideration of $210 million. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2015 acquisitions primarily included: XO1 Limited, a privately-held biopharmaceutical company developing an anti-thrombin antibody and Novira Therapeutics, Inc., a privately held clinical-stage biopharmaceutical company developing innovative therapies for curative treatment of chronic hepatitis B virus infection.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $1,173 million and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately $839 million has been identified as the value of IPR&D primarily associated with the acquisitions of XO1 Limited and Novira Therapeutics, Inc. The value of the IPR&D was calculated using cash flow projections discounted for the inherent risk in the projects.

The IPR&D related to the acquisition of XO1 Limited of $360 million is associated with a recombinant human antibody developed to mimic the activity of a human antibody which appears to produce an anticoagulated state without predisposition to bleeding. A probability of success factor of 36.0% was used to reflect inherent clinical and regulatory risk. The discount rate applied was 11.75%.

The IPR&D related to the acquisition of Novira Therapeutics, Inc. of $396 million is associated with its lead candidate NVR 3-778 which is an investigational small molecule, direct-acting antiviral, for oral administration in patients with HBV that inhibits the HBV core or capsid protein. A probability of success factor of 51.0% was used to reflect inherent clinical and regulatory risk. The discount rate applied was 16.0%.

Certain businesses were acquired for $2,129 million in cash and $38 million of liabilities assumed during 2014. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2014 acquisitions included: Covagen AG, a privately-held, biopharmaceutical company specializing in the development of multispecific protein therapeutics through the FynomAb® technology platform; Alios BioPharma, Inc., a privately-held, clinical stage biopharmaceutical company focused on developing therapies for viral diseases; and the ORSL™ electrolyte ready-to-drink brand from Jagdale Industries Ltd. The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $2,069 million and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately $1,913 million has been identified as the value of IPR&D associated with the acquisitions of Covagen AG and Alios BioPharma, Inc. The value of the IPR&D was calculated using cash flow projections discounted for the inherent risk in the projects.

The IPR&D related to the acquisition of Alios BioPharma, Inc. of $1,688 million is associated with Alios' lead compound AL-8176, an orally administered antiviral therapy for treatment of infants with respiratory syncytial virus (RSV). A probability of success factor of 60.0% was used to reflect inherent clinical and regulatory risk. The discount rate applied was 11.4%. The IPR&D related to the acquisition of Covagen AG of $225 million is associated with Covagen's lead compound COVA-322, currently in Phase 1b study for psoriasis and holding potential as a treatment for a broad range of inflammatory diseases including rheumatoid arthritis. A probability of success factor of 26.0% was used to reflect inherent clinical and regulatory risk. The discount rate applied was 12.5%. During 2015, the Company recorded a charge for the impairment of the IPR&D related to the acquisition of Covagen AG.

In 2012, the Company completed the acquisition of Synthes, Inc. for a purchase price of $20.2 billion in cash and stock. In connection with the acquisition of Synthes, Inc. the Company entered into two accelerated share repurchase (ASR) agreements. In 2013, the Company settled the remaining liabilities under the ASR agreements. While the Company believes that the transactions under each ASR agreement and a series of related internal transactions were consummated in a tax efficient manner in accordance with applicable law, it is possible that the Internal Revenue Service could assert one or more contrary positions to challenge the transactions from a tax perspective. If challenged, an amount up to the total purchase price for the Synthes shares could be treated as subject to applicable U.S. tax at approximately the statutory rate to the Company, plus interest.

Supplemental pro forma information for 2016, 2015 and 2014 in accordance with U.S. GAAP standards related to business combinations, and goodwill and other intangible assets, is not provided, as the impact of the aforementioned acquisitions did not have a material effect on the Company's results of operations, cash flows or financial position.

During 2016, the Company divestitures included: the controlled substance raw material and active pharmaceutical ingredient (API) business; certain anesthetic products in Europe; and certain non-strategic Consumer brands. In 2016, the pre-tax gains on the divestitures were approximately $0.6 billion.

During 2015, the Company divestitures included: the Cordis business to Cardinal Health; the SPLENDA® brand to Heartland Food Products Group; and the U.S. license rights to NUCYNTA® (tapentadol), NUCYNTA® ER (tapentadol extended-release tablets), and NUCYNTA® (tapentadol) oral solution. In 2015, the pre-tax gains on the divestitures were approximately $2.6 billion.

During 2014, the Company divestitures included: the Ortho-Clinical Diagnostics business to The Carlyle Group; the K-Y® brand to Reckitt Benckiser Group PLC in the U.S. and certain other markets; and the BENECOL® brand to Raisio plc. In 2014, the pre-tax gains on the divestitures were approximately $2.4 billion. The Company completed the divestiture of its Ortho-Clinical Diagnostics business to The Carlyle Group for approximately $4.0 billion and the Company recorded a pre-tax gain of approximately $1.9 billion. Ortho-Clinical Diagnostics' results are included in the Company's Medical Devices segment.

21. Legal Proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability, intellectual property, commercial and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of their business.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of January 1, 2017, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series

of judgments about future events and uncertainties that rely heavily on estimates and assumptions. The ability to make such estimates and judgments can be affected by various factors, including whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; or there are numerous parties involved.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution of, or increase in accruals for, one or more of these matters in any reporting period may have a material adverse effect on the Company's results of operations and cash flows for that period.

PRODUCT LIABILITY

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While the Company believes it has substantial defenses, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

The most significant of these cases include the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, the PINNACLE® Acetabular Cup System, pelvic meshes, RISPERDAL®, XARELTO® and JOHNSON'S® Baby Powder. As of January 1, 2017, in the U.S. there were approximately 2,000 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, 9,400 with respect to the PINNACLE® Acetabular Cup System, 54,800 with respect to pelvic meshes, 18,500 with respect to RISPERDAL®, 16,900 with respect to XARELTO® and 3,100 with respect to JOHNSON'S® Baby Powder.

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System used in hip replacement surgery. Claims for personal injury have been made against DePuy and Johnson & Johnson. The number of pending lawsuits is expected to fluctuate as certain lawsuits are settled or dismissed and additional lawsuits are filed. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada, Australia, Ireland, Germany and Italy. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR Hip System plaintiffs to establish a program to settle claims with eligible ASR Hip patients in the United States who had surgery to replace their ASR Hips, known as revision surgery, as of August 31, 2013. This settlement covered approximately 8,000 patients. In February 2015, DePuy reached an additional agreement, which effectively extends the existing settlement program to ASR Hip patients who had revision surgeries after August 31, 2013 and prior to February 1, 2015. This second agreement is estimated to cover approximately 1,800 additional patients. The estimated cost of these agreements is covered by existing accruals. This settlement program is expected to bring to a close significant ASR Hip litigation activity in the United States. However, many lawsuits in the United States will remain, and the settlement program does not address litigation outside of the United States. In Australia, a settlement was reached with representatives of a class action lawsuit pending in the Federal Court of New South Wales that resolves the claims of the majority of ASR Hip patients in that country. The Company continues to receive information with respect to potential costs associated with this recall on a worldwide basis. The Company has established accruals for the costs associated with the DePuy ASR™ Hip program and related product liability litigation. Changes to these accruals may be required in the future as additional information becomes available.

Claims for personal injury have also been made against DePuy and Johnson & Johnson relating to the PINNACLE® Acetabular Cup System used in hip replacement surgery. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Texas. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom. The Company has established an accrual for defense costs in connection with product liability litigation associated

with the PINNACLE® Acetabular Cup System. Changes to this accrual may be required in the future as additional information becomes available. 754

Claims for personal injury have been made against Ethicon, Inc. (Ethicon) and Johnson & Johnson arising out of Ethicon's pelvic mesh devices used to treat stress urinary incontinence and pelvic organ prolapse. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Southern District of West Virginia. In addition, class actions and individual personal injury cases or claims have been commenced in various countries outside of the United States, including claims and cases in the United Kingdom, the Netherlands, Belgium, Italy and Venezuela, and class actions in Israel, Australia and Canada, seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices. The Company has established an accrual with respect to product liability litigation associated with Ethicon's pelvic mesh products. Changes to this accrual may be required in the future as additional information becomes available.

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and Johnson & Johnson arising out of the use of RISPERDAL®, indicated for the treatment of schizophrenia, acute manic or mixed episodes associated with bipolar I disorder and irritability associated with autism, and related compounds. Lawsuits have been primarily filed in state courts in Pennsylvania, California, and Missouri. Other actions are pending in various courts in the United States and Canada. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has established an accrual with respect to product liability litigation associated with RISPERDAL®. Changes to this accrual may be required in the future as additional information becomes available.

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and Johnson & Johnson arising out of the use of XARELTO®, an oral anticoagulant. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Eastern District of Louisiana. In addition, cases have been filed in state courts across the United States. Many of these cases have been consolidated into a state mass tort litigation in Philadelphia, Pennsylvania; and there are coordinated proceedings in Delaware, California and Missouri. Class action lawsuits also have been filed in Canada. The Company has established an accrual for defense costs in connection with product liability litigation associated with XARELTO®. Changes to this accrual may be required in the future as additional information becomes available.

Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of JOHNSON'S® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. In addition, a federal multi-district litigation proceeding has been created for this litigation in the District Court of New Jersey. The Company has established an accrual for defense costs in connection with product liability litigation associated with JOHNSON'S® Baby Powder. Changes to this accrual may be required in the future as additional information becomes available.

INTELLECTUAL PROPERTY

Certain subsidiaries of Johnson & Johnson are subject, from time to time, to legal proceedings and claims related to patent, trademark and other intellectual property matters arising out of their businesses. Many of these matters involve challenges to the coverage and/or validity of the patents on various products and allegations that certain of the Company’s products infringe the patents of third parties. Although these subsidiaries believe that they have substantial defenses to these challenges and allegations with respect to all significant patents, there can be no assurance as to the outcome of these matters. A loss in any of these cases could adversely affect the ability of these subsidiaries to sell their products, result in loss of sales due to loss of market exclusivity, require the payment of past damages and future royalties, and may result in a non-cash impairment charge for any associated intangible asset. The most significant of these matters are described below.

Medical Devices

In June 2009, Rembrandt Vision Technologies, L.P. (Rembrandt) filed a patent infringement lawsuit against Johnson & Johnson Vision Care, Inc. (JJVCI) in the United States District Court for the Eastern District of Texas alleging that JJVCI's manufacture and sale of its ACUVUE® ADVANCE and ACUVUE OASYS® Hydrogel Contact Lenses infringe their U.S. Patent No. 5,712,327 (the '327 patent). Rembrandt is seeking monetary relief. The case was transferred to the United States District Court for the Middle District of Florida. In May 2012, the jury returned a verdict holding that neither of the accused lenses infringes

the '327 patent. Rembrandt appealed, and in August 2013, the United States Court of Appeals for the Federal Circuit affirmed the District Court's judgment. Rembrandt asked the District Court to grant it a new trial based on alleged new evidence, and in July 2014, the District Court denied Rembrandt's motion. Rembrandt appealed and the Court of Appeals overturned that ruling in April 2016 and remanded the case to the District Court for a new trial. JJVCI's motion to reconsider and petition for review with the United States Supreme Court were both denied. A new trial is scheduled for August 2017.

In December 2009, the State of Israel filed a lawsuit in the District Court in Tel Aviv Jaffa against Omrix Biopharmaceuticals, Inc. and various affiliates (Omrix). In the lawsuit, the State claimed that an employee of a government-owned hospital was the inventor on several patents related to fibrin glue technology that the employee developed while he was a government employee. The State claimed that he had no right to transfer any intellectual property to Omrix because it belongs to the State. The State sought damages plus royalties on QUIXIL™ and EVICEL® products, or alternatively, transfer of the patents to the State. The case was settled in December 2016.

LifeScan filed a patent infringement lawsuit against UniStrip Technologies, LLC (UniStrip) in the United States District Court for the District of North Carolina in May 2014, alleging that the making and marketing of UniStrip's strips for use in LifeScan's blood glucose monitors infringe U.S. Patent Nos. 6,241,862 (the '862 patent) and 7,250,105 (the '105 patent). In August 2014, the United States Patent and Trademark Office (USPTO) determined that the '105 patent is invalid. In January 2016, the invalidity decision was upheld on appeal. LifeScan filed a motion for rehearing, which was denied. In July 2014, UniStrip brought a lawsuit against LifeScan in the United States District Court for the Eastern District of Pennsylvania, alleging antitrust violations relating to marketing practices for LifeScan strips.

In March 2013, Medinol Ltd. (Medinol) filed a patent infringement lawsuit against Cordis Corporation (Cordis) and Johnson & Johnson in the United States District Court for the Southern District of New York alleging that all of Cordis's sales of the CYPHER™ and CYPHER SELECT™ Stents made in the United States since 2005 willfully infringed four of Medinol's patents directed to the geometry of articulated stents. Medinol is seeking damages and attorneys' fees. After trial in January 2014, the District Court dismissed the case, finding Medinol unreasonably delayed bringing its claims, and Medinol did not appeal the decision. In September 2014, the District Court denied a motion by Medinol to vacate the judgment and grant it a new trial. Medinol's appeal of this decision has been dismissed. Medinol has filed a petition for review with the United States Supreme Court. Cordis was divested in 2015 and the Company retained any liability that may result from this case.

In November 2016, MedIdea, L.L.C. (MedIdea) filed a patent infringement lawsuit against DePuy Orthopaedics, Inc. in the United States District Court for the Northern District of Illinois alleging infringement by the ATTUNE® Knee System of two patents relating to posterior stabilized knee systems. Specifically, MedIdea alleges that the SOFCAM™ Contact feature of the ATTUNE® posterior stabilized knee products infringes the patents-in-suit. MedIdea is seeking monetary damages and injunctive relief.

In December 2016, Ethicon Endo-Surgery, Inc. and Ethicon Endo-Surgery, LLC (now known as Ethicon LLC) sued Covidien, Inc. in the U.S. District Court for the District of Massachusetts seeking a declaration that Covidien's U.S. Patent Nos. 6,585,735; 7,118,587; 7,473,253; 8,070,748; and 8,241,284 are either invalid or not infringed by Ethicon's ENSEAL® X1 Large Jaw Tissue Sealer product (ENSEAL X1). The ENSEAL X1 product is scheduled to launch in the United States and Europe in the first quarter of 2017.

Pharmaceutical

In April 2016, MorphoSys AG, a German biotech company, filed a patent infringement lawsuit against Janssen Biotech, Inc. (JBI), Genmab U.S. Inc. and Genmab A/S (collectively, Genmab) in the United States District Court for the District of Delaware, alleging that JBI's manufacture and sale of DARZALEX® (daratumumab) willfully infringes MorphoSys' U.S. Patent No. 8,263,746. MorphoSys is seeking money damages. JBI licenses patents and the commercial rights to DARZALEX® from Genmab. In June 2016, JBI filed a motion to dismiss the lawsuit. In November 2016, MorphoSys sought leave to add another patent to the case (U.S. Patent No. 9,200,061), and in February 2017, the Court granted the request. Trial in the case is currently scheduled to commence in August 2018.

In August 2016, Sandoz Ltd and Hexal AG (collectively, Sandoz) filed a lawsuit in the English High Court against G.D. Searle LLC (a Pfizer company) and Janssen Sciences Ireland UC (JSI) alleging that Searle's supplementary protection certificate SPC/GB07/038 (SPC), which is exclusively licensed to JSI, is invalid and should be revoked. Janssen-Cilag Limited sells PREZISTA® (darunavir) in the UK pursuant to this license. In October 2016, Searle and JSI counterclaimed against Sandoz for threatened infringement of the SPC based on statements of its plans to launch generic darunavir in the UK. Trial of the case has been scheduled to begin in late April/early May 2017.

U.S. Proceedings

In September 2013, Janssen Biotech, Inc. (JBI) and NYU Langone Medical Center (NYU) received an Office Action from the United States Patent and Trademark Office (USPTO) rejecting the claims in U.S. Patent No. 6,284,471 relating to REMICADE® (infliximab) (the '471 patent) in a reexamination proceeding instituted by a third party. The '471 patent is co-owned by JBI and NYU, and NYU granted JBI an exclusive license to NYU's rights under the patent. The '471 patent expires in September 2018. Following several office actions by the patent examiner, including two further rejections, and responses by JBI, the USPTO issued a further action maintaining its rejection of the '471 patent. JBI filed a notice of appeal to the USPTO's Patent Trial and Appeal Board. In November 2016, the Patent Trial and Appeal Board issued a decision upholding the examiner's rejection. JBI has filed an appeal to the U.S. Court of Appeals for the Federal Circuit.

In August 2014, Celltrion Healthcare Co. Ltd. and Celltrion Inc. (together, Celltrion) filed an application with the U.S. Food and Drug Administration (FDA) for approval to make and sell its own infliximab biosimilar. In March 2015, JBI filed a lawsuit in the United States District Court for the District of Massachusetts against Celltrion and Hospira Healthcare Corporation (Hospira), which has exclusive U.S. marketing rights for Celltrion's infliximab biosimilar, seeking, among other things, a declaratory judgment that their biosimilar product infringes or potentially infringes several JBI patents, including the '471 patent and U.S. Patent No. 7,598,083 (the '083 patent). In August 2016, the District Court granted both Celltrion's and Hospira's motions for summary judgment of invalidity of the '471 patent. JBI has appealed those decisions to the U.S. Court of Appeals for the Federal Circuit. This case and the appeal of the reexamination of the '471 patent have been designated companion cases and will be heard by the same panel of judges in the Federal Circuit.

In June 2016, JBI filed two additional patent infringement lawsuits asserting the '083 patent, one against Celltrion in the United States District Court for the District of Massachusetts and the other against HyClone Laboratories, Inc., the manufacturer of the cell culture media that Celltrion uses to make its biosimilar product, in the United States District Court for the District of Utah. Although the '083 patent is already asserted in the existing lawsuit against Celltrion, the additional lawsuit expands the claims to include any use of the cell culture media made in the United States to manufacture Celltrion's biosimilar. This additional lawsuit against Celltrion has been consolidated with the existing lawsuit discussed above. Hospira has moved to dismiss all counts of the lawsuit related to the '083 patent as to it. Celltrion has moved to dismiss all counts of the lawsuit related to the '083 patent without prejudice for failure to join all the co-owners of the '083 patent as plaintiffs. The trial has been postponed pending resolution of these motions.

The FDA approved Celltrion's infliximab biosimilar for sale in the United States in April 2016, and the 180-day period for notice of launch of a biosimilar product under the Biologics Price Competition and Innovation Act has passed.
Hospira's parent company, Pfizer Inc., began shipment of Celltrion's infliximab biosimilar to wholesalers in the United States in late November 2016. Introduction to the U.S. market of the biosimilar will result in a reduction in U.S. sales of REMICADE®.

Canadian Proceedings

In March 2013, Hospira filed an impeachment proceeding against The Kennedy Institute of Rheumatology (Kennedy) challenging the validity of a Canadian patent related to REMICADE® (a Feldman patent), which is exclusively licensed to JBI. In October 2013, Kennedy, along with JBI, Janssen Inc. (Janssen) and Cilag GmbH International (both affiliates of JBI), filed a counterclaim for infringement against Celltrion and Hospira. The counterclaim alleges that the products described in Celltrion's and Hospira's marketing applications to Health Canada for their subsequent entry biologics (SEB) to REMICADE® would infringe the Feldman patents owned by Kennedy. A trial in this patent action concluded in October 2016, and closing arguments took place in January 2017. The parties are awaiting a decision.

In January 2014, Health Canada approved Celltrion's SEB to REMICADE®, allowing Celltrion to market its infliximab biosimilar in Canada, regardless of the pending patent action. In June 2014, Health Canada approved Hospira's SEB to REMICADE®. In July 2014, Janssen filed a lawsuit to compel the Canadian Minister of Health to withdraw the Notice of Compliance for Hospira's SEB because Hospira did not serve a Notice of Allegation on Janssen to address the patent listed by Janssen on the Patent Register. In March 2015, the parties entered into a settlement agreement whereby Health Canada agreed to a Consent Judgment setting aside Hospira's Notice of Compliance, subject to Health Canada's appeal, which was filed in June 2015. Nevertheless, Hospira began marketing an infliximab biosimilar as a distributor under Celltrion's Notice of Compliance. In October 2016, the appeals court reversed the Consent Judgment. Janssen has filed an application for leave to appeal with the Supreme Court of Canada. Hospira continues to market and sell Celltrion's infliximab biosimilar in Canada.

In Canada, if the REMICADE® patent discussed above is found to be invalid following all appeals, it could not be relied upon to prevent the further introduction of infliximab biosimilars prior to the August 1, 2017 expiry date of the patent.

Litigation Against Filers of Abbreviated New Drug Applications (ANDAs)

The following summarizes lawsuits pending against generic companies that have filed Abbreviated New Drug Applications (ANDAs) with the FDA, or undertaken similar regulatory processes outside of the United States, seeking to market generic forms of products sold by various subsidiaries of Johnson & Johnson prior to expiration of the applicable patents covering those products. These ANDAs typically include allegations of non-infringement, invalidity and unenforceability of the applicable patents. In the event the subsidiaries are not successful in these actions, or the statutory 30-month stays of the ANDAs expire before the United States District Court rulings are obtained, the third-party companies involved will have the ability, upon approval of the FDA, to introduce generic versions of the products at issue to the market, resulting in the potential for substantial market share and revenue losses for those products, and which may result in a non-cash impairment charge in any associated intangible asset. In addition, from time to time, subsidiaries may settle these actions and such settlements can involve the introduction of generic versions of the products at issue to the market prior to the expiration of the relevant patents. The inter partes review (IPR) process with the United States Patent and Trademark Office (USPTO), created under the 2011 America Invents Act, is also being used by generic companies in conjunction with these ANDAs and lawsuits to challenge patents held by the Company's subsidiaries.

CONCERTA®

In December 2014, Janssen Inc. and ALZA Corporation filed a Notice of Application against Actavis Pharma Company (Actavis) in response to Actavis' Notice of Allegation seeking approval to market a generic version of CONCERTA® before the expiration of Canadian Patent No. 2,264,852 (the '852 patent). In December 2016, the Canadian Federal Court allowed the Application and issued an order preventing Actavis from obtaining marketing approval (a Notice of Compliance) for its generic version of CONCERTA® until the expiration of the '852 patent. Actavis did not commence an appeal prior to the deadline for doing so and thus, is prevented from obtaining a Notice of Compliance for a generic version of CONCERTA® until the expiration of the '852 patent.

In October 2016, ALZA Corporation and Janssen Pharmaceuticals, Inc. filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Amneal Pharmaceuticals of New York, LLC and Amneal Pharmaceuticals LLC in response to Amneal's ANDA seeking approval to market a generic version of CONCERTA® before the expiration of United States Patent Nos. 8,163,798 and 9,144,549. In November 2016, Amneal filed a motion for judgment on the pleadings, arguing that certain claims of the patents are invalid and others are not infringed. Janssen has opposed the motion.

ZYTIGA®

In June and July 2015, Janssen Biotech, Inc. (JBI) received notices of paragraph IV certification from several companies advising of their respective ANDAs seeking approval for a generic version of ZYTIGA® before the expiration of one or more patents relating to ZYTIGA®. In July 2015, JBI, Janssen Oncology, Inc. (Janssen Oncology) and Janssen Research & Development, LLC (collectively, Janssen) and BTG International Ltd. (BTG) filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against several generic ANDA applicants (and certain of their affiliates and/or suppliers) in response to their respective ANDAs seeking approval to market a generic version of ZYTIGA® before the expiration of United States Patent Nos. 5,604,213 (the '213 patent) and/or 8,822,438 (the '438 patent). The generic companies include Actavis Laboratories, FL, Inc. (Actavis); Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC (collectively, Amneal); Apotex Inc. and Apotex Corp. (collectively, Apotex); Citron Pharma LLC (Citron); Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, Dr. Reddy's); Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, Mylan); Par Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc. (collectively, Par); Sun Pharmaceutical Industries Ltd. and Sun Pharmaceuticals Industries, Inc. (collectively, Sun); Teva Pharmaceuticals USA, Inc. (Teva); Wockhardt Bio A.G.; Wockhardt USA LLC and Wockhardt Ltd. (collectively, Wockhardt); West-Ward Pharmaceutical Corp. (West-Ward); and Hikma Pharmaceuticals, LLC (Hikma). The Court entered a stay of the lawsuit against Par and Citron, as each agreed to be bound by the decision against the other defendants in the action. The '213 patent expired in December 2016 and thus the infringement actions concern only the '438 patent. In February 2016, the Court set a trial date of October 2017.

In August 2015, Janssen and BTG filed an additional jurisdictional protective lawsuit against the Mylan defendants in the United States District Court for the Northern District of West Virginia, which has been stayed.

In August 2015, Janssen received a notice of paragraph IV certification from Hetero USA Inc., the U.S. Regulatory Agent for Hetero Labs Limited Unit V, a division of Hetero Labs Limited (collectively, Hetero) advising of Hetero's ANDA seeking approval for a generic version of ZYTIGA® before expiration of the '438 patent. In September 2015, Janssen and BTG filed an amended complaint in the New Jersey lawsuit to add alleged infringement of the '438 patent by Hetero.

In March 2016, Janssen filed a motion in the New Jersey lawsuit to correct inventorship of the '438 patent to add an inventor and, if granted, for leave to amend the complaint accordingly. In January 2017, the Court granted Janssen's motion, and Janssen filed a second amended complaint adding BTG as a co-owner of the '438 patent and a co-plaintiff regarding the '438 patent infringement claims.

In March 2016, Janssen received a notice from Amerigen Pharmaceuticals Limited (Amerigen) advising of Amerigen's ANDA seeking approval for a generic version of ZYTIGA® before expiration of the '438 patent. In response, Janssen and BTG filed a separate patent infringement lawsuit in the United States District Court for the District of New Jersey against Amerigen in May 2016.

In May 2016, Janssen received a notice of paragraph IV certification from Glenmark Pharmaceuticals Inc., on behalf of Glenmark Pharmaceuticals SA, a wholly owned subsidiary of Glenmark Pharmaceuticals Ltd. (collectively, Glenmark) advising of Glenmark's ANDA seeking approval for a generic version of ZYTIGA® before expiration of the '438 patent. In response, in June 2016, Janssen and BTG filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Glenmark. The parties have stipulated to a dismissal of Glenmark Pharmaceuticals Ltd.

The filing of the above-referenced lawsuits triggered a stay until October 2018 during which time the FDA will not grant final approval of the generics' ANDAs unless there is an earlier District Court decision finding the patents-in-suit invalid or not infringed.

In each of the above lawsuits, Janssen is seeking an order enjoining the defendants from marketing their generic versions of ZYTIGA® before the expiration of the relevant patents.

In December 2015, Amerigen filed a petition for an inter partes review in the USPTO seeking to invalidate the '438 patent. In May 2016, the USPTO granted the inter partes review, and a decision as to the validity of the '438 patent is expected by May 2017. In June 2016, Argentum Pharmaceuticals LLC and Mylan Pharmaceuticals Inc. filed petitions for inter partes review in the USPTO seeking to invalidate the '438 patent and moved to join the inter partes review filed by Amerigen. The USPTO instituted Argentum's petition and granted Argentum's motion for joinder and, in January 2017, granted Mylan's petition for inter partes review but denied Mylan's motion for joinder. In August 2016, Wockhardt Bio AG filed a petition for inter partes review in the USPTO seeking to invalidate the '438 patent, which the USPTO granted in January 2017. In February 2017, Actavis, Amneal, Dr. Reddy's, Sun, Teva, West-Ward and Hikma filed a joint petition for inter partes review in the USPTO seeking to invalidate the '438 patent and moved to join the inter partes review filed by Mylan.

COMPLERA®

In August and September 2015, Janssen Pharmaceutica NV and Janssen Sciences Ireland UC (collectively, Janssen) and Gilead Sciences, Inc. and Gilead Sciences Ireland UC (collectively, Gilead) filed patent infringement lawsuits in the United States District Courts for the District of Delaware and the District of West Virginia, respectively, against Mylan, Inc. and Mylan Pharmaceuticals, Inc. (collectively, Mylan) in response to Mylan's ANDA seeking approval to market a generic version of COMPLERA® before the expiration of United States Patent Nos. 8,841,310 (the '310 patent), 7,125,879 (the '879 patent) and 8,101,629 (the '629 patent).

In the West Virginia action, in September 2015, Mylan filed an answer and counterclaims asserting invalidity and non-infringement of the '310 patent, '879 patent, and '629 patent, as well as United States Patent No. 8,080,551 (the '551 patent). In March 2016, the District of West Virginia Court stayed the lawsuit and scheduled a conditional trial date in February 2018, in accordance with the schedule in the first-filed Delaware lawsuit described below.

In the Delaware action, in January and March 2016, Janssen and Gilead amended their complaint to add claims for patent infringement with respect to the '551 patent and United States Patent Nos. 7,399,856 (the '856 patent), 7,563,922 (the '922 patent), 8,101,752 (the '752 patent) and 8,618,291 (the '291 patent). Mylan filed a motion to dismiss the suit for lack of personal jurisdiction and a motion to dismiss, strike or sever the infringement claims regarding the '752 and '291 patents. In September 2016, the Delaware District Court denied both of Mylan's motions. A trial in the Delaware action has been scheduled for February 2018.

In each of these lawsuits, Janssen is seeking an order enjoining the defendants from marketing their generic versions of COMPLERA® before the expiration of the relevant patents.

XARELTO®

A number of generic companies have filed ANDAs seeking approval to market generic versions of XARELTO®. In October 2015, Janssen Pharmaceuticals, Inc. (JPI) and Bayer Pharma AG and Bayer Intellectual Property GmbH (collectively, Bayer) filed patent infringement lawsuits in the United States District Court for the District of Delaware against Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc., Breckenridge Pharmaceutical, Inc., Micro Labs USA Inc. and Micro Labs Ltd. (collectively, Micro), Mylan Pharmaceuticals Inc., Mylan Inc. (Mylan), Prinston Pharmaceutical, Inc., Sigmapharm Laboratories, LLC, Torrent Pharmaceuticals, Limited and Torrent Pharma Inc., in response to those parties' respective ANDAs seeking approval to market generic versions of XARELTO® before the expiration of Bayer's United States Patent Nos. 7,157,456 (the '456 patent), 7,585,860 (the '860 patent) and 7,592,339 (the '339 patent) relating to XARELTO®. JPI is the exclusive licensee of the asserted patents.

In November 2015, Mylan moved to dismiss the action. In December 2015, JPI, Bayer, and Mylan stipulated and agreed to dismiss the claims against Mylan, and suspend further briefing and argument on Mylan's motion to dismiss, pending appeals relating to personal jurisdiction over Mylan Pharmaceuticals Inc. in the District of Delaware. In February 2016, a similar patent infringement action by JPI and Bayer against Invagen Pharmaceuticals Inc. (Invagen), in response to Invagen's notice of paragraph IV certification advising of its ANDA seeking FDA approval for a generic XARELTO® product before expiration of the relevant patents, was consolidated with the original case. The District Court has set a trial date of March 2018.

In April 2016, JPI and Bayer filed a separate patent infringement action in the District of Delaware against Micro, in response to their notice of paragraph IV certification advising of their ANDA seeking FDA approval for a generic XARELTO® product before expiration of the '860 and '339 patents. In May 2016, this action was consolidated with the original action.

In July 2016, JPI and Bayer filed a separate patent infringement action in the District of Delaware against Breckenridge Pharmaceutical, Inc., in response to its notice of paragraph IV certification advising of its ANDA seeking FDA approval for a generic XARELTO® product before expiration of the '456 and '339 patents. This action has been consolidated with the original action.

In each of these lawsuits, JPI is seeking an order enjoining the defendants from marketing their generic versions of XARELTO® before the expiration of the relevant patents.

In October 2016, Mylan filed petitions for inter partes review in the USPTO seeking to invalidate the '339, '456 and '860 patents.

GOVERNMENT PROCEEDINGS

Like other companies in the pharmaceutical and medical devices industries, Johnson & Johnson and certain of its subsidiaries are subject to extensive regulation by national, state and local government agencies in the United States and other countries in which they operate. As a result, interaction with government agencies is ongoing. The most significant litigation brought by, and investigations conducted by, government agencies are listed below. It is possible that criminal charges and substantial fines and/or civil penalties or damages could result from government investigations or litigation.

Average Wholesale Price (AWP) Litigation

Johnson & Johnson and several of its pharmaceutical subsidiaries (the J&J AWP Defendants), along with numerous other pharmaceutical companies, are defendants in a series of lawsuits in state and federal courts involving allegations that the pricing and marketing of certain pharmaceutical products amounted to fraudulent and otherwise actionable conduct because, among other things, the companies allegedly reported an inflated Average Wholesale Price (AWP) for the drugs at issue. Payors alleged that they used those AWPs in calculating provider reimbursement levels. Many of these cases, both federal actions and state actions removed to federal court, were consolidated for pre-trial purposes in a Multi-District Litigation (MDL) in the United States District Court for the District of Massachusetts. The plaintiffs in these cases included three classes of private persons or entities that paid for any portion of the purchase of the drugs at issue based on AWP, and state government entities that made Medicaid payments for the drugs at issue based on AWP. In June 2007, after a trial on the merits, the MDL Court dismissed the claims of two of the plaintiff classes against the J&J AWP Defendants. In March 2011, the Court dismissed the claims of the third class against the J&J AWP Defendants without prejudice.

AWP cases brought by various Attorneys General have proceeded to trial against other manufacturers. Several state cases against certain Johnson & Johnson subsidiaries have been settled, including the case in Wisconsin, which settled in February 2016. Cases are still pending in Illinois, New Jersey, and Utah. The cases in Illinois and New Jersey have not yet proceeded to trial. In Utah, the claims brought by the Attorney General were dismissed by the Court in 2013, but the State may appeal the dismissal after the conclusion of similar pending matters against other defendants. In the AWP case against the J&J AWP Defendants brought by the Commonwealth of Pennsylvania, following a trial in 2010, the Pennsylvania Commonwealth Court found in favor of the Commonwealth with regard to certain of its claims under the Pennsylvania Unfair Trade Practices and Consumer Protection Law, and in favor of the J&J AWP Defendants on the Commonwealth's remaining claims. Following an appeal to the Pennsylvania Supreme Court that vacated that judgment, the Commonwealth Court entered a subsequent judgment in favor of the J&J AWP Defendants on all claims. That subsequent judgment has been upheld by the Pennsylvania Supreme Court in a successive appeal.

McNeil Consumer Healthcare

Starting in June 2010, McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. (now Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division) (McNeil Consumer Healthcare) and certain affiliates, including Johnson & Johnson (the Companies), received grand jury subpoenas from the United States Attorney's Office for the Eastern District of Pennsylvania requesting documents broadly relating to recalls of various products of McNeil Consumer Healthcare, and the FDA inspections of the Fort Washington, Pennsylvania and Lancaster, Pennsylvania manufacturing facilities, as well as certain documents relating to recalls of a small number of products of other subsidiaries. In addition, in February 2011, the government served McNEIL-PPC, Inc. (now Johnson & Johnson Consumer Inc.) (JJCI) with a Civil Investigative Demand seeking records relevant to its investigation to determine if there was a violation of the Federal False Claims Act. In March 2015, McNEIL-PPC, Inc. (now JJCI) entered a guilty plea in the United States District Court for the Eastern District of Pennsylvania to a misdemeanor violation of the U.S. Food, Drug and Cosmetic Act. McNEIL-PPC, Inc. (now JJCI) agreed to pay a $20 million fine and a $5 million forfeiture to resolve the matter.

The Companies have also received Civil Investigative Demands from multiple State Attorneys General Offices broadly relating to the McNeil recall issues. The Companies continue to cooperate with these inquiries, which are being coordinated through a multi-state coalition. If a resolution cannot be reached with this multi-state coalition, it is possible that individual State Attorneys General Offices may file civil monetary claims against the Companies.

In January 2011, the Oregon Attorney General filed a civil complaint against Johnson & Johnson, McNEIL-PPC, Inc. (now JJCI) and McNeil Healthcare LLC in state court alleging civil violations of the Oregon Unlawful Trade Practices Act relating to an earlier recall of a McNeil OTC product. In November 2012, the state court granted a motion by the Companies to dismiss Oregon's complaint in its entirety, with prejudice. In November 2015, the State Court of Appeals reversed the trial court and reinstated Oregon's consumer protection claims. In February 2016, the Oregon Supreme Court denied the Companies' petition for review, and the case was sent back to the trial court.

Opioids Litigation

As described below, Johnson & Johnson (J&J) and Janssen Pharmaceuticals, Inc. (JPI), along with other pharmaceutical companies, have been named in four lawsuits alleging claims related to marketing of opioids, including DURAGESIC®, NUCYNTA® and NUCYNTA® ER, and have been subpoenaed by two other states for information related to opioid marketing practices.

In May 2014, Santa Clara and Orange Counties in California filed a complaint in state court in Orange County, California against numerous pharmaceutical manufacturers, including J&J and JPI, alleging claims related to opioid marketing practices, including false advertising, unfair competition, and public nuisance. The counties seek injunctive and monetary relief. In February 2015, the defendants filed motions challenging the sufficiency of the complaint. In August 2015, the Court stayed the case until the FDA concludes its ongoing inquiry into the safety and effectiveness of long-term opioid treatment. Following a motion by the counties to lift the stay, in October 2016, the Court kept the stay in place in part, requested the parties to confer, and adjourned the matter until a later date.

In June 2014, the City of Chicago filed a complaint in Cook County Circuit Court against the same group of pharmaceutical manufacturers, including J&J and JPI, alleging a number of claims related to opioid marketing practices, including consumer fraud violations and false claims, and seeking injunctive and monetary relief. The case was later removed to the United States District Court for the Northern District of Illinois. In December 2014, J&J and JPI filed a motion to dismiss the City of Chicago's first amended complaint, which was granted with leave to file an amended complaint. The City filed a second

amended complaint, and in November 2015, J&J and JPI filed a motion to dismiss the second amended complaint. In September 2016, the Court dismissed eight of the City's ten causes of action and granted the City one final opportunity to replead the dismissed claims. The City filed a third amended complaint in October 2016, and, in December 2016, J&J and JPI filed an answer as to two causes of action and a motion to dismiss the remaining causes of action.

In September 2014, the Tennessee Attorney General Division of Consumer Affairs issued a Request for Information to JPI and other pharmaceutical companies related to opioids marketing practices.

In August 2015, the New Hampshire Attorney General, Consumer Protection and Antitrust Bureau issued a subpoena to JPI and other pharmaceutical companies related to opioids marketing practices. In October 2015, the State filed a motion in the State of New Hampshire Superior Court to enforce the subpoena. JPI and the other pharmaceutical companies subsequently filed a joint motion for injunctive relief and a protective order to preclude the State from engaging private contingent fee counsel to participate in the State's investigation or any subsequent enforcement action. In March 2016, the Court granted the protective order on the grounds that the State had not obtained requisite executive and legislative approvals to retain private counsel, but rejected the contention that the contingency fee agreement was otherwise unlawful. All parties have appealed the March 2016 ruling to the New Hampshire Supreme Court. In August 2016, the Court denied the pharmaceutical companies' joint motion to enforce the protective order on the ground that the underlying deficiency (legislative approval) had been cured. In September 2016, the State stipulated to stay enforcement of any subpoenas pending the New Hampshire Supreme Court's consideration of the companies' appeal of the March 2016 ruling.

In December 2015, the State of Mississippi filed a complaint in the Chancery Court of the First Judicial District of Hinds County against substantially the same group of pharmaceutical manufacturers as in the suits brought by the California counties and City of Chicago, including J&J and JPI, alleging a number of claims related to opioid marketing practices and seeking penalties and injunctive and monetary relief. In March 2016, defendants filed a motion to transfer venue and motions to dismiss the complaint.

In August 2016, the County of Suffolk in New York filed a complaint against several pharmaceutical manufacturers in New York Supreme Court, including J&J and JPI, alleging claims related to opioid marketing, including claims based on deceptive acts and practices, false advertising, fraud and unjust enrichment. The complaint seeks penalties and injunctive and monetary relief.

In February 2017, the County of Erie and the County of Broome in New York each filed a complaint in New York Supreme Court against several pharmaceutical manufacturers, including JPI. Both complaints allege claims related to opioid marketing practices, including statutory claims for deceptive acts and practices, false advertising, and violation of New York's Social Services Law, and common law causes of action for public nuisance, fraud, and unjust enrichment. Each county is seeking compensatory and punitive damages and costs.

Other

In September 2011, Synthes, Inc. (Synthes) received a Civil Investigative Demand issued pursuant to the False Claims Act from the United States Attorney's Office for the Eastern District of Pennsylvania. The demand sought information regarding allegations that fellowships had been offered to hospitals in exchange for agreements to purchase products. Synthes has produced documents and information in response to the demand and is cooperating with the inquiry.

In May 2012, Acclarent, Inc. (Acclarent) received a subpoena from the United States Attorney's Office for the District of Massachusetts requesting documents broadly relating to the sales, marketing and alleged off-label promotion by Acclarent of the RELIEVA STRATUS® MicroFlow Spacer product (the RELIEVA STRATUS® Spacer). In March 2016, Acclarent executed a civil settlement with the United States Justice Department and other agencies to resolve this investigation. Johnson & Johnson was not a party to this settlement and there was no admission of liability. In a separate matter, in July 2016, the former President/CEO and Vice President of Sales of Acclarent (the former Acclarent officers), were convicted of misdemeanor violations in connection with the sale and marketing of the RELIEVA STRATUS® Spacer. There are no charges against Acclarent, Ethicon, Inc. or Johnson & Johnson in this matter.

In August 2012, DePuy Orthopaedics, Inc., DePuy, Inc. (now DePuy Synthes, Inc.), and Johnson & Johnson Services, Inc. received an informal request from the United States Attorney's Office for the District of Massachusetts and the Civil Division of the United States Department of Justice (the United States) for the production of materials relating to the DePuy ASR™ XL Hip device. In July 2014, the United States notified the United States District Court for the District of Massachusetts that it had declined to intervene in a qui tam case filed pursuant to the False Claims Act against the companies. In February 2016, the District Court granted the companies' motion to dismiss with prejudice, unsealed the qui tam complaint, and denied the qui tam

relators' request for leave to file a further amended complaint. The qui tam relators appealed the case to the United States Court of Appeals for the First Circuit. The First Circuit's decision in the case is pending. Since October 2013, a group of State Attorneys General have issued Civil Investigative Demands relating to the development, sales and marketing of several of DePuy Orthopaedics, Inc.'s hip products. The states are seeking monetary and injunctive relief. In July 2014, the Oregon Department of Justice, which was investigating these matters independently of the other states, announced a settlement of its ASR XL Hip device investigation for a total payment of $4 million to the State of Oregon.

In October 2012, Johnson & Johnson was contacted by the California Attorney General's office regarding a multi-state Attorney General investigation of the marketing of surgical mesh products for hernia and urogynecological purposes by Johnson & Johnson's subsidiary, Ethicon, Inc. (Ethicon). Johnson & Johnson and Ethicon have since entered into a series of tolling agreements with the 47 states and the District of Columbia participating in the multi-state investigation and have responded to Civil Investigative Demands served by certain of the participating states. The states are seeking monetary and injunctive relief. In May 2016, California and Washington filed civil complaints against Johnson & Johnson and Ethicon alleging violations of their consumer protection statutes. In August 2016, Kentucky filed a similar complaint against the companies. Johnson & Johnson and Ethicon have entered into a new tolling agreement with the remaining 44 states and the District of Columbia.

In December 2012, Therakos, Inc. (Therakos), formerly a subsidiary of Johnson & Johnson and part of the Ortho-Clinical Diagnostics, Inc. (OCD) franchise, received a letter from the civil division of the United States Attorney's Office for the Eastern District of Pennsylvania informing Therakos that the United States Attorney's Office was investigating the sales and marketing of Uvadex® (methoxsalen) and the Uvar Xts® System during the period 2000 to the present. The United States Attorney's Office requested that OCD and Johnson & Johnson preserve documents that could relate to the investigation. Therakos was subsequently acquired by an affiliate of Gores Capital Partners III, L.P. in January 2013, and OCD was divested in June 2014. Following the divestiture of OCD, Johnson & Johnson retains OCD's portion of any liability that may result from the investigation for activity that occurred prior to the sale of Therakos. In March 2014 and March 2016, the United States Attorney's Office requested that Johnson & Johnson produce certain documents, and Johnson & Johnson is cooperating with the requests.

In June 2014, the Mississippi Attorney General filed a complaint in Chancery Court of The First Judicial District of Hinds County, Mississippi against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (now Johnson & Johnson Consumer Inc.) (JJCI). The complaint alleges that defendants failed to disclose alleged health risks associated with female consumers' use of talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product no longer sold by JJCI) and seeks injunctive and monetary relief. This matter is currently scheduled for trial in September 2017.

In March 2016, Janssen Pharmaceuticals, Inc. (JPI) received a Civil Investigative Demand from the United States Attorney's Office for the Southern District of New York related to JPI's contractual relationships with pharmacy benefit managers over the period from January 1, 2006 to the present with regard to certain of JPI's pharmaceutical products. The demand was issued in connection with an investigation under the False Claims Act.

In January 2017, Janssen Pharmaceuticals, Inc. (JPI) received a Civil Investigative Demand (CID) from the United States Department of Justice (DOJ) relating to allegations concerning the sales and marketing practices of OLYSIO™. JPI is cooperating with DOJ in appropriately responding to the CID.

In February 2017, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts seeking the production of records pertaining to payments to any 501(c)(3) charitable organization that provides financial assistance to Medicare patients. Multiple pharmaceutical companies have publicly reported receipt of similar subpoenas and ongoing inquiries.

In recent years, Johnson & Johnson has received numerous requests from a variety of United States Congressional Committees to produce information relevant to ongoing congressional inquiries. It is the policy of Johnson & Johnson to cooperate with these inquiries by producing the requested information.

GENERAL LITIGATION

In June 2009, following the public announcement that Ortho-Clinical Diagnostics, Inc. (OCD) had received a grand jury subpoena from the United States Department of Justice, Antitrust Division, in connection with an investigation that has since been closed, multiple class action complaints were filed against OCD by direct purchasers seeking damages for alleged price fixing. These cases were consolidated for pre-trial purposes in the United States District Court for the Eastern District of Pennsylvania as In re Blood Reagent Antitrust Litigation. In August 2012, the District Court granted a motion filed by the plaintiffs for class certification. In April 2015, the United States Court of Appeals for the Third Circuit reversed the class

certification ruling and remanded the case to the District Court for further proceedings. In October 2015, the District Court again granted the motion by the plaintiffs for class certification. In July 2016, OCD filed a motion for summary judgment. OCD was divested in 2014 and Johnson & Johnson retained any liability that may result from these cases.

In September 2011, Johnson & Johnson, Johnson & Johnson Inc. and McNeil Consumer Healthcare Division of Johnson & Johnson Inc. received a Notice of Civil Claim filed by Nick Field in the Supreme Court of British Columbia, Canada (the BC Civil Claim). The BC Civil Claim is a putative class action brought on behalf of persons who reside in British Columbia and who purchased during the period between September 20, 2001 and in or about December 2010 one or more various McNeil infants' or children's over-the-counter medicines that were manufactured at the Fort Washington, Pennsylvania facility. The BC Civil Claim alleges that the defendants violated the BC Business Practices and Consumer Protection Act, and other Canadian statutes and common laws, by selling medicines that were allegedly not safe and/or effective or did not comply with Canadian Good Manufacturing Practices. The class certification hearing scheduled for October 2015 was adjourned, and there is currently no date set for that hearing.

In May 2014, two purported class actions were filed in federal court, one in the United States District Court for the Central District of California and one in the United States District Court for the Southern District of Illinois, against Johnson & Johnson (J&J) and Johnson & Johnson Consumer Companies, Inc. (now Johnson & Johnson Consumer Inc.) (JJCI), alleging violations of state consumer fraud statutes based on nondisclosure of alleged health risks associated with talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product no longer sold by JJCI). Both cases seek injunctive relief and monetary damages; neither includes a claim for personal injuries. In October 2016, both cases were transferred to the United States District Court for the District Court of New Jersey as part of a newly created federal multi-district litigation. In December 2016, J&J and JJCI filed a motion to dismiss one of the cases.

In August 2014, United States Customs and Border Protection (US CBP) issued a Penalty Notice against Janssen Ortho LLC (Janssen Ortho), assessing penalties for the alleged improper classification of darunavir ethanolate (the active pharmaceutical ingredient in PREZISTA®) in connection with its importation into the United States. In October 2014, Janssen Ortho submitted a Petition for Relief in response to the Penalty Notice. In May 2015, US CBP issued an Amended Penalty Notice assessing substantial penalties and Janssen Ortho filed its Petition for Relief in July 2015.

In March and April 2015, over 30 putative class action complaints were filed by contact lens patients in a number of courts around the United States against Johnson & Johnson Vision Care, Inc. (JJVCI), other contact lens manufacturers, distributors, and retailers, alleging vertical and horizontal conspiracies to fix the retail prices of contact lenses. The complaints allege that the manufacturers reached agreements with each other and certain distributors and retailers concerning the prices at which some contact lenses could be sold to consumers. The plaintiffs are seeking damages and injunctive relief. All of the class action cases were transferred to the United States District Court for the Middle District of Florida in June 2015. The plaintiffs filed a Consolidated Class Action complaint in November 2015, and in December 2015, JJVCI and other defendants filed motions to dismiss. In June 2016, the Court denied the motions to dismiss. Discovery is ongoing.

In April 2015, Johnson & Johnson Vision Care, Inc. (JJVCI) filed a complaint in the United States District Court for the District of Utah against the State of Utah seeking a declaratory judgment that a law passed by the State to ban unilateral pricing policies solely in the contact lens market violates the Commerce Clause of the United States Constitution. The Court denied JJVCI's motion for a preliminary injunction. JJVCI appealed. Argument on the appeal was held in August 2015. In December 2016, the appellate court denied JJVCI's appeal.

In April 2015, Adimmune Corporation Ltd (Adimmune) commenced an arbitration in the International Court of Arbitration - International Chamber of Commerce against Crucell Switzerland AG (now Janssen Vaccines AG) and Crucell Holland B.V. (now Janssen Vaccines & Prevention B.V.) (collectively, Crucell). Adimmune claims that Crucell breached certain agreements relating to the supply of flu antigen when Crucell ceased purchasing flu antigen from Adimmune. In December 2015, Adimmune filed its Statement of Claim seeking monetary damages. The arbitration hearing took place in November 2016 and the parties are awaiting a ruling.

In August 2015, two third-party payors filed a purported class action in the United States District Court for the Eastern District of Louisiana against Janssen Research & Development, LLC, Janssen Ortho LLC, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Johnson & Johnson (as well as certain Bayer entities), alleging that the defendants improperly marketed and promoted XARELTO® as safer and more effective than less expensive alternative medications while failing to fully disclose its risks. The complaint seeks damages in an unspecified amount.

Johnson & Johnson or its subsidiaries are also parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the cost of past and/or future remediation.

22. Restructuring

The Company announced restructuring actions in its Medical Devices segment to better serve the needs of patients and customers in today's evolving healthcare marketplace. The Company is undertaking actions to strengthen its go-to-market model, accelerate the pace of innovation, further prioritize key platforms and geographies, and streamline operations while maintaining high quality standards.

The Company estimates that, in connection with its plans, it will record pre-tax restructuring related charges of approximately $2.0 billion to $2.4 billion. In 2016, the Company recorded a pre-tax charge of $685 million, of which $45 million was included in cost of products sold and $149 million was included in other (income) expense. See table below for additional details. Total project costs of $1.275 billion have been recorded since the restructuring has been announced.

Additionally, as part of the plan, the Company expects that the restructuring actions will result in position eliminations of approximately 4 to 6 percent of the Medical Devices segment's global workforce over the next two years, subject to any consultation procedures in countries, where required. Approximately 1,500 positions have been eliminated since the restructuring was announced.

The Company estimates that approximately one-half of the cumulative pre-tax costs will result in cash outlays, including approximately $500 million of employee severance. Approximately one half of the cumulative pre-tax costs are non-cash, relating primarily to facility rationalization, inventory write-offs and intangible asset write-offs.

The following table summarizes the severance charges and the associated spending under this initiative through the fiscal year ended 2016:

(Dollars in Millions)		Severance	Asset Write-offs	Other**	Total
2015 restructuring charge	$	484	86	20	590
2015 activity			(86)	(3)	(89)
Reserve balance, January 3, 2016		484	—	17	501
Current year activity:					
Charges		—	249	436	685
Cash payments		(104)	—	(452)	(556)
Settled non cash		—	(249)	—	(249)
Reserve balance, January 1, 2017*	$	380	—	1	381

*Cash outlays for severance are expected to be substantially paid out over the next 18 months in accordance with the Company's plans and local laws.
**Other includes project expense such as salaries for employees supporting the initiative and consulting expenses.

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of Johnson & Johnson

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of earnings, of comprehensive income, of equity, and of cash flows present fairly, in all material respects, the financial position of Johnson & Johnson and its subsidiaries at January 1, 2017 and January 3, 2016, and the results of their operations and their cash flows for each of the three years in the period ended January 1, 2017 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of January 1, 2017, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 1 to the consolidated financial statements, the Company changed the manner in which it accounts for and presents certain elements of share based payments in 2016.

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 27, 2017

Management's Report on Internal Control Over Financial Reporting

Under Section 404 of the Sarbanes-Oxley Act of 2002, management is required to assess the effectiveness of the Company's internal control over financial reporting as of the end of each fiscal year and report, based on that assessment, whether the Company's internal control over financial reporting is effective.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is designed to provide reasonable assurance as to the reliability of the Company's financial reporting and the preparation of external financial statements in accordance with generally accepted accounting principles.

Internal controls over financial reporting, no matter how well designed, have inherent limitations. Therefore, internal control over financial reporting determined to be effective can provide only reasonable assurance with respect to financial statement preparation and may not prevent or detect all misstatements. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management has assessed the effectiveness of the Company's internal control over financial reporting as of January 1, 2017. In making this assessment, the Company used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework (2013)." These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. The Company's assessment included extensive documenting, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

Based on the Company's processes and assessment, as described above, management has concluded that, as of January 1, 2017, the Company's internal control over financial reporting was effective.

The effectiveness of the Company's internal control over financial reporting as of January 1, 2017 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which appears herein.

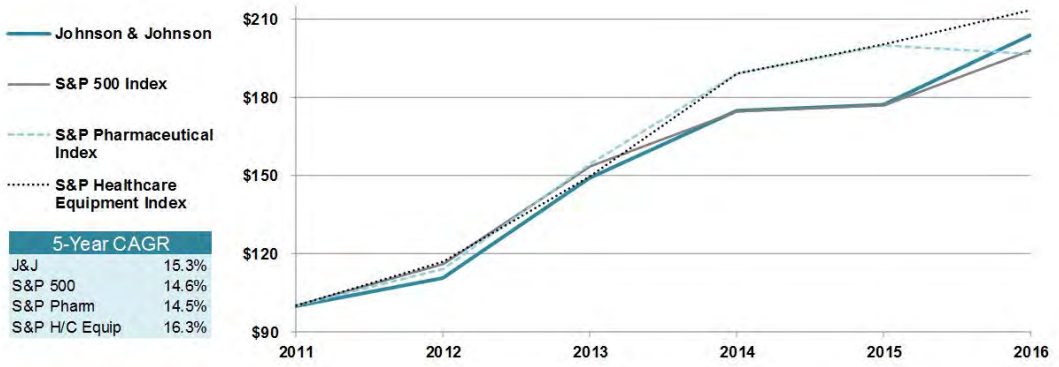
/s/ Alex Gorsky
Alex Gorsky
Chairman, Board of Directors
Chief Executive Officer

/s/ Dominic J. Caruso
Dominic J. Caruso
Executive Vice President, Chief Financial Officer

Shareholder Return Performance Graphs

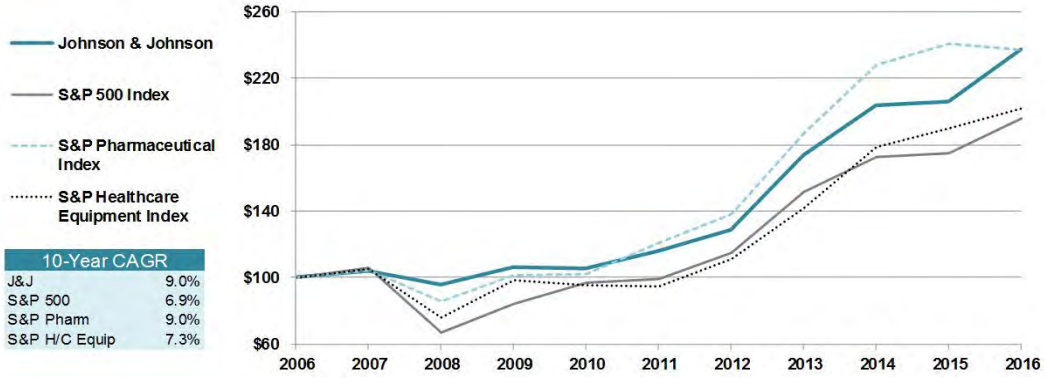
Set forth below are line graphs comparing the cumulative total shareholder return on the Company's Common Stock for periods of five years and ten years ending December 31, 2016, against the cumulative total return of the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index. The graphs and tables assume that $100 was invested on December 31, 2011 and December 31, 2006 in each of the Company's Common Stock, the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index and that all dividends were reinvested.

5 Year Shareholder Return Performance J&J vs. Indices



	2011	2012	2013	2014	2015	2016
Johnson & Johnson	$100.00	$110.83	$149.19	$175.05	$177.08	$204.21
S&P 500 Index	$100.00	$115.99	$153.55	$174.55	$176.95	$198.10
S&P Pharmaceutical Index	$100.00	$114.43	$154.73	$189.12	$200.06	$196.93
S&P Healthcare Equipment Index	$100.00	$117.27	$149.74	$189.09	$200.39	$213.38

10 Year Shareholder Return Performance J&J vs. Indices



	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Johnson & Johnson	$100.00	$103.61	$95.56	$106.34	$105.72	$116.17	$128.75	$173.32	$203.36	$205.72	$237.24
S&P 500 Index	$100.00	$105.57	$66.51	$84.10	$96.76	$98.80	$114.60	$151.71	$172.46	$174.83	$195.72
S&P Pharmaceutical Index	$100.00	$104.66	$85.61	$101.55	$102.34	$120.51	$137.90	$186.48	$227.91	$241.09	$237.32
S&P Healthcare Equipment Index	$100.00	$105.13	$76.07	$97.97	$95.32	$94.55	$110.88	$141.58	$178.79	$189.47	$201.76

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE 768

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures. At the end of the period covered by this Report, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Alex Gorsky, Chairman and Chief Executive Officer, and Dominic J. Caruso, Executive Vice President, Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Gorsky and Caruso concluded that, as of the end of the period covered by this Report, the Company's disclosure controls and procedures were effective

Reports on Internal Control Over Financial Reporting. The information called for by this item is incorporated herein by reference to "Management's Report on Internal Control Over Financial Reporting", and the attestation regarding internal controls over financial reporting included in the "Report of Independent Registered Public Accounting Firm" included in Item 8 of this Report.

Changes in Internal Control Over Financial Reporting. During the fiscal quarter ended January 1, 2017, there were no changes in the Company's internal control over financial reporting identified in connection with the evaluation required under Rules 13a-15 and 15d-15 under the Exchange Act that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

The Company is implementing a multi-year, enterprise-wide initiative to integrate, simplify and standardize processes and systems for the human resources, information technology, procurement, supply chain and finance functions. These are enhancements to support the growth of the Company's financial shared service capabilities and standardize financial systems. This initiative is not in response to any identified deficiency or weakness in the Company's internal control over financial reporting. In response to this initiative, the Company has and will continue to align and streamline the design and operation of its financial control environment.

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information called for by this item is incorporated herein by reference to the discussion of the Audit Committee under the caption "Item 1. Election of Directors - Board Committees"; and the material under the captions "Item 1. Election of Directors" and "Stock Ownership and Section 16 Compliance – Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement; and the material under the caption "Executive Officers of the Registrant" in Part I of this Report.

The Company's Code of Business Conduct, which covers all employees (including the Chief Executive Officer, Chief Financial Officer and Controller), meets the requirements of the SEC rules promulgated under Section 406 of the Sarbanes-Oxley Act of 2002. The Code of Business Conduct is available on the Company's website at *www.jnj.com/code-of-business-conduct*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code of Business Conduct or any waiver of the Code granted to the Chief Executive Officer, the Chief Financial Officer or the Controller will be posted on the Company's website at *www.investor.jnj.com/gov.cfm* within five business days (and retained on the website for at least one year).

In addition, the Company has adopted a Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers. The Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers is available on the Company's website at *www.investor.jnj.com/gov/boardconduct.cfm*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code or any waiver of the Code granted to any member of the Board of Directors or any executive officer will be posted

on the Company's website at *www.investor.jnj.com/gov.cfm* within five business days (and retained on the website for at least one year).

Item 11. EXECUTIVE COMPENSATION

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1. Election of Directors – Director Compensation," "Compensation Committee Report," "Compensation Discussion and Analysis" and "Executive Compensation Tables" in the Proxy Statement.

The material incorporated herein by reference to the material under the caption "Compensation Committee Report" in the Proxy Statement shall be deemed furnished, and not filed, in this Report and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, as a result of this furnishing, except to the extent that the Company specifically incorporates it by reference.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information called for by this item is incorporated herein by reference to the material under the caption "Item 1. Stock Ownership and Section 16 Compliance" in the Proxy Statement; and Note 17 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements in Item 8 of this Report.

Equity Compensation Plan Information

The following table provides certain information as of January 1, 2017 concerning the shares of the Company's Common Stock that may be issued under existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights	Weighted Average Exercise Price of Outstanding Options and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans[2][3]
Equity Compensation Plans Approved by Security Holders[1]	137,289,904	$68.72	439,398,804
Equity Compensation Plans Not Approved by Security Holders	-	-	-
Total	137,289,904	$68.72	439,398,804

(1) Included in this category are the following equity compensation plans which have been approved by the Company's shareholders: 2005 Long-Term Incentive Plan and 2012 Long-Term Incentive Plan.

(2) This column excludes shares reflected under the column "Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights."

(3) The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1. Election of Directors - Director Independence" and "Related Party Transactions" in the Proxy Statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information called for by this item is incorporated herein by reference to the material under the caption "Item 5. Ratification of Appointment of Independent Registered Public Accounting Firm" in the Proxy Statement.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this report:

1. *Financial Statements*

   Consolidated Balance Sheets at end of Fiscal Years 2016 and 2015

   Consolidated Statements of Earnings for Fiscal Years 2016, 2015 and 2014

   Consolidated Statements of Comprehensive Income for Fiscal Years 2016, 2015 and 2014

   Consolidated Statements of Equity for Fiscal Years 2016, 2015 and 2014

   Consolidated Statements of Cash Flows for Fiscal Years 2016, 2015 and 2014

   Notes to Consolidated Financial Statements

   Report of Independent Registered Public Accounting Firm

   All schedules are omitted because they are not applicable or the required information is included in the financial statements or notes.

2. *Exhibits* Required *to be Filed by Item 601 of Regulation S-K*

   The information called for by this item is incorporated herein by reference to the Exhibit Index in this Report.

Item 16. FORM 10-K SUMMARY

Registrants may voluntarily include a summary of information required by Form 10-K under this Item 16. The Company has elected not to include such summary information.

SIGNATURES

Pursuant to the requirements of Section 13 of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 27, 2017

JOHNSON & JOHNSON
(Registrant)

By /s/ A. Gorsky
A. Gorsky, Chairman, Board of Directors,
and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ A. Gorsky A. Gorsky	Chairman, Board of Directors Chief Executive Officer (Principal Executive Officer)	February 27, 2017
/s/ D. J. Caruso D. J. Caruso	Chief Financial Officer (Principal Financial Officer)	February 27, 2017
/s/ R. A. Kapusta R. A. Kapusta	Controller and Chief Accounting Officer (Principal Accounting Officer)	February 27, 2017
/s/ M. C. Beckerle M. C. Beckerle	Director	February 27, 2017
/s/ D. S. Davis D. S. Davis	Director	February 27, 2017
/s/ I. E. L. Davis I. E. L. Davis	Director	February 27, 2017

Signature	Title	Date
/s/ M. B. McClellan M. B. McClellan	Director	February 27, 2017
/s/ A. M. Mulcahy A. M. Mulcahy	Director	February 27, 2017
/s/ W. D. Perez W. D. Perez	Director	February 27, 2017
/s/ C. Prince C. Prince	Director	February 27, 2017
/s/ A. E. Washington A. E. Washington	Director	February 27, 2017
/s/ R. A. Williams R. A. Williams	Director	February 27, 2017

EXHIBIT INDEX

Reg. S-K Exhibit Table Item No.	Description of Exhibit
3(i)	Restated Certificate of Incorporation effective February 19, 2016 — Incorporated herein by reference to Exhibit 3(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.
3(ii)	By-Laws of the Company, as amended effective January 26, 2016 — Incorporated herein by reference to Exhibit 3.1 the Registrant's Form 8-K Current Report filed January 26, 2016.
4(a)	Upon the request of the Securities and Exchange Commission, the Registrant will furnish a copy of all instruments defining the rights of holders of long-term debt of the Registrant.
10(a)	2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 4 of the Registrant's S-8 Registration Statement filed with the Commission on May 10, 2005 (file no. 333-124785).*
10(b)	Form of Stock Option Certificate, Restricted Share Unit Certificate and Performance Share Unit Certificate under the 2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.1, 10.2 and 10.3 of the Registrant's Form 8-K Current Report filed January 13, 2012.*
10(c)	2012 Long-Term Incentive Plan — Incorporated herein by reference to Appendix A of the Registrant's Proxy Statement filed with the Commission on March 14, 2012 .*
10(d)	Form of Stock Option Certificate, Restricted Share Unit Certificate and Performance Share Unit Certificate under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.2, 10.3 and 10.4 of the Registrant's Form 10-Q Quarterly Report filed May 7, 2012.*
10(e)	Executive Incentive Plan (as amended) — Incorporated herein by reference to Exhibit 10(f) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 31, 2000.*
10(f)	Domestic Deferred Compensation (Certificate of Extra Compensation) Plan — Incorporated herein by reference to Exhibit 10(g) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2003.*
10(g)	Amendments to the Certificate of Extra Compensation Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(h)	2009 Certificates of Long-Term Performance Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 27, 2009.*
10(i)	Amended and Restated Deferred Fee Plan for Directors — Incorporated herein by reference to Exhibit 10(k) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 1, 2012.*
10(j)	Executive Income Deferral Plan (Amended and Restated) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*
10(k)	Excess Savings Plan — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 29, 1996.*
10(l)	Amendments to the Johnson & Johnson Excess Savings Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(p) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2008.*
10(m)	Excess Benefit Plan (Supplemental Retirement Plan) — Incorporated herein by reference to Exhibit 10(h) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 1993.*
10(n)	Amendments to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(r) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2008.*
10(o)	Amendment to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies, effective as of January 1, 2015 — Incorporated herein by reference to Exhibit 10(q) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2014.*
10(p)	Executive Life Plan Agreement — Incorporated herein by reference to Exhibit 10(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 1993.*
10(q)	Executive Life Plan Agreement Closure Letter — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended March 29, 2015.*
10(r)	Johnson & Johnson Retirement Savings Plan, Johnson & Johnson Savings Plan for Union Represented Employees, and Johnson & Johnson Savings Plan - Incorporated herein by reference to Exhibits 99.1, 99.2 and 99.3 of the Registrant's Form S-8 filed with the Commission on May 6, 2013.*
10(s)	Employment Agreement for Dr. Paulus Stoffels - Incorporated herein by reference to Exhibit 10.2 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*
10(t)	Summary of Employment Arrangements for Sandra E. Peterson — Incorporated herein by reference to Exhibit 10(t) of the Registrant's Form 10-K Annual Report for the year ended December 30, 2012.*

Reg. S-K Exhibit Table Item No.	Description of Exhibit
10(u)	Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies, Amended and Restated as of October 1, 2014 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 28, 2014.*
10(v)	First Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended June 28, 2015.*
10(w)	Second Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10(x) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.*
12	Statement of Computation of Ratio of Earnings to Fixed Charges — Filed with this document.
21	Subsidiaries - Filed with this document.
23	Consent of Independent Registered Public Accounting Firm — Filed with this document.
31(a)	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
31(b)	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
32(a)	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
32(b)	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
101	XBRL (Extensible Business Reporting Language) The following materials from this Report for the fiscal year ended January 1, 2017, formatted in Extensive Business Reporting Language (XBRL): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Earnings, (iii) Consolidated Statements of Comprehensive Income, (iv) Consolidated Statements of Equity, (v) Consolidated Statements of Cash Flows, and (vi) Notes to the Consolidated Financial Statements.

* Management contract or compensatory plan.

A copy of any of the Exhibits listed above will be provided without charge to any shareholder submitting a written request specifying the desired exhibit(s) to the Secretary at the principal executive offices of the Company.

Exhibit “J15”

This is Exhibit “J15” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2017 **Commission file number 1-3215**

JOHNSON & JOHNSON

(Exact name of registrant as specified in its charter)

New Jersey	**22-1024240**
(State of incorporation)	(I.R.S. Employer Identification No.)
One Johnson & Johnson Plaza **New Brunswick, New Jersey**	**08933**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(732) 524-0400**

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT

Title of each class	Name of each exchange on which registered
Common Stock, Par Value $1.00	New York Stock Exchange
4.75% Notes Due November 2019	New York Stock Exchange
0.250% Notes Due January 2022	New York Stock Exchange
0.650% Notes Due May 2024	New York Stock Exchange
5.50% Notes Due November 2024	New York Stock Exchange
1.150% Notes Due November 2028	New York Stock Exchange
1.650% Notes Due May 2035	New York Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☑	Accelerated filer ☐
Non-accelerated filer ☐	(Do not check if a smaller reporting company)
Smaller reporting company ☐	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $355 billion.

On February 16, 2018, there were 2,682,901,553 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Parts I and III:	Portions of registrant's proxy statement for its 2018 annual meeting of shareholders filed within 120 days after the close of the registrant's fiscal year (the "Proxy Statement"), are incorporated by reference to this report on Form 10-K (this "Report").

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and Johnson & Johnson's other publicly available documents contain "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Management and representatives of Johnson & Johnson and its subsidiaries (the "Company") also may from time to time make forward-looking statements. Forward-looking statements do not relate strictly to historical or current facts and reflect management's assumptions, views, plans, objectives and projections about the future. Forward-looking statements may be identified by the use of words such as "plans," "expects," "will," "anticipates," "estimates" and other words of similar meaning in conjunction with, among other things: discussions of future operations; expected operating results and financial performance; impact of planned acquisitions and dispositions; the Company's strategy for growth; product development; regulatory approvals; market position and expenditures.

Because forward-looking statements are based on current beliefs, expectations and assumptions regarding future events, they are subject to uncertainties, risks and changes that are difficult to predict and many of which are outside of the Company's control. Investors should realize that if underlying assumptions prove inaccurate, or known or unknown risks or uncertainties materialize, the Company's actual results and financial condition could vary materially from expectations and projections expressed or implied in its forward-looking statements. Investors are therefore cautioned not to rely on these forward-looking statements. Risks and uncertainties include, but are not limited to:

Risks Related to Product Development, Market Success and Competition

- Challenges and uncertainties inherent in innovation and development of new and improved products and technologies on which the Company's continued growth and success depend, including uncertainty of clinical outcomes, obtaining regulatory approvals, health plan coverage and customer access, and initial and continued commercial success;
- Challenges to the Company's ability to obtain and protect adequate patent and other intellectual property rights for new and existing products and technologies in the U.S. and other important markets;
- The impact of patent expirations, typically followed by the introduction of competing biosimilars and generics and resulting revenue and market share losses;
- Increasingly aggressive and frequent challenges to the Company's patents by competitors and others seeking to launch competing generic, biosimilar or other products, and increased receptivity of courts, the United States Patent and Trademark Office and other decision makers to such challenges, potentially resulting in loss of market exclusivity and rapid decline in sales for the relevant product;
- Competition in research and development of new and improved products, processes and technologies, which can result in product and process obsolescence;
- Competition to reach agreement with third parties for collaboration, licensing, development and marketing agreements for products and technologies;
- Competition on the basis of cost-effectiveness, product performance, technological advances and patents attained by competitors; and
- Allegations that the Company's products infringe the patents and other intellectual property rights of third parties, which could adversely affect the Company's ability to sell the products in question and require the payment of money damages and future royalties.

Risks Related to Product Liability, Litigation and Regulatory Activity

- Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the U.S. Food and Drug Administration (or international counterparts), declining sales and reputational damage;
- Impact of significant litigation or government action adverse to the Company, including product liability claims and allegations related to pharmaceutical marketing practices and contracting strategies;
- Increased scrutiny of the health care industry by government agencies and state attorneys general resulting in investigations and prosecutions, which carry the risk of significant civil and criminal penalties, including, but not limited to, debarment from government business;
- Failure to meet compliance obligations in the McNEIL-PPC, Inc. Consent Decree or the Corporate Integrity Agreements of the Johnson & Johnson Pharmaceutical Affiliates, or any other compliance agreements with governments or government agencies, which could result in significant sanctions;

- Potential changes to applicable laws and regulations affecting U.S. and international operations, including relating to: approval of new products; licensing and patent rights; sales and promotion of health care products; access to, and reimbursement and pricing for, health care products and services; environmental protection and sourcing of raw materials;
- Changes in tax laws and regulations, increasing audit scrutiny by tax authorities around the world and exposures to additional tax liabilities potentially in excess of reserves; and
- Issuance of new or revised accounting standards by the Financial Accounting Standards Board and the Securities and Exchange Commission.

Risks Related to the Company's Strategic Initiatives and Health Care Market Trends

- Pricing pressures resulting from trends toward health care cost containment, including the continued consolidation among health care providers, trends toward managed care, the shift toward governments increasingly becoming the primary payers of health care expenses, and significant new entrants to the health care markets seeking to reduce costs;
- Restricted spending patterns of individual, institutional and governmental purchasers of health care products and services due to economic hardship and budgetary constraints;
- Challenges to the Company's ability to realize its strategy for growth including through externally sourced innovations, such as development collaborations, strategic acquisitions, licensing and marketing agreements, and the potential heightened costs of any such external arrangements due to competitive pressures;
- The potential that the expected strategic benefits and opportunities from any planned or completed acquisition or divestiture by the Company, including the integration of Actelion Ltd., may not be realized or may take longer to realize than expected; and
- The potential that the expected benefits and opportunities related to past and future restructuring actions may not be realized or may take longer to realize than expected, including due to any required consultation procedures relating to restructuring of workforce.

Risks Related to Economic Conditions, Financial Markets and Operating Internationally

- Impact of inflation and fluctuations in interest rates and currency exchange rates and the potential effect of such fluctuations on revenues, expenses and resulting margins;
- Potential changes in export/import and trade laws, regulations and policies of the U.S., U.K. and other countries, including any increased trade restrictions and potential drug reimportation legislation;
- The impact on international operations from financial instability in international economies, sovereign risk, possible imposition of governmental controls and restrictive economic policies, and unstable international governments and legal systems;
- Changes to global climate, extreme weather and natural disasters that could affect demand for the Company's products and services, cause disruptions in manufacturing and distribution networks, alter the availability of goods and services within the supply chain, and affect the overall design and integrity of the Company's products and operations; and
- The impact of armed conflicts and terrorist attacks in the U.S. and other parts of the world including social and economic disruptions and instability of financial and other markets.

Risks Related to Supply Chain and Operations

- Difficulties and delays in manufacturing, internally or within the supply chain, that may lead to voluntary or involuntary business interruptions or shutdowns, product shortages, withdrawals or suspensions of products from the market, and potential regulatory action;
- Interruptions and breaches of the Company's information technology systems, and those of the Company's vendors, could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action; and
- Reliance on global supply chains and production and distribution processes that are complex and subject to increasing regulatory requirements that may adversely affect supply, sourcing and pricing of materials used in the Company's products.

Investors also should carefully read the Risk Factors described in Item 1A of this Annual Report on Form 10-K for a description of certain risks that could, among other things, cause the Company's actual results to differ materially from those expressed in its forward-looking statements. Investors should understand that it is not possible to predict or identify all such factors and should not consider the risks described above and in Item 1A to be a complete statement of all potential risks and uncertainties. The Company does not undertake to publicly update any forward-looking statement that may be made from time to time, whether as a result of new information or future events or developments.

PART I

Item 1. BUSINESS

General

Johnson & Johnson and its subsidiaries (the Company) have approximately 134,000 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. Johnson & Johnson is a holding company, which has more than 260 operating companies conducting business in virtually all countries of the world. The Company's primary focus is products related to human health and well-being. Johnson & Johnson was incorporated in the State of New Jersey in 1887.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Company's three business segments: Consumer, Pharmaceutical and Medical Devices. Within the strategic parameters provided by the Committee, senior management groups at U.S. and international operating companies are each responsible for their own strategic plans and the day-to-day operations of those companies. Each subsidiary within the business segments is, with limited exceptions, managed by residents of the country where located.

Segments of Business

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. Additional information required by this item is incorporated herein by reference to the narrative and tabular descriptions of segments and operating results under: "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition" of this Report; and Note 18 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Consumer

The Consumer segment includes a broad range of products used in the baby care, oral care, beauty, over-the-counter pharmaceutical, women's health and wound care markets. Baby Care includes the JOHNSON'S® line of products. Oral Care includes the LISTERINE® product line. Major brands in Beauty include the AVEENO®; CLEAN & CLEAR®; DABAO™; JOHNSON'S® Adult; LE PETITE MARSEILLAIS®; NEUTROGENA®; RoC® and OGX® product lines. Over-the-counter medicines include the broad family of TYLENOL® acetaminophen products; SUDAFED® cold, flu and allergy products; BENADRYL® and ZYRTEC® allergy products; MOTRIN® IB ibuprofen products; and the PEPCID® line of acid reflux products. Major brands in Women's Health outside of North America are STAYFREE® and CAREFREE® sanitary pads and o.b.® tampon brands. Wound Care brands include the BAND-AID® Brand Adhesive Bandages and NEOSPORIN® First Aid product lines. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world.

Pharmaceutical

The Pharmaceutical segment is focused on six therapeutic areas: Immunology (e.g., rheumatoid arthritis, inflammatory bowel disease and psoriasis), Infectious Diseases and Vaccines (e.g., HIV/AIDS), Neuroscience (e.g., mood disorders and schizophrenia), Oncology (e.g., prostate cancer and hematologic malignancies), Cardiovascular and Metabolism (e.g., thrombosis and diabetes) and Pulmonary Hypertension (e.g., Pulmonary Arterial Hypertension), a new therapeutic area, which was established with the acquisition of Actelion in June 2017. Medicines in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. Key products in the Pharmaceutical segment include: REMICADE® (infliximab), a treatment for a number of immune-mediated inflammatory diseases; SIMPONI® (golimumab), a subcutaneous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis and moderately active to severely active ulcerative colitis; SIMPONI ARIA® (golimumab), an intravenous treatment for adults with moderate to severe rheumatoid arthritis; STELARA® (ustekinumab), a treatment for adults with moderate to severe plaque psoriasis and active psoriatic arthritis, and for adults with moderately to severely active Crohn's disease; EDURANT® (rilpivirine) and PREZISTA® (darunavir) and PREZCOBIX®/REZOLSTA® (darunavir/cobicistat), antiretroviral medicines for the treatment of human immunodeficiency virus (HIV-1) in combination with other antiretroviral products; CONCERTA® (methylphenidate HCl) extended-release tablets CII, a treatment for attention deficit hyperactivity disorder; INVEGA SUSTENNA®/XEPLION® (paliperidone palmitate), for the treatment of schizophrenia and schizoaffective disorder in adults; INVEGA TRINZA®/TREVICTA® (paliperidone palmitate), for the treatment of schizophrenia in patients after they have been adequately treated with INVEGA SUSTENNA® for at least four months; RISPERDAL CONSTA® (risperidone long-acting injection), for the treatment of schizophrenia and the maintenance treatment of Bipolar 1 Disorder in adults; VELCADE® (bortezomib), a treatment for multiple myeloma and for use in combination with rituximab, cyclophosphamide, doxorubicin and prednisone for the treatment of adult patients with previously untreated mantle cell lymphoma; ZYTIGA® (abiraterone

acetate), used in combination with prednisone as a treatment for metastatic castration-resistant prostate cancer; IMBRUVICA® (ibrutinib), an oral, once-daily therapy approved for use in treating certain B-cell malignancies, or blood cancers, and Waldenström's Macroglobulinemia; DARZALEX® (daratumumab), for the treatment of relapsed/refractory multiple myeloma; PROCRIT®/ EPREX®, to stimulate red blood cell production; XARELTO® (rivaroxaban), an oral anticoagulant for the prevention of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery, to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, and for the treatment and reduction of risk of recurrence of DVT and PE; INVOKANA® (canagliflozin), for the treatment of adults with type 2 diabetes; INVOKAMET®/VOKANAMET® (canagliflozin/metformin HCl), a combination therapy of fixed doses of canagliflozin and metformin hydrochloride for the treatment of adults with type 2 diabetes; and INVOKAMET® XR (canagliflozin/metformin hydrochloride extended-release), a once-daily, fixed-dose combination therapy of canagliflozin and metformin hydrochloride extended-release, for the treatment of adults with type 2 diabetes; OPSUMIT® (macitentan) as monotherapy or in combination, indicated for the long-term treatment of pulmonary arterial hypertension (PAH); UPTRAVI® (selexipag), the only approved oral, selective IP receptor agonist targeting a prostacyclin pathway in PAH. Many of these medicines were developed in collaboration with strategic partners or are licensed from other companies and maintain active lifecycle development programs.

Medical Devices

The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, cardiovascular, diabetes care and eye health fields. These products are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics. They include orthopaedic products; general surgery, biosurgical, endomechanical and energy products; electrophysiology products to treat cardiovascular disease; sterilization and disinfection products to reduce surgical infection; diabetes care products, such as blood glucose monitoring; and vision care products such as disposable contact lenses and ophthalmic products related to cataract and laser refractive surgery.

Geographic Areas

The business of Johnson & Johnson is conducted by more than 260 operating companies located in more than 60 countries, including the U.S., which sell products in virtually all countries throughout the world. The products made and sold in the international business include many of those described above under "– Segments of Business – Consumer," "– Pharmaceutical" and "– Medical Devices." However, the principal markets, products and methods of distribution in the international business vary with the country and the culture. The products sold in international business include those developed in the U.S. and by subsidiaries abroad.

Investments and activities in some countries outside the U.S. are subject to higher risks than comparable U.S. activities because the investment and commercial climate may be influenced by financial instability in international economies, restrictive economic policies and political and legal system uncertainties.

Raw Materials

Raw materials essential to the Company's business are generally readily available from multiple sources. Where there are exceptions, the temporary unavailability of those raw materials would not likely have a material adverse effect on the financial results of the Company.

Patents

The Company's subsidiaries have made a practice of obtaining patent protection on their products and processes where possible. They own, or are licensed under, a significant number of patents in the U.S. and other countries relating to their products, product uses, formulations and manufacturing processes, which in the aggregate are believed to be of material importance to the Company in the operation of its businesses. The Company's subsidiaries face patent challenges from third parties, including challenges seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. Significant legal proceedings and claims involving the Company's patent and other intellectual property are described in Note 21, "Legal Proceedings—Intellectual Property" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Sales of the Company's largest product, REMICADE® (infliximab), accounted for approximately 8.3% of the Company's total net trade sales for fiscal 2017.

There are two sets of patents related specifically to REMICADE®. The first set of patents is co-owned by Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson, and NYU Langone Medical Center (NYU). Janssen Biotech, Inc. has an exclusive license to NYU's interests in the patents. These patents have expired in all countries outside the United States. In the United States, the one remaining patent, which expires in September 2018, stands rejected following

reexamination proceedings instituted by a third party in the United States Patent and Trademark Office (USPTO). The patent has also been held invalid by the Federal District Court in the District of Massachusetts. In January 2018, the U.S. Court of Appeals for the Federal Circuit affirmed the invalidity of the remaining patent.

The second set of patents specifically related to REMICADE® was granted to The Kennedy Institute of Rheumatology in Europe, Canada, Australia and the United States. Janssen Biotech, Inc. has licenses (exclusive for human anti-TNF antibodies and semi-exclusive for non-human anti-TNF antibodies) to these patents, which expired in 2017 outside of the United States and will expire in August 2018 in the United States. Certain of these patents have been successfully challenged and invalidated, and others are under review in various patent offices around the world and are also subject to litigation in Canada.

The Company does not expect that any extensions will be available for the above described patents specifically related to REMICADE®. In the United States, a biosimilar version of REMICADE® was introduced in 2016, and additional competitors continue to enter the market. For a more extensive description of legal matters regarding the patents related to REMICADE®, see Note 21 "Legal Proceedings – Intellectual Property – Pharmaceutical – REMICADE® Related Cases" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

In addition to competing in the immunology market with REMICADE®, the Company is currently marketing STELARA® (ustekinumab), SIMPONI® (golimumab), SIMPONI ARIA® (golimumab) and TREMFYA® (guselkumab), next generation immunology products with remaining patent lives of up to six years.

Trademarks

The Company's subsidiaries have made a practice of selling their products under trademarks and of obtaining protection for these trademarks by all available means. These trademarks are protected by registration in the U.S. and other countries where such products are marketed. The Company considers these trademarks in the aggregate to be of material importance in the operation of its businesses.

Seasonality

Worldwide sales do not reflect any significant degree of seasonality; however, spending has been heavier in the fourth quarter of each year than in other quarters. This reflects increased spending decisions, principally for advertising and research and development activity.

Competition

In all of their product lines, the Company's subsidiaries compete with companies both locally and globally. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, both internally and externally sourced, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products, as well as protecting the underlying intellectual property of the Company's product portfolio, is important to the Company's success in all areas of its business. The competitive environment requires substantial investments in continuing research. In addition, the development and maintenance of customer demand for the Company's consumer products involve significant expenditures for advertising and promotion.

Research and Development

Research activities represent a significant part of the Company's businesses. Research and development expenditures relate to the processes of discovering, testing and developing new products, upfront payments and milestones, improving existing products, as well as demonstrating product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products. Worldwide costs of research and development activities amounted to $10.6 billion, $9.1 billion and $9.0 billion for fiscal years 2017, 2016 and 2015, respectively. Research facilities are located in the United States, Belgium, Brazil, Canada, China, France, Germany, Israel, Japan, the Netherlands, Switzerland and the United Kingdom with additional R&D support in over 30 other countries.

Environment

The Company is subject to a variety of U.S. and international environmental protection measures. The Company believes that its operations comply in all material respects with applicable environmental laws and regulations. The Company's compliance with these requirements did not change during the past year, and is not expected to have a material effect upon its capital expenditures, cash flows, earnings or competitive position.

Regulation

The Company's businesses are subject to varying degrees of governmental regulation in the countries in which operations are conducted, and the general trend is toward increasingly stringent regulation. In the U.S., the drug, device and cosmetic industries have long been subject to regulation by various federal and state agencies, primarily as to product safety, efficacy, manufacturing, advertising, labeling and safety reporting. The exercise of broad regulatory powers by the U.S. Food and Drug Administration (the FDA) continues to result in increases in the amounts of testing and documentation required for FDA approval of new drugs and devices and a corresponding increase in the expense of product introduction. Similar trends are also evident in major markets outside of the U.S. The new medical device regulatory framework and the new privacy regulations in Europe are examples of such increased regulation.

The costs of human health care have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. In the U.S., attention has been focused on drug prices and profits and programs that encourage doctors to write prescriptions for particular drugs, or to recommend, use or purchase particular medical devices. Payers have become a more potent force in the market place and increased attention is being paid to drug and medical device pricing, appropriate drug and medical device utilization and the quality and costs of health care generally.

U.S. government agencies continue to implement the extensive requirements of the Patient Protection and Affordable Care Act (the ACA). These have both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of the ACA, and potential modification or repeal of ACA provisions, will ultimately affect the industry.

The regulatory agencies under whose purview the Company operates have administrative powers that may subject it to actions such as product withdrawals, recalls, seizure of products and other civil and criminal sanctions. In some cases, the Company's subsidiaries may deem it advisable to initiate product recalls.

In addition, business practices in the health care industry have come under increased scrutiny, particularly in the United States, by government agencies and state attorneys general, and resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Further, the Company relies on global supply chains, and production and distribution processes, that are complex, are subject to increasing regulatory requirements, and may be faced with unexpected changes such as those resulting from Brexit, that may affect sourcing, supply and pricing of materials used in the Company's products. These processes also are subject to lengthy regulatory approvals.

Available Information

The Company's main corporate website address is *www.jnj.com*. Copies of the Company's Quarterly Reports on Form 10-Q, Annual Report on Form 10-K and Current Reports on Form 8-K filed or furnished to the U.S. Securities and Exchange Commission (the SEC), and any amendments to the foregoing, will be provided without charge to any shareholder submitting a written request to the Secretary at the principal executive offices of the Company or by calling 1-800-950-5089. All of the Company's SEC filings are also available on the Company's website at *www.investor.jnj.com/sec.cfm*, as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*. In addition, the written charters of the Audit Committee, the Compensation & Benefits Committee, the Nominating & Corporate Governance Committee, the Regulatory, Compliance & Government Affairs Committee and the Science, Technology & Sustainability Committee of the Board of Directors and the Company's Principles of Corporate Governance, Code of Business Conduct (for employees), Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers, and other corporate governance materials, are available at *www.investor.jnj.com/gov.cfm* on the Company's website and will be provided without charge to any shareholder submitting a written request, as provided above. The information on the Company's website is not, and will not be deemed, a part of this Report or incorporated into any other filings the Company makes with the SEC.

Item 1A. RISK FACTORS

The Company faces a number of uncertainties and risks that are difficult to predict and many of which are outside of the Company's control. In addition to the other information in this report and the Company's other filings with the SEC, investors should consider carefully the factors set forth below. Investors should be aware that it is not possible to predict or identify all such factors and that the following is not meant to be a complete discussion of all potential risks or uncertainties. If known or unknown risks or uncertainties materialize, the Company's business, results of operations or financial condition could be adversely affected, potentially in a material way.

The Company's largest product, REMICADE® (infliximab), is experiencing biosimilar competition, which will result in a reduction in U.S. sales of REMICADE®.

The Company has experienced significant challenges to patents covering its largest product, REMICADE® (infliximab) (accounting for approximately 8.3% of the Company's total net trade sales for fiscal 2017), and continues to assert certain patents related to the product. In the United States, a biosimilar version of REMICADE® was introduced in 2016, and additional competitors continue to enter the market. Sales of infliximab biosimilars in the U.S. market will result in a continued reduction in U.S. sales of REMICADE®.

Global sales in the Company's pharmaceutical and medical devices segments may be negatively impacted by healthcare reforms and increasing pricing pressures.

Sales of the Company's pharmaceutical and medical device products are significantly affected by reimbursements by third-party payers such as government healthcare programs, private insurance plans and managed care organizations. As part of various efforts to contain healthcare costs, these payers are putting downward pressure on prices at which products will be reimbursed. In the United States, increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, in part due to continued consolidation among health care providers, could result in further pricing pressures. In addition, increased political scrutiny could result in additional pricing pressures. Outside the United States, numerous major markets, including the EU and Japan, have pervasive government involvement in funding healthcare and, in that regard, directly or indirectly impose price controls, limit access to, or reimbursement for, the Company's products, or reduce the value of its intellectual property protection.

The Company is subject to significant legal proceedings that can result in significant expenses, fines and reputational damage.

In the ordinary course of business, Johnson & Johnson and its subsidiaries are subject to numerous claims and lawsuits involving various issues such as patent disputes, product liability and claims that their product sales, marketing and pricing practices violate various antitrust, unfair trade practices and/or consumer protection laws. The most significant of these proceedings are described in Note 21, "Legal Proceedings" under Notes to the Consolidated Financial Statements included in Item 8 of this Report. While the Company believes it has substantial defenses in these matters, it is not feasible to predict the ultimate outcome of litigation. The Company could in the future be required to pay significant amounts as a result of settlements or judgments in these matters, potentially in excess of accruals. The resolution of, or increase in accruals for, one or more of these matters in any reporting period could have a material adverse effect on the Company's results of operations and cash flows for that period. Furthermore, as a result of cost and availability factors, effective November 1, 2005, the Company ceased purchasing third-party product liability insurance.

Product reliability, safety and effectiveness concerns can have significant negative impacts on sales and results of operations, lead to litigation and cause reputational damage.

Concerns about product safety, whether raised internally or by litigants, regulators or consumer advocates, and whether or not based on scientific evidence, can result in safety alerts, product recalls, governmental investigations, regulatory action on the part of the FDA (or its counterpart in other countries), private claims and lawsuits, payment of fines and settlements, declining sales and reputational damage. These circumstances can also result in damage to brand image, brand equity and consumer trust in the Company's products. Product recalls have in the past, and could in the future, prompt government investigations and inspections, the shutdown of manufacturing facilities, continued product shortages and related sales declines, significant remediation costs, reputational damage, possible civil penalties and criminal prosecution.

Changes in tax laws or exposures to additional tax liabilities could negatively impact the Company's operating results.

Changes in tax laws or regulations could negatively impact the Company's effective tax rate and results of operations. On December 22, 2017, the U.S. enacted The Tax Cuts and Jobs Act (the TCJA), which resulted in the revaluation of the Company's U.S. related deferred tax assets and liabilities and had an impact on the Company's Consolidated Statement of Earnings. The TCJA introduces significant changes to U.S. corporate income tax law that will have a meaningful impact on the

Company's provision for income taxes. Accounting for the income tax effects of the TCJA requires significant judgments to be made in interpreting its provisions. Due to the timing of the enactment and the complexity involved in applying the provisions of the TCJA, the Company made reasonable estimates of the effects and recorded provisional amounts in the financial statements for fiscal year 2017. These provisional amounts are based on the Company's initial analysis of the TCJA as of January 18, 2018. Anticipated guidance from the U.S. Treasury about implementing the TCJA, and the potential for additional guidance from the Securities and Exchange Commission or the Financial Accounting Standards Board related to the TCJA, may result in adjustments to these estimates which could materially affect the Company's financial position and results of operations as well as the effective tax rate in the period in which the adjustments are made.

The government in Switzerland is currently considering tax reform legislation, which could have a material impact on the Company's effective tax rate if enacted into law.

The Company conducts business and files tax returns in numerous countries and is addressing tax audits and disputes with many tax authorities. In connection with the Organization for Economic Cooperation and Development Base Erosion and Profit Shifting (BEPS) project, companies are required to disclose more information to tax authorities on operations around the world, which may lead to greater audit scrutiny of profits earned in other countries. The Company regularly assesses the likely outcomes of its tax audits and disputes to determine the appropriateness of its tax reserves. However, any tax authority could take a position on tax treatment that is contrary to the Company's expectations, which could result in tax liabilities in excess of reserves.

The Company may not be able to successfully secure and defend intellectual property rights essential to the Company's businesses.

The Company owns or licenses a significant number of patents and other proprietary rights, determined by patent offices, courts and lawmakers in various countries, relating to its products and manufacturing processes. These rights are essential to the Company's businesses and materially important to the Company's results of operations. Public policy, both within and outside the U.S., has become increasingly unfavorable toward intellectual property rights. The Company cannot be certain that it will obtain adequate patent protection for new products and technologies in the U.S. and other important markets or that such protections, once granted, will last as long as originally anticipated.

Competitors routinely challenge the validity or extent of the Company's owned or licensed patents and proprietary rights through litigation, interferences, oppositions and other proceedings. These proceedings absorb resources and can be protracted as well as unpredictable. In addition, challenges that the Company's products infringe the patents of third parties could result in the need to pay past damages and future royalties and adversely affect the competitive position and sales of the products in question.

The Company has faced increasing patent challenges from third parties seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the United States, manufacturers of generic versions of innovative human pharmaceutical products may challenge the validity, or claim non-infringement, of innovator products through the Abbreviated New Drug Application, or ANDA, process with the FDA. The Biologics Price Competition and Innovation Act (BPCIA), enacted in 2010, which created a new regulatory pathway for the approval by the FDA of biosimilar alternatives to innovator-developed biological products, also created mechanisms for biosimilar applicants to challenge the patents on the innovator biologics. The inter partes review (IPR) process with the USPTO, created under the 2011 America Invents Act, is also being used by competitors to challenge patents held by the Company's subsidiaries. For example, the key patent for ZYTIGA® is currently subject to patent litigation, and the USPTO has issued a decision invalidating that patent in a related IPR action.

In the event the Company is not successful in defending its patents against such challenges, or upon the "at-risk" launch (despite pending patent infringement litigation) by the generic or biosimilar firm of its product, the Company can lose a major portion of revenues for the referenced product in a very short period of time. Current legal proceedings involving the Company's patents and other intellectual property rights are described in Note 21, "Legal Proceedings—Intellectual Property" of the Notes to the Consolidated Financial Statements included in Item 8 of this Report.

The Company's businesses operate in highly competitive product markets and competitive pressures could adversely affect the Company's earnings.

The Company faces substantial competition in all three operating segments and in all geographic markets. The Company's businesses compete with companies of all sizes on the basis of cost-effectiveness, technological innovations, intellectual property rights, product performance, real or perceived product advantages, pricing and availability and rate of reimbursement. The Company also competes with other market participants in securing rights to acquisitions, collaborations and licensing

agreements with third parties. Competition for rights to product candidates and technologies may result in significant investment and acquisition costs and onerous agreement terms for the Company. Competitors' development of more effective or less costly products, and/or their ability to secure patent and other intellectual property rights and successfully market products ahead of the Company, could negatively impact sales of the Company's existing products as well as its ability to bring new products to market despite significant prior investment in the related product development.

For the Company's pharmaceutical businesses, loss of patent exclusivity for a product often is followed by a substantial reduction in sales as competitors gain regulatory approval for generic and other competing products and enter the market. Similar competition can be triggered by the loss of exclusivity for a biological product. For the Company's medical device businesses, technological innovation, product quality, reputation and customer service are especially important to competitiveness. Development by other companies of new or improved products, processes and technologies could threaten to make the Company's products or technologies less desirable, less economical or obsolete. The Company's consumer businesses face intense competition from other branded products and retailers' private-label brands. If the Company fails to sufficiently differentiate and market its brand name consumer products, this could adversely affect revenues and profitability of those products.

Significant challenges or delays in the Company's innovation and development of new products, technologies and indications could have an adverse impact on the Company's long-term success.

The Company's continued growth and success depends on its ability to innovate and develop new and differentiated products and services that address the evolving health care needs of patients, providers and consumers. Development of successful products and technologies is also necessary to offset revenue losses when the Company's existing products lose market share due to various factors such as competition and loss of patent exclusivity. New products introduced within the past five years accounted for approximately 22% of 2017 sales. The Company cannot be certain when or whether it will be able to develop, license or otherwise acquire companies, products and technologies, whether particular product candidates will be granted regulatory approval, and, if approved, whether the products will be commercially successful.

The Company pursues product development through internal research and development as well as through collaborations, acquisitions, joint ventures and licensing or other arrangements with third parties. In all of these contexts, developing new products, particularly pharmaceutical and biotechnology products and medical devices, requires significant investment of resources over many years. Only a very few biopharmaceutical research and development programs result in commercially viable products. The process depends on many factors including the ability to discern patients' and health care providers' future needs; develop promising new compounds, strategies and technologies; achieve successful clinical trial results; secure effective intellectual property protection; obtain regulatory approvals on a timely basis; and, if and when they reach the market, successfully differentiate the Company's products from competing products and approaches to treatment. New products or enhancements to existing products may not be accepted quickly or significantly in the marketplace due to product and price competition, changes in customer preferences or healthcare purchasing patterns, resistance by healthcare providers or uncertainty over third-party reimbursement. Even following initial regulatory approval, the success of a product can be adversely impacted by safety and efficacy findings in larger real world patient populations, as well as market entry of competitive products.

The Company faces increasing regulatory scrutiny which imposes significant compliance costs and exposes the Company to government investigations, legal actions and penalties.

Like other companies in the healthcare industry, the Company is subject to extensive regulation, investigations and legal action, by national, state and local government agencies in the United States and other countries in which they operate. Regulatory issues regarding compliance with Good Manufacturing Practices (cGMP) (and comparable quality regulations in foreign countries) by manufacturers of drugs, devices and consumer products can lead to fines and penalties, product recalls, product shortages, interruptions in production, delays in new product approvals and litigation. In addition, the marketing, pricing and sale of the Company's products are subject to regulation, investigations and legal actions including under the Federal Food, Drug, and Cosmetic Act, the Medicaid Rebate Program, federal and state false claims acts, state unfair trade practices acts and consumer protection laws. Increased scrutiny of health care industry business practices in recent years by government agencies and state attorneys general in the U.S., and any resulting investigations and prosecutions, carry risk of significant civil and criminal penalties including, but not limited to, debarment from participation in government healthcare programs. Any such debarment could have a material adverse effect on the Company's business and results of operations. The most significant current investigations and litigation brought by government agencies are described in Note 21, "Legal Proceedings-Government Proceedings" under Notes to the Consolidated Financial Statements included in Item 8 of this Report.

The Company faces a variety of risks associated with conducting business internationally.

The Company's extensive operations and business activity outside the U.S. are accompanied by certain financial, economic and political risks, including those listed below.

Foreign Currency Exchange: In fiscal 2017, approximately 48% of the Company's sales occurred outside of the U.S., with approximately 22% in Europe, 8% in the Western Hemisphere, excluding the U.S., and 18% in the Asia-Pacific and Africa region. Changes in non-U.S. currencies relative to the U.S. dollar impact the Company's revenues and expenses. While the Company uses financial instruments to mitigate the impact of fluctuations in currency exchange rates on its cash flows, unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the U.S. dollar may result in significant favorable or unfavorable translation effects when the operating results of the Company's non-U.S. business activity are translated into U.S. dollars.

Inflation and Currency Devaluation Risks: The Company faces challenges in maintaining profitability of operations in economies experiencing high inflation rates. The Company has accounted for operations in Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. While the Company strives to maintain profit margins in these areas through cost reduction programs, productivity improvements and periodic price increases, it might experience operating losses as a result of continued inflation. In addition, the impact of currency devaluations in countries experiencing high inflation rates or significant currency exchange fluctuations could negatively impact the Company's operating results.

Illegal Importation of Pharmaceutical Products: The illegal importation of pharmaceutical products from countries where government price controls or other market dynamics result in lower prices may adversely affect the Company's sales and profitability in the U.S. and other countries in which the Company operates. With the exception of limited quantities of prescription drugs for personal use, foreign imports of pharmaceutical products are illegal under current U.S. law. However, the volume of illegal imports continues to rise as the ability of patients and other customers to obtain the lower-priced imports has grown significantly.

Anti-Bribery and Other Regulations: The Company is subject to various federal and foreign laws that govern its international business practices with respect to payments to government officials. Those laws include the U.S. Foreign Corrupt Practices Act (FCPA), which prohibits U.S. publicly traded companies from promising, offering, or giving anything of value to foreign officials with the corrupt intent of influencing the foreign official for the purpose of helping the Company obtain or retain business or gain any improper advantage. The Company's business is heavily regulated and therefore involves significant interaction with foreign officials. Also, in many countries outside the U.S., the health care providers who prescribe human pharmaceuticals are employed by the government and the purchasers of human pharmaceuticals are government entities; therefore, the Company's interactions with these prescribers and purchasers are subject to regulation under the FCPA. In addition to the U.S. application and enforcement of the FCPA, various jurisdictions in which the Company operates have laws and regulations, including the U.K Bribery Act 2010, aimed at preventing and penalizing corrupt and anticompetitive behavior. Enforcement activities under these laws could subject the Company to additional administrative and legal proceedings and actions, which could include claims for civil penalties, criminal sanctions, and administrative remedies, including exclusion from health care programs.

Other Legal, Social and Political Risks. Other risks inherent in conducting business globally include:

- protective economic policies taken by governments such as trade protection measures and import/export licensing requirements;
- compliance with local regulations and laws including, in some countries, regulatory requirements restricting the Company's ability to manufacture or sell its products in the relevant market;
- diminished protection of intellectual property and contractual rights in certain jurisdictions;
- potential nationalization or expropriation of the Company's foreign assets; and
- disruptions to markets due to war, armed conflict, terrorism, social upheavals or pandemics.

Interruptions and delays in manufacturing operations could adversely affect the Company's business, sales and reputation.

The Company's manufacture of products requires the timely delivery of sufficient amounts of complex, high-quality components and materials. The Company's subsidiaries operate 125 manufacturing facilities as well as sourcing from hundreds of suppliers around the world. The Company has in the past, and may in the future, face unanticipated interruptions and delays in manufacturing through its internal or external supply chain. Manufacturing disruptions can occur for many reasons including regulatory action, production quality deviations or safety issues, labor disputes, site-specific incidents (such as fires), natural disasters such as hurricanes and other severe weather events, raw material shortages, political unrest and terrorist attacks. Such

delays and difficulties in manufacturing can result in product shortages, declines in sales and reputational impact as well as significant remediation and related costs associated with addressing the shortage.

An information security incident, including a cybersecurity breach, could have a negative impact to the Company's business or reputation

To meet business objectives, the Company relies on both internal information technology (IT) systems and networks, and those of third parties and their vendors, to process and store sensitive data, including confidential research, business plans, financial information, intellectual property, and personal data that may be subject to legal protection. The extensive information security and cybersecurity threats, which affect companies globally, pose a risk to the security and availability of these IT systems and networks, and the confidentiality, integrity, and availability of the Company's sensitive data. The Company continually assesses these threats and makes investments to increase internal protection, detection, and response capabilities, as well as ensure the Company's third party providers have required capabilities and controls, to address this risk. To date, the Company has not experienced any material impact to the business or operations resulting from information or cybersecurity attacks; however, because of the frequently changing attack techniques, along with the increased volume and sophistication of the attacks, there is the potential for the Company to be adversely impacted. This impact could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

The Company's subsidiaries operate 125 manufacturing facilities occupying approximately 21.9 million square feet of floor space. The manufacturing facilities are used by the industry segments of the Company's business approximately as follows:

Segment	Square Feet (in thousands)
Consumer	6,787
Pharmaceutical	7,304
Medical Devices	7,782
Worldwide Total	21,873

Within the United States, seven facilities are used by the Consumer segment, six by the Pharmaceutical segment and 27 by the Medical Devices segment. Outside of the United States, 30 facilities are used by the Consumer segment, 16 by the Pharmaceutical segment and 39 by the Medical Devices segment.

The locations of the manufacturing facilities by major geographic areas of the world are as follows:

Geographic Area	Number of Facilities	Square Feet (in thousands)
United States	40	6,300
Europe	37	7,939
Western Hemisphere, excluding U.S.	14	2,800
Africa, Asia and Pacific	34	4,834
Worldwide Total	125	21,873

In addition to the manufacturing facilities discussed above, the Company maintains numerous office and warehouse facilities throughout the world. Research facilities are also discussed in Item 1 of this Report under "Business – Research and Development."

The Company's subsidiaries generally seek to own their manufacturing facilities, although some, principally in non-U.S. locations, are leased. Office and warehouse facilities are often leased. The Company also engages contract manufacturers.

The Company is committed to maintaining all of its properties in good operating condition.

McNEIL-PPC, Inc. (now Johnson & Johnson Consumer Inc.) (McNEIL-PPC) continues to operate under a consent decree, signed in 2011 with the FDA, which governs certain McNeil Consumer Healthcare manufacturing operations, and requires McNEIL-PPC to remediate the facilities it operates in Lancaster, Pennsylvania, Fort Washington, Pennsylvania, and Las Piedras, Puerto Rico (the "Consent Decree"). Following FDA inspections in 2015, McNEIL-PPC received notifications from the FDA that all three manufacturing facilities are in conformity with applicable laws and regulations, and commercial production has restarted.

Under the Consent Decree, after receiving notice from the FDA of being in compliance with applicable laws and regulations, each of the three facilities is subject to a five-year audit period by a third-party cGMP expert. Thus, a third-party expert will continue to reassess the sites at various times until at least 2020.

For information regarding lease obligations, see Note 16 "Rental Expense and Lease Commitments" of the Notes to Consolidated Financial Statements included in Item 8 of this Report. Segment information on additions to property, plant and equipment is contained in Note 18 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 3. LEGAL PROCEEDINGS

The information called for by this item is incorporated herein by reference to the information set forth in Note 21 "Legal Proceedings" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

In addition, Johnson & Johnson and its subsidiaries are from time to time party to government investigations, inspections or other proceedings relating to environmental matters, including their compliance with applicable environmental laws.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

EXECUTIVE OFFICERS OF THE REGISTRANT

Listed below are the executive officers of the Company. There are no family relationships between any of the executive officers, and there is no arrangement or understanding between any executive officer and any other person pursuant to which the executive officer was selected. At the annual meeting of the Board of Directors, the executive officers are elected by the Board to hold office for one year and until their respective successors are elected and qualified, or until earlier resignation or removal.

Information with regard to the directors of the Company, including information for Alex Gorsky, who is also an executive officer, is incorporated herein by reference to the material captioned "Item 1. Election of Directors" in the Proxy Statement.

Name	Age	Position
Dominic J. Caruso	60	Member, Executive Committee; Executive Vice President; Chief Financial Officer [(a)]
Joaquin Duato	55	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Pharmaceuticals[(b)]
Peter M. Fasolo	55	Member, Executive Committee; Executive Vice President, Chief Human Resources Officer[(c)]
Alex Gorsky	57	Chairman, Board of Directors; Chairman, Executive Committee; Chief Executive Officer
Jorge Mesquita	56	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Consumer[(d)]
Sandra E. Peterson	59	Member, Executive Committee; Executive Vice President, Group Worldwide Chairman[(e)]
Paulus Stoffels	56	Member, Executive Committee; Executive Vice President, Chief Scientific Officer[(f)]
Michael H. Ullmann	59	Member, Executive Committee; Executive Vice President, General Counsel[(g)]

(a) Mr. D. J. Caruso joined the Company in 1999 when the Company acquired Centocor, Inc., where he was Senior Vice President, Finance. Mr. Caruso was named Vice President, Finance of Ortho-McNeil Pharmaceutical, Inc., a subsidiary of the Company, in 2001, and Vice President, Group Finance of the Company's Medical Devices and Diagnostics Group in 2003. In 2005, Mr. Caruso was named Vice President of the Company's Group Finance organization. Mr. Caruso became a member of the Executive Committee and Vice President, Finance and Chief Financial Officer in 2007. In April 2016, he was named Executive Vice President, Chief Financial Officer. Mr. Caruso has responsibility for financial and investor relations activities, as well as the Company's procurement organization.

(b) Mr. J. Duato joined the Company in 1989 with Janssen-Farmaceutica S.A. (Spain) and in 1997 became Managing Director of Janssen-Cilag S.p.A. (Italy). In 2000, he led Ortho Biotech Europe before relocating to the United States in 2002 to serve as Vice President, and, in 2005, President of Ortho Biotech Inc. In 2008, he was named Company Group Chairman, Ortho-Clinical Diagnostics, and in 2009, Company Group Chairman, Pharmaceuticals, where he oversaw pharmaceutical product launches and the major therapeutic franchises in Canada, the United States and Latin America. In 2011, he was named Worldwide Chairman, Pharmaceuticals, responsible for the global commercial businesses of the Janssen Pharmaceutical Companies, including functional support for the research & development organizations. In April 2016, Mr. Duato became a member of the Executive Committee and was named Executive Vice President, Worldwide Chairman, Pharmaceuticals.

(c) Dr. P. M. Fasolo joined the Company in 2004 as Vice President, Worldwide Human Resources for Cordis Corporation, a subsidiary of the Company, and was subsequently named Vice President, Global Talent Management for the Company. He left Johnson & Johnson in 2007 to join Kohlberg Kravis Roberts & Co. as Chief Talent Officer. Dr. Fasolo returned to the Company in 2010 as the Vice President, Global Human Resources, and in 2011, he became a member of the Executive Committee. In April 2016, he was named Executive Vice President, Chief Human Resources Officer. Mr. Fasolo has responsibility for global talent, recruiting, diversity, compensation, benefits, employee relations and all aspects of human resources for the Company.

(d) Mr. J. Mesquita joined the Company in 2014 as Worldwide Chairman, Consumer. Prior to joining the Company, he served in various marketing and leadership capacities across Latin America, including roles in Oral Care and Beauty at The Procter & Gamble Company from 1984 to 2013. In April 2016, Mr. Mesquita became a member of the Executive Committee and was named as Executive Vice President, Worldwide Chairman, Consumer.

(e) Ms. S. E. Peterson joined the Company in 2012 as Group Worldwide Chairman and a member of the Executive Committee. Prior to joining the Company, Ms. Peterson was Chairman and Chief Executive Officer of Bayer CropScience AG in Germany, previously serving as President and Chief Executive Officer of Bayer Medical Care and President of Bayer HealthCare AG's Diabetes Care Division. Before joining Bayer in 2005, Ms. Peterson held a number of leadership roles at Medco Health Solutions (previously known as Merck-Medco). In April 2016, Ms. Peterson was named Executive Vice President, Group Worldwide Chairman of Johnson & Johnson. Ms. Peterson is responsible for the Company’s consumer-facing businesses, including the consumer family of companies and the consumer medical device businesses; the Company’s medical device businesses; and for supply chain, quality, information technology, and design across the enterprise.

(f) Dr. P. Stoffels joined the Company in 2002 with the acquisition of Tibotec Virco NV, where he was Chief Executive Officer of Virco NV and Chairman of Tibotec NV. In 2005, he was appointed Company Group Chairman, Global Virology. In 2006, he assumed the role of Company Group Chairman, Pharmaceuticals, with responsibility for worldwide research and development for the Central Nervous System and Internal Medicine Franchises. Dr. Stoffels was appointed Global Head, Research & Development, Pharmaceuticals in 2009, and in 2011, became Worldwide Chairman, Pharmaceuticals, with responsibility for the Company's therapeutic pipeline through global research and development and strategic business development. In 2012, Dr. Stoffels was appointed Chief Scientific Officer, with responsibility for enterprise-wide innovation and product safety, and became a member of the Executive Committee. In April 2016, Dr. Stoffels was named Executive Vice President, Chief Scientific Officer. He is responsible for the Company’s innovation pipeline across the pharmaceutical, medical devices and consumer segments and steers the Company’s global public health strategy.

(g) Mr. M. H. Ullmann joined the Company in 1989 as a corporate attorney in the Law Department. He was appointed Corporate Secretary in 1999 and served in that role until 2006. During that time, he also held various management positions in the Law Department. In 2006, he was named General Counsel, Medical Devices and Diagnostics and was appointed Vice President, General Counsel and became a member of the Executive Committee in 2012. In April 2016, Mr. Ullmann was named Executive Vice President, General Counsel. Mr. Ullmann has worldwide responsibility for legal, government affairs & policy, global security, aviation and health care compliance & privacy.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

As of February 16, 2018, there were 147,484 record holders of common stock of the Company. Additional information called for by this item is incorporated herein by reference to the following sections of this Report: "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition – Liquidity and Capital Resources – Dividends" and "— Other Information — Common Stock Market Prices"; Note 17 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements included in Item 8; and Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters – Equity Compensation Plan Information".

Issuer Purchases of Equity Securities

On October 13, 2015, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $10.0 billion of the Company's Common Stock. Share repurchases take place on the open market from time to time based on market conditions. As of July 2, 2017, $10.0 billion was repurchased under the program and the program was completed.

The following table provides information with respect to common stock purchases by the Company during the fiscal fourth quarter of 2017. Common stock purchases on the open market are made as part of a systematic plan to meet the needs of the Company's compensation programs. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal fourth quarter.

Period	Total Number of Shares Purchased[1]	Avg. Price Paid Per Share	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs[2]	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
October 2, 2017 through October 29, 2017	335,583	$ 141.89	-	-
October 30, 2017 through November 26, 2017	2,139,701	139.98	-	-
November 27, 2017 through December 31, 2017	3,318,630	141.06	-	-
Total	5,793,914			

(1) During the fiscal fourth quarter of 2017, the Company repurchased an aggregate of 5,793,914 shares of Johnson & Johnson Common Stock in open-market transactions as part of a systematic plan to meet the needs of the Company's compensation programs.

(2) As of July 2, 2017, the share repurchase program was completed with an aggregate of 86,592,946 shares purchased for a total of $10.0 billion since the inception of the repurchase program announced on October 13, 2015.

Item 6. SELECTED FINANCIAL DATA

Summary of Operations and Statistical Data 2007-2017

(Dollars in Millions Except Per Share Amounts)	2017	2016	2015	2014	2013	2012	2011	2010	2009	2008	2007
Sales to customers — U.S.	$39,863	37,811	35,687	34,782	31,910	29,830	28,908	29,450	30,889	32,309	32,444
Sales to customers — International	36,587	34,079	34,387	39,549	39,402	37,394	36,122	32,137	31,008	31,438	28,651
Total sales	76,450	71,890	70,074	74,331	71,312	67,224	65,030	61,587	61,897	63,747	61,095
Cost of products sold	25,354	21,685	21,536	22,746	22,342	21,658	20,360	18,792	18,447	18,511	17,751
Selling, marketing and administrative expenses	21,420	19,945	21,203	21,954	21,830	20,869	20,969	19,424	19,801	21,490	20,451
Research and development expense	10,554	9,095	9,046	8,494	8,183	7,665	7,548	6,844	6,986	7,577	7,680
In-process research and development	408	29	224	178	580	1,163	—	—	—	181	807
Interest income	(385)	(368)	(128)	(67)	(74)	(64)	(91)	(107)	(90)	(361)	(452)
Interest expense, net of portion capitalized	934	726	552	533	482	532	571	455	451	435	296
Other (income) expense, net	183	484	(2,064)	(70)	2,498	1,626	2,743	(768)	(526)	(1,015)	534
Restructuring	309	491	509	—	—	—	569	—	1,073	—	745
	58,777	52,087	50,878	53,768	55,841	53,449	52,669	44,640	46,142	46,818	47,812
Earnings before provision for taxes on income	$17,673	19,803	19,196	20,563	15,471	13,775	12,361	16,947	15,755	16,929	13,283
Provision for taxes on income	16,373	3,263	3,787	4,240	1,640	3,261	2,689	3,613	3,489	3,980	2,707
Net earnings	1,300	16,540	15,409	16,323	13,831	10,514	9,672	13,334	12,266	12,949	10,576
Add: Net loss attributable to noncontrolling interest	—	—	—	—	—	339	—	—	—	—	—
Net earnings attributable to Johnson & Johnson	1,300	16,540	15,409	16,323	13,831	10,853	9,672	13,334	12,266	12,949	10,576
Percent of sales to customers	1.7%	23.0	22.0	22.0	19.4	16.1	14.9	21.7	19.8	20.3	17.3
Diluted net earnings per share of common stock [1]	$0.47	5.93	5.48	5.70	4.81	3.86	3.49	4.78	4.40	4.57	3.63
Percent return on average shareholders' equity	2.0%	23.4	21.9	22.7	19.9	17.8	17.0	24.9	26.4	30.2	25.6
Percent increase (decrease) over previous year:											
Sales to customers	6.3%	2.6	(5.7)	4.2	6.1	3.4	5.6	(0.5)	(2.9)	4.3	14.6
Diluted net earnings per share	(92.1)%	8.2	(3.9)	18.5	24.6	10.6	(27.0)	8.6	(3.7)	25.9	(2.7)
Supplementary balance sheet data:											
Property, plant and equipment, net	17,005	15,912	15,905	16,126	16,710	16,097	14,739	14,553	14,759	14,365	14,185
Additions to property, plant and equipment	3,279	3,226	3,463	3,714	3,595	2,934	2,893	2,384	2,365	3,066	2,942
Total assets	157,303	141,208	133,411	130,358	131,754	121,347	113,644	102,908	94,682	84,912	80,954
Long-term debt	30,675	22,442	12,857	15,122	13,328	11,489	12,969	9,156	8,223	8,120	7,074
Operating cash flow	21,056	18,767	19,569	18,710	17,414	15,396	14,298	16,385	16,571	14,972	15,022
Common stock information											
Dividends paid per share	$3.32	3.15	2.95	2.76	2.59	2.40	2.25	2.11	1.93	1.795	1.62
Shareholders' equity per share	22.43	26.02	25.82	25.06	26.25	23.33	20.95	20.66	18.37	15.35	15.25
Market price per share (year-end close)	$139.72	115.21	102.72	105.06	92.35	69.48	65.58	61.85	64.41	58.56	67.38
Average shares outstanding (millions)											
— basic	2,692.0	2,737.3	2,771.8	2,815.2	2,809.2	2,753.3	2,736.0	2,751.4	2,759.5	2,802.5	2,882.9
— diluted	2,745.3	2,788.9	2,812.9	2,863.9	2,877.0	2,812.6	2,775.3	2,788.8	2,789.1	2,835.6	2,910.7
Employees (thousands)	134.0	126.4	127.1	126.5	128.1	127.6	117.9	114.0	115.5	118.7	119.2

[1] Attributable to Johnson & Johnson

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF RESULTS OF OPERATIONS AND FINANCIAL CONDITION

Organization and Business Segments

Description of the Company and Business Segments

Johnson & Johnson and its subsidiaries (the Company) have approximately 134,000 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. The Consumer segment includes a broad range of products used in the baby care, oral care, beauty, over-the-counter pharmaceutical, women's health and wound care markets. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on six therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, pulmonary hypertension, and cardiovascular and metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, cardiovascular, diabetes care and vision care fields which are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Consumer, Pharmaceutical and Medical Devices business segments.

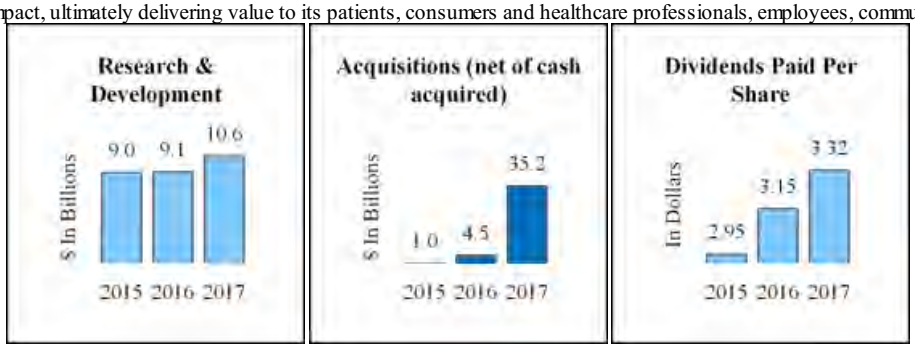
In all of its product lines, the Company competes with companies both locally and globally, throughout the world. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products, as well as protecting the underlying intellectual property of the Company's product portfolio, is important to the Company's success in all areas of its business. The competitive environment requires substantial investments in continuing research. In addition, the development and maintenance of customer demand for the Company's consumer products involves significant expenditures for advertising and promotion.

Management's Objectives

With "Our Credo" as the foundation, the Company's purpose is to blend heart, science and ingenuity to profoundly change the trajectory of health for humanity. The Company is committed to bringing its full breadth and depth to ensure health for people today and for future generations. United around this common ambition, the Company is poised to fulfill its purpose and successfully meet the demands of the rapidly evolving markets in which it competes.

The Company is broadly based in human healthcare, and is committed to creating value by developing accessible, high quality, innovative products and services. New products introduced within the past five years accounted for approximately 22% of 2017 sales. In 2017, $10.6 billion was invested in research and development and $35.2 billion spent on acquisitions, reflecting management's commitment to create life-enhancing innovations and to create value through partnerships that will profoundly change the trajectory of health for humanity.

A critical driver of the Company's success, is the 134,000 diverse employees that work across more than 260 operating companies, which are located in more than 60 countries. Employees are empowered and inspired to lead with the Company's Our Credo and purpose as guides. This allows every employee to use the Company's reach and size to advance the Company's purpose, and to also lead with agility and urgency. Leveraging the extensive resources across the enterprise, enables the Company to innovate and execute with excellence. This ensures the Company can remain focused on addressing the unmet needs of society every day and invest for an enduring impact, ultimately delivering value to its patients, consumers and healthcare professionals, employees, communities and shareholders.



Results of Operations

Analysis of Consolidated Sales

In 2017, worldwide sales increased 6.3% to $76.5 billion, compared to an increase of 2.6% in 2016 and a decrease of 5.7% in 2015. These sales changes consisted of the following:

Sales increase/(decrease) due to:	2017	2016	2015
Volume	8.0 %	3.2%	1.2 %
Price	(2.0)	0.7	0.6
Currency	0.3	(1.3)	(7.5)
Total	**6.3 %**	**2.6%**	**(5.7)%**

In 2017, the net impact of acquisitions and divestitures on the worldwide sales growth was a positive impact of 3.6%. In 2016, acquisitions and divestitures had a negative impact of 1.1% on the worldwide sales growth and competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a negative impact of 0.8% on the worldwide sales growth. Operations in Venezuela negatively impacted the worldwide sales growth 0.3%. In 2015, the introduction of competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a negative impact of 2.7% on the worldwide sales growth. In 2015, the impact of acquisitions and divestitures on the worldwide sales growth was negative 2.0%.

Sales by U.S. companies were $39.9 billion in 2017, $37.8 billion in 2016 and $35.7 billion in 2015. This represents increases of 5.4% in 2017, 6.0% in 2016 and 2.6% in 2015. Sales by international companies were $36.6 billion in 2017, $34.1 billion in 2016 and $34.4 billion in 2015. This represents an increase of 7.4% in 2017, and decreases of 0.9% in 2016, and 13.1% in 2015.

The five-year compound annual growth rates for worldwide, U.S. and international sales were 2.6%, 6.0% and (0.4)%, respectively. The ten-year compound annual growth rates for worldwide, U.S. and international sales were 2.3%, 2.1% and 2.5%, respectively.

In 2017, sales by companies in Europe achieved growth of 8.6% as compared to the prior year, including operational growth of 7.2% and a positive currency impact of 1.4%. Sales by companies in the Western Hemisphere (excluding the U.S.) achieved growth of 5.4% as compared to the prior year, including operational growth of 2.8% and a positive currency impact of 2.6%. Sales by companies in the Asia-Pacific, Africa region achieved growth of 6.7% as compared to the prior year, including operational growth of 7.5% partially offset by a negative currency impact of 0.8%.

The 2016 sales growth percentage as compared to the prior year was negatively impacted by approximately 1.3% from additional shipping days in 2015. (See Note 1 to the Consolidated Financial Statements for Annual Closing Date details). While the additional week in 2015 added a few days to sales, it also added a full week's worth of operating costs; therefore, the net earnings impact was negligible.

In 2017, the Company had two wholesalers distributing products for all three segments that represented approximately 14.0% and 10.0% of the total consolidated revenues. In 2016, the Company had two wholesalers distributing products for all three segments that represented approximately 13.5% and 10.7% of the total consolidated revenues. In 2015, the Company had one wholesaler distributing products for all three segments that represented approximately 12.5% of the total consolidated revenues.

Analysis of Sales by Business Segments

Consumer Segment

Consumer segment sales in 2017 were $13.6 billion, an increase of 2.2% from 2016, which included 1.3% operational growth and a positive currency impact of 0.9%. U.S. Consumer segment sales were $5.6 billion, an increase of 2.7%. International sales were $8.0 billion, an increase of 1.9%, which included 0.4% operational growth and a positive currency impact of 1.5%. In 2017, acquisitions and divestitures had a net positive impact of 1.8% on the operational sales growth of the worldwide Consumer segment.

Major Consumer Franchise Sales:

				% Change	
(Dollars in Millions)	**2017**	**2016**	**2015**	**'17 vs. '16**	**'16 vs. '15**
Beauty	$ 4,200	3,897	3,633	7.8 %	7.3
OTC	4,126	3,977	3,895	3.7	2.1
Baby Care	1,916	2,001	2,157	(4.2)	(7.2)
Oral Care	1,531	1,568	1,580	(2.4)	(0.8)
Women's Health	1,050	1,067	1,200	(1.6)	(11.1)
Wound Care/Other	779	797	1,042	(2.3)	(23.5)
Total Consumer Sales	**$ 13,602**	**13,307**	**13,507**	**2.2 %**	**(1.5)**

The Beauty franchise sales of $4.2 billion increased 7.8% as compared to the prior year. Growth was primarily driven by the inclusion of sales from the recent acquisitions, Vogue International LLC and Dr. Ci: Labo, as well as sales growth of NEUTROGENA® products.

The Over-the-Counter (OTC) franchise sales of $4.1 billion increased 3.7% as compared to the prior year. Growth was primarily driven by analgesic products in the U.S., upper respiratory products outside the U.S., sales from the recent acquisition of Rhinocort and anti-smoking aids.

The Baby Care franchise sales were $1.9 billion in 2017, a decrease of 4.2% compared to the prior year, primarily due to competitive pressure.

The Oral Care franchise sales were $1.5 billion in 2017, a decrease of 2.4% as compared to the prior year, primarily driven by category declines and competitive pressure partially offset by new product launches outside the U.S.

The Women's Health franchise sales were $1.1 billion in 2017, a decrease of 1.6% as compared to the prior year, primarily due to category declines in EMEA and share loss in Brazil.

The Wound Care/Other franchise sales were $0.8 billion in 2017, a decrease of 2.3% as compared to the prior year, primarily due to private label competitive pressure in the U.S. partially offset by BAND-AID® new product launches outside the U.S.

Consumer segment sales in 2016 were $13.3 billion, a decrease of 1.5% from 2015, which included 1.5% operational growth offset by a negative currency impact of 3.0%. U.S. Consumer segment sales were $5.4 billion, an increase of 3.8%. International sales were $7.9 billion, a decrease of 4.8%, which included 0.1% operational growth offset by a negative currency impact of 4.9%. In 2016, the impact of acquisitions and divestitures on the Consumer segment operational sales growth was negative 0.5%. In 2016, the Consumer segment operational sales growth was negatively impacted 1.2% by operations in Venezuela and negatively impacted by 1.1% due to additional shipping days in 2015.

Pharmaceutical Segment

Pharmaceutical segment sales in 2017 were $36.3 billion, an increase of 8.3% from 2016, which included operational growth of 8.0% and a positive currency impact of 0.3%. U.S. sales were $21.5 billion, an increase of 6.7%. International sales were $14.8 billion, an increase of 10.8%, which included 10.1% operational growth and a positive currency impact of 0.7%. In 2017, acquisitions and divestitures had a net positive impact of 3.8% on the operational sales growth of the worldwide Pharmaceutical segment. Adjustments to previous reserve estimates, as compared to the prior year, negatively impacted the reported Pharmaceutical segment operational growth by approximately 1.8%, primarily in the Immunology and Cardiovascular/Metabolism/Other therapeutic areas.

Major Pharmaceutical Therapeutic Area Sales:*

				% Change	
(Dollars in Millions)	**2017**	**2016**	**2015**	**'17 vs. '16**	**'16 vs. '15**
Total Immunology	**$ 12,244**	**11,968**	**10,402**	**2.3 %**	**15.1**
REMICADE®	6,315	6,966	6,561	(9.3)	6.2
SIMPONI®/SIMPONI ARIA®	1,833	1,745	1,328	5.0	31.4
STELARA®	4,011	3,232	2,474	24.1	30.6
Other Immunology	85	25	39	**	(35.9)
Total Infectious Diseases	**3,154**	**3,208**	**3,656**	**(1.7)**	**(12.3)**
EDURANT®/rilpivirine	714	573	410	24.6	39.8
PREZISTA®/ PREZCOBIX®/REZOLSTA®/SYMTUZA®	1,821	1,851	1,810	(1.6)	2.3
Other Infectious Diseases	619	784	1,436	(21.0)	(45.4)
Total Neuroscience	**5,986**	**6,085**	**6,259**	**(1.6)**	**(2.8)**
CONCERTA®/methylphenidate	791	863	821	(8.3)	5.1
INVEGA SUSTENNA®/XEPLION®/TRINZA®/TREVICTA®	2,569	2,214	1,830	16.0	21.0
RISPERDAL CONSTA®	805	893	970	(9.9)	(7.9)
Other Neuroscience	1,821	2,115	2,638	(13.9)	(19.8)
Total Oncology	**7,258**	**5,807**	**4,695**	**25.0**	**23.7**
DARZALEX®	1,242	572	20	**	**
IMBRUVICA®	1,893	1,251	689	51.3	81.6
VELCADE®	1,114	1,224	1,333	(9.0)	(8.2)
ZYTIGA®	2,505	2,260	2,231	10.8	1.3
Other Oncology	504	500	422	0.8	18.5
Pulmonary Hypertension	**1,327**	**—**	**—**	***	***
OPSUMIT®	573	—	—	***	***
TRACLEER®	403	—	—	***	***
UPTRAVI®	263	—	—	***	***
Other	88	—	—	***	***
Cardiovascular / Metabolism / Other	**6,287**	**6,396**	**6,418**	**(1.7)**	**(0.3)**
XARELTO®	2,500	2,288	1,868	9.3	22.5
INVOKANA®/ INVOKAMET®	1,111	1,407	1,308	(21.0)	**7.6**
PROCRIT®/EPREX®	972	1,105	1,068	(12.0)	3.5
Other	1,704	1,596	2,174	6.8	(26.6)
Total Pharmaceutical Sales	**$ 36,256**	**33,464**	**31,430**	**8.3 %**	**6.5**

* Prior year amounts have been reclassified to conform to current year presentation.
** Percentage greater than 100% or not meaningful
***Products acquired from Actelion on June 16, 2017

Immunology products achieved sales of $12.2 billion in 2017, representing an increase of 2.3% as compared to the prior year. Growth was driven by strong uptake of STELARA® (ustekinumab), the launch of TREMFYA® (guselkumab) and sales growth of SIMPONI®/SIMPONI ARIA® (golimumab) outside the U.S. Lower sales of REMICADE® (infliximab) were due to increased discounts/rebates and biosimilar competition.

The patents for REMICADE® (infliximab) in certain countries in Europe expired in February 2015. Biosimilar versions of REMICADE® have been introduced in certain markets outside the United States, resulting in a reduction in sales of REMICADE® in those markets. Additional biosimilar competition will likely result in a further reduction in REMICADE® sales in markets outside the United States. In the United States, a biosimilar version of REMICADE® was introduced in 2016, and additional competitors continue to enter the market. Continued infliximab biosimilar competition in the U.S. market will result in a further reduction in U.S. sales of REMICADE®. The Company continues to assert REMICADE® related patent rights. See Note 21 to the Consolidated Financial Statements for a description of legal matters regarding the REMICADE® patents.

Infectious disease products sales were $3.2 billion, a decline of 1.7% from 2016. Lower sales of OLYSIO® (simeprevir), vaccines and PREZISTA® (darunavir/cobicistat) were partially offset by sales growth of EDURANT®/rilpivirine, PREZCOBIX®/REZOLSTA® and the launch of SYMTUZA®.

Neuroscience products sales were $6.0 billion, a decrease of 1.6% from 2016. Lower sales of RISPERDAL CONSTA® (risperidone) and CONCERTA®/methylphenidate as well as the impact of divestitures were partially offset by strong sales of INVEGA SUSTENNA®/XEPLION®/ TRINZA®/TREVICTA® (paliperidone palmitate) long-acting injectables.

Oncology products achieved sales of $7.3 billion in 2017, representing an increase of 25.0% as compared to the prior year. Contributors to the growth of Oncology products were strong sales of DARZALEX® (daratumumab) and IMBRUVICA® (ibrutinib) driven by market share and market growth and sales of ZYTIGA® (abiraterone acetate) driven by market growth. Several generic companies are challenging the remaining patent for ZYTIGA® in the USPTO and in the United States District Court for the District of New Jersey. The Company is appealing a decision by the USPTO invalidating this patent, and the parties are awaiting a decision on a motion for summary judgment of non-infringement filed by the generic companies. In the event that the rulings are unfavorable to the Company, a generic launch is expected to follow. If there is a launch of a generic version of ZYTIGA® following FDA approval, it will result in a reduction in U.S. sales, and such reduction could occur in a short period of time. In 2017, the Company reported U.S. sales of $1.2 billion for ZYTIGA®. See Note 21 to the Consolidated Financial Statements for a description of legal matters regarding ZYTIGA®.

Pulmonary Hypertension is a new therapeutic area which was established with the acquisition of Actelion Ltd on June 16, 2017. See Note 20 to the Consolidated Financial Statements for additional details regarding the acquisition.

Cardiovascular/Metabolism/Other products sales were $6.3 billion, a decline of 1.7% as compared to the prior year attributable to lower sales of INVOKANA®/INVOKAMET® (canagliflozin) in the U.S. primarily due to an increase in price discounts and market share decline driven by competitive pressure. This was partially offset by sales growth of XARELTO® (rivaroxaban) due to increased market growth and market share, as well as sales of non-PAH (pulmonary arterial hypertension) products from the Actelion acquisition.

During 2017, the Company advanced its pipeline with several regulatory submissions and approvals for new drugs and additional indications for existing drugs as follows:

Product Name (Chemical Name)	Indication	US Approv	EU Approv	US Filing	EU Filing
apalutamide	An oral androgen receptor inhibitor for men with non-metastatic castration-resistant prostate cancer			✓	
DARZALEX® (daratumumab)	In combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy		✓		
	In combination with pomalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least two prior therapies	✓			
	Frontline multiple myeloma transplant ineligible patients in combination with bortezomib, melphalan, and prednisone			✓	✓
IMBRUVICA® (ibrutinib)	Treatment for adult patients with chronic graft-versus-host-disease after failure of one or more lines of systemic therapy	✓			
	Marginal zone lymphoma	✓			
INVOKANA® (canagliflozin)	Reduce the risk of death in type 2 diabetes with established, or risk for, cardiovascular disease. (CANVAS/CANVAS-R)			✓	✓
JULUCA® (rilpivirine and dolutegravir)	Single-tablet, two-drug regimen of dolutegravir and rilpivirine for the maintenance treatment of HIV-1 infection	✓			✓
SIMPONI ARIA® (golimumab)	Treatment of adults living with active psoriatic arthritis and the treatment of adults living with active ankylosing spondylitis	✓			
STELARA® (ustekinumab)	Treatment of adolescents (12 to 17 years of age) with moderate to severe plaque psoriasis	✓			
SYMTUZA® (darunavir/cobicistat/ emtricitabine/tenofovir alafenamide)	Single tablet regimen for HIV in treatment naïve patients and treatment experienced patients		✓	✓	
TREMFYA® (guselkumab)	Treatment of adults living with moderate to severe plaque psoriasis	✓	✓		
XARELTO® (rivaroxaban)	A 10 mg once-daily dose for reducing the continued risk for recurrent venous thromboembolism after completing at least six months of initial anticoagulation therapy	✓			
	For two new vascular indications: reducing the risk of major cardiovascular events and reducing the risk of acute limb ischemia in patients with PAD			✓	
ZYTIGA® (abiraterone acetate)	Prostate Cancer Newly Diagnosed Hormone Naïve Metastatic		✓	✓	

Pharmaceutical segment sales in 2016 were $33.5 billion, an increase of 6.5% from 2015, which included operational growth of 7.4% partially offset by a negative currency impact of 0.9%. U.S. sales were $20.1 billion, an increase of 9.8%. International sales were $13.3 billion, an increase of 1.8%, which included 4.0% operational growth partially offset by a negative currency impact of 2.2%. In 2016, acquisitions, divestitures and competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a negative impact of 2.5% on the operational growth of the Pharmaceutical segment. In 2016, the Pharmaceutical segment operational growth was negatively impacted by 1.5% due to additional shipping days in 2015. The Pharmaceutical segment operational growth for 2016, as compared to the prior year, was not impacted by adjustments to previous reserve estimates as both periods included approximately $0.5 billion of adjustments.

Medical Devices Segment

The Medical Devices segment sales in 2017 were $26.6 billion, an increase of 5.9% from 2016, which included an operational increase of 5.7% and a positive currency impact of 0.2%. U.S. sales were $12.8 billion, an increase of 4.5% as compared to the prior year. International sales were $13.8 billion, an increase of 7.1% as compared to the prior year, with an operational increase of 6.7% and a positive currency impact of 0.4%. In 2017, acquisitions and divestitures had a net positive impact of 4.2% on the worldwide operational sales growth of the Medical Devices segment as compared to 2016.

Major Medical Devices Franchise Sales:

				% Change	
(Dollars in Millions)	**2017**	**2016**	**2015**	**'17 vs. '16**	**'16 vs. '15**
Surgery	**$ 9,559**	**9,296**	**9,217**	2.8 %	0.9
Advanced	3,756	3,517	3,275	6.8	7.4
General	4,463	4,362	4,482	2.3	(2.7)
Specialty	1,340	1,417	1,460	(5.4)	(2.9)
Orthopaedics	**9,258**	**9,334**	**9,262**	(0.8)	0.8
Hips	1,394	1,361	1,332	2.4	2.2
Knees	1,523	1,524	1,496	(0.1)	1.9
Trauma	2,616	2,569	2,528	1.8	1.6
Spine & Other	3,725	3,880	3,906	(4.0)	(0.7)
Vision Care	**4,063**	**2,785**	**2,608**	45.9	6.8
Contact Lenses/Other	3,036	2,785	2,608	9.0	6.8
Surgical	1,027	—	—	*	*
Cardiovascular	**2,096**	**1,849**	**2,036**	13.4	(9.2)
Diabetes Care	**1,615**	**1,789**	**1,928**	(9.7)	(7.2)
Diagnostics	**1**	**66**	**86**	**	**
Total Medical Devices Sales	**$ 26,592**	**$ 25,119**	**25,137**	**5.9 %**	**(0.1)**

*Products acquired from Abbott Medical Optics (AMO) on February 27, 2017

** On June 30, 2014, the Company divested the Ortho-Clinical Diagnostics business (the Diagnostics Franchise)

The Surgery franchise sales were $9.6 billion in 2017, an increase of 2.8% from 2016. Growth in Advanced Surgery was primarily driven by endocutter, energy, including the acquisition of Megadyne Medical Products, Inc., and biosurgery products. Growth in General Surgery was primarily driven by sutures and sales from the acquisition of Torax Medical, Inc. The sales decline in Specialty Surgery was primarily due to lower sales of aesthetic, Advanced Sterilization and Sterilmed products.

The Orthopaedics franchise sales were $9.3 billion in 2017, a decrease of 0.8% from 2016. The decline in Spine & Other was primarily due to the Codman Neurosurgery divestiture, share loss in U.S. Spine, pricing and competitive pressures. This was partially offset by sales growth of trauma, sports medicine products and U.S. hips.

The Vision Care franchise achieved sales of $4.1 billion in 2017, an increase of 45.9% from 2016. Growth was driven by sales from the acquisition of AMO, with the majority of AMO sales in the surgical category, and new product launches in the contact lenses category.

The Cardiovascular franchise sales were $2.1 billion, an increase of 13.4% from 2016. Strong growth in the electrophysiology business was driven by market growth and continued uptake of the THERMOCOOL SMARTTOUCH® Contact Force Sensing Catheter.

The Diabetes Care franchise sales were $1.6 billion, a decrease of 9.7% from 2016. The decline was primarily due to price declines and competitive pressures. Additionally, in the fourth quarter of 2017, the Company announced its decision to exit the Animas insulin pump business. Animas has selected Medtronic plc to facilitate a seamless transition for patients, caregivers and healthcare providers. The Company is continuing to evaluate potential strategic options for LifeScan, Inc. and determine the best opportunity to drive future growth and maximize shareholder value.

The Medical Devices segment sales in 2016 were $25.1 billion, a decrease of 0.1% from 2015, which included an operational increase of 0.9% and a negative currency impact of 1.0%. U.S. sales were $12.3 billion, an increase of 1.1% as compared to the prior year. International sales were $12.9 billion, a decrease of 1.2% as compared to the prior year, with an operational increase of 0.7% and a negative currency impact of 1.9%. In 2016, acquisitions and divestitures had a negative

impact of 1.8% on the worldwide operational growth of the Medical Devices segment as compared to 2015. In 2016, the Medical Devices segment operational growth was negatively impacted by 0.9% due to additional shipping days in 2015.

Analysis of Consolidated Earnings Before Provision for Taxes on Income

Consolidated earnings before provision for taxes on income decreased to $17.7 billion in 2017, as compared to $19.8 billion in 2016, a decrease of 10.8%. The decrease was primarily attributable to higher amortization expense and other charges related to recent acquisitions, higher selling, marketing and administrative costs due to investments in new product launches and higher research and development costs due to general portfolio progression and collaborations.

Consolidated earnings before provision for taxes on income increased to $19.8 billion in 2016, as compared to $19.2 billion in 2015, an increase of 3.2%. The increase was primarily attributable to higher sales volume, favorable mix in the business and lower selling, marketing and administrative costs. This was partially offset by higher net litigation expense of $0.7 billion and a higher restructuring charge of $0.1 billion as compared to 2015. Additionally, the fiscal year 2015 included higher gains on the sale of assets/businesses as compared to 2016.

As a percent to sales, consolidated earnings before provision for taxes on income in 2017 was 23.1% versus 27.5% in 2016.

Cost of Products Sold and Selling, Marketing and Administrative Expenses: Cost of products sold and selling, marketing and administrative expenses as a percent to sales were as follows:

% of Sales	2017	2016	2015
Cost of products sold	33.2%	30.2%	30.7
Percent point increase/(decrease) over the prior year	3.0	(0.5)	0.1
Selling, marketing and administrative expenses	28.0%	27.7%	30.3
Percent point increase/(decrease) over the prior year	0.3	(2.6)	0.8

In 2017, cost of products sold as a percent to sales increased to 33.2% from 30.2% as compared to the same period a year ago. The unfavorable increase was primarily driven by $2.3 billion of higher amortization expense and charges for inventory step-up related to the recent acquisitions, primarily Actelion. Intangible asset amortization expense of $3.0 billion was included in cost of products sold for 2017 as compared to $1.2 billion in 2016. There was an increase in the percent to sales of selling, marketing and administrative expenses in 2017 as compared to the prior year, primarily due to investments in new product launches partially offset by favorable mix.

In 2016, cost of products sold as a percent to sales decreased to 30.2% from 30.7% as compared to the same period a year ago. Favorable mix in the business and cost improvement programs was partially offset by the unfavorable impact of transactional currency. Intangible asset amortization expense of $1.2 billion was included in cost of products sold for 2016 and 2015. There was a decrease in the percent to sales of selling, marketing and administrative expenses in 2016 compared to the prior year, primarily due to cost management in all the segments and favorable mix.

Research and Development Expense: Research and development expense by segment of business was as follows:

	2017		2016		2015	
(Dollars in Millions)	Amount	% of Sales*	Amount	% of Sales*	Amount	% of Sales*
Consumer	$ 584	4.3%	$ 580	4.4%	625	4.6
Pharmaceutical	8,360	23.1	6,967	20.8	6,821	21.7
Medical Devices	1,610	6.1	1,548	6.2	1,600	6.4
Total research and development expense	$ 10,554	13.8%	$ 9,095	12.7%	9,046	12.9
Percent increase/(decrease) over the prior year	16.0%		0.5%		6.5	

* As a percent to segment sales

Research and development activities represent a significant part of the Company's business. These expenditures relate to the processes of discovering, testing and developing new products, upfront payments and milestones, improving existing products, as well as ensuring product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products. In 2017, worldwide costs of research and development activities increased by 16.0% compared to 2016. The increase as a percent of sales was primarily in the pharmaceutical segment due to general portfolio progression as well as collaborative agreements entered into with Idorsia Ltd. and Legend Biotech. In 2016, worldwide costs of research and development activities increased by 0.5% compared to

2015 but decreased as a percent of sales. The decrease as a percent of sales was attributable to higher overall sales in the Pharmaceutical segment. The increased dollar spend in the Pharmaceutical segment was for investment spending to advance the pipeline.

In-Process Research and Development (IPR&D): In 2017, the Company recorded an IPR&D charge of $0.4 billion primarily for the discontinuation of certain development projects related to Novira which was acquired in 2015. The product development was canceled due to safety concerns. In 2016, the Company recorded an IPR&D charge of $29 million for the discontinuation of a development program related to Crucell. In 2015, the Company recorded an IPR&D charge of $0.2 billion primarily for the discontinuation of certain development projects related to Covagen.

Other (Income) Expense, Net: Other (income) expense, net is the account where the Company records gains and losses related to the sale and write-down of certain investments in equity securities held by Johnson & Johnson Innovation - JJDC, Inc. (JJDC), gains and losses on divestitures, transactional currency gains and losses, acquisition-related costs, litigation accruals and settlements, as well as royalty income. The change in other (income) expense, net for the fiscal year 2017 was a favorable change of $0.3 billion due to higher gains of $0.7 billion on the sale of assets/businesses, primarily the Codman Neurosurgery and COMPEED® divestitures, a gain of $0.2 billion related to monetization of future royalty receivables and a higher gain of $0.3 billion related to the sale of certain investments in equity securities as compared to the prior year. This was partially offset by higher litigation expense of $0.4 billion, $0.3 billion of acquisition costs related to Actelion and AMO, an asset impairment charge of $0.2 billion primarily related to the insulin pump business and a higher restructuring related charge of $0.2 billion as compared to the fiscal year 2016.

The change in other (income) expense, net for the fiscal year 2016 was an unfavorable change of $2.5 billion as compared to the prior year primarily due to higher gains on the sale of assets/businesses in the fiscal year 2015 as compared to 2016. The fiscal year of 2016 included gains of $0.6 billion from the divestitures of the controlled substance raw material and API business, certain anesthetic products in Europe and certain non-strategic Consumer brands versus gains of $2.6 billion recorded in 2015 primarily from the divestiture of the Cordis business, the U.S. divestiture of NUCYNTA® and the SPLENDA® brand. Additionally, the fiscal year of 2016 included higher litigation expense of $0.7 billion as compared to 2015. This was partially offset by a $0.3 billion intangible asset write-down related to Acclarent included in the fiscal year 2015.

Interest (Income) Expense: Interest income in 2017 increased slightly as compared to 2016 due to higher average interest rates partially offset by lower cash, cash equivalents and marketable securities balances during the period. Cash, cash equivalents and marketable securities totaled $18.3 billion at the end of 2017, and averaged $30.1 billion as compared to the $40.1 billion average cash balance in 2016. The decrease in the balance of cash, cash equivalents and marketable securities was due to the use of cash for general corporate purposes including acquisitions, primarily the Actelion acquisition for $29.6 billion, net of cash acquired.

Interest expense in 2017 was higher as compared to 2016. The average debt balance was $30.9 billion in 2017 versus $23.5 billion in 2016. The total debt balance at the end of 2017 was $34.6 billion as compared to $27.1 billion at the end of 2016. The higher debt balance of approximately $7.5 billion was primarily due to increased borrowings. The Company increased borrowings in February and November of 2017, capitalizing on favorable terms in the capital markets. The proceeds of the borrowings were used for general corporate purposes, including the completion of the stock repurchase program.

Interest income in 2016 increased by $0.2 billion as compared to 2015 due to a higher average balance of cash, cash equivalents and marketable securities and higher interest rates. Cash, cash equivalents and marketable securities totaled $41.9 billion at the end of 2016, and averaged $40.1 billion as compared to the $35.7 billion average cash balance in 2015.

Interest expense in 2016 was higher as compared to 2015. The average debt balance was $23.5 billion in 2016 versus $19.3 billion in 2015. The total debt balance at the end of 2016 was $27.1 billion as compared to $19.9 billion at the end of 2015. The higher debt balance of approximately $7.2 billion was primarily due to increased borrowings in February and May of 2016. The Company increased borrowings, capitalizing on favorable terms in the capital markets. The proceeds of the borrowings were used for general corporate purposes, primarily the stock repurchase program.

Income Before Tax by Segment
Income before tax by segment of business were as follows:

	Income Before Tax		Segment Sales		Percent of Segment Sales	
(Dollars in Millions)	2017	2016	2017	2016	2017	2016
Consumer	$ 2,524	2,441	$ 13,602	13,307	18.6%	18.3
Pharmaceutical	11,083	12,827	36,256	33,464	30.6	38.3
Medical Devices	5,392	5,578	26,592	25,119	20.3	22.2
Total [1]	18,999	20,846	76,450	71,890	24.9	29.0
Less: Expenses not allocated to segments [2]	1,326	1,043				
Earnings before provision for taxes on income	$ 17,673	19,803	$ 76,450	71,890	23.1%	27.5

(1) See Note 18 to the Consolidated Financial Statements for more details.
(2) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense. Increase in 2017 was primarily due to higher interest expense of $0.2 billion on higher debt balance.

Consumer Segment: In 2017, the Consumer segment income before tax as a percent to sales was 18.6%, versus 18.3% in 2016. The increase in the income before tax as a percent of sales in 2017 as compared to 2016 was attributable to higher gains on divestitures, primarily the divestiture of COMPEED® in 2017. This was partially offset by higher selling, marketing and administrative expenses as compared to the prior year due to increased advertising and promotional spending and slightly higher amortization expense in 2017 related to acquisitions. Additionally, the fiscal year 2016 was negatively impacted by operations in Venezuela.

In 2016, the Consumer segment income before tax as a percent to sales was 18.3%, versus 13.2% in 2015, primarily driven by favorable selling, marketing and administrative expenses due to cost management and higher gross profit margins from cost improvement projects and favorable mix. This was partially offset by higher gains in 2015 related to divestitures, primarily the divestiture of the SPLENDA® brand. Additionally, operations in Venezuela negatively impacted the Consumer segment income before tax in 2016 as compared to 2015.

Pharmaceutical Segment: In 2017, the Pharmaceutical segment income before tax as a percent to sales was 30.6% versus 38.3% in 2016. The decrease in the income before tax as a percent of sales was primarily due to $2.3 billion of higher amortization expense and other costs related to the Actelion acquisition, higher research and development expense, a higher IPR&D charge of $0.4 billion related to Novira and lower gains on divestitures as compared to the prior year. Additionally, the fiscal year 2016 included a positive adjustment of $0.5 billion to previous reserve estimates. This was partially offset by a gain of $0.2 billion related to monetization of future royalty receivables, a higher gain of $0.2 billion related to the sale of certain investments in equity securities and favorable product mix in 2017.

In 2016, the Pharmaceutical segment income before tax as a percent to sales was 38.3% versus 37.3% in 2015. The increase in income before tax was primarily due to strong sales volume growth and favorable selling, marketing and administrative expenses due to cost management. Additionally, the fiscal year 2015, had higher gains of $0.7 billion related to divestitures partially offset by a higher IPR&D charge of $0.2 billion as compared to 2016. The fiscal year of 2016 included the gains from the divestitures of the controlled substance raw material and API business and certain anesthetic products in Europe versus the gains recorded in 2015 from the U.S. divestiture of NUCYNTA®.

Medical Devices Segment: In 2017, the Medical Devices segment income before tax as a percent to sales was 20.3% versus 22.2% in 2016. The decrease in the income before tax as a percent to sales was primarily due to $0.3 billion of higher amortization expense and other acquisition costs related to AMO, $0.3 billion of higher litigation, an asset impairment charge of $0.2 billion primarily related to the insulin pump business, $0.1 billion of higher restructuring and investments in new product launches as compared to the fiscal year 2016. This was partially offset by $0.8 billion higher gains in 2017 related to divestitures, primarily the divestiture of Codman Neurosurgery.

In 2016, the Medical Devices segment income before tax as a percent to sales was 22.2% versus 27.2% in 2015. The decrease in the income before tax as a percent to sales was primarily due to lower gains of $1.4 billion related to divestitures, higher litigation expense of $0.8 billion and a higher restructuring charge of $0.1 billion as compared to 2015. This was partially offset by an intangible asset write-down of $0.3 billion related to Acclarent in 2015 and favorable selling, marketing and administrative expenses in 2016.

Restructuring: In the first quarter of 2016, the Company announced restructuring actions in its Medical Devices segment. The restructuring actions are expected to result in annualized pre-tax cost savings of $800 million to $1.0 billion, the majority of which is expected to be realized by the end of 2018. Approximately $500 million in savings were realized in 2017. The savings will provide the Company with added flexibility and resources to fund investment in new growth opportunities and innovative solutions for customers and patients. The Company estimates that, in connection with its plans, it will record pre-tax restructuring related charges of approximately $2.0 billion to $2.4 billion. In 2017, the Company recorded a pre-tax charge of $760 million, of which $88 million is included in cost of products sold and $363 million is included in other (income) expense. In 2016, the Company recorded a pre-tax charge of $685 million, of which $45 million is included in cost of products sold and $149 million is included in other (income) expense. In 2015, the Company recorded a pre-tax charge of $590 million, of which $81 million was included in cost of products sold. Restructuring related charges of $2.0 billion have been recorded since the restructuring was announced. See Note 22 to the Consolidated Financial Statements for additional details related to the restructuring.

Provision for Taxes on Income: The worldwide effective income tax rate was 92.6% in 2017, 16.5% in 2016 and 19.7% in 2015. The 2017 effective tax rate increased by 76.1% as compared to 2016, primarily driven by the enactment of the Tax Cuts and Jobs Act (TCJA) in the United States in December 2017. The enactment of the TCJA resulted in a provisional tax charge in the fourth quarter of 2017, of approximately $13.0 billion or approximately 73.3 percentage point increase to the effective tax rate. See Note 8 to the Consolidated Financial Statements for additional details related to the TCJA.

The remainder of the increase in the tax rate for 2017 was related to the remeasurement of the Company's deferred tax assets in Belgium, as a result of changes in the Belgian statutory corporate tax rate, enacted in December 2017, offset by a tax benefit for the closure of the Company's Animas insulin pump business.

The government in Switzerland is currently considering tax reform legislation, which could have a material impact on the Company's effective tax rate if enacted into law.

The decrease in the 2016 effective tax rate, as compared to 2015 was primarily attributable to the Company adopting a new accounting standard for the reporting of additional tax benefits on share-based compensation that vested or were exercised during the fiscal year. The remainder of the change in the effective tax rate was primarily related to the lower earnings before taxes in the United States and the settlement of several uncertain tax positions in 2016 versus 2015.

The decrease in the 2015 effective tax rate, as compared to 2014 was primarily attributable to the increases in taxable income in lower tax jurisdictions relative to higher tax jurisdictions and a tax benefit resulting from a restructuring of international affiliates.

Liquidity and Capital Resources

Liquidity & Cash Flows

Cash and cash equivalents were $17.8 billion at the end of 2017 as compared to $19.0 billion at the end of 2016. The primary sources and uses of cash that contributed to the $1.2 billion decrease were approximately $21.1 billion of cash generated from operating activities and $0.3 billion due to the effect on exchange rate changes on cash and cash equivalents offset by $14.9 billion net cash used by investing activities and $7.7 billion net cash used by financing activities. In addition, the Company had $0.5 billion in marketable securities at the end of 2017 and $22.9 billion at the end of 2016. See Note 1 to the Consolidated Financial Statements for additional details on cash, cash equivalents and marketable securities.

Cash flow from operations of $21.1 billion was the result of $1.3 billion of net earnings and $9.8 billion of non-cash expenses and other adjustments for depreciation and amortization, stock-based compensation, assets write-downs and deferred tax provision, reduced by $1.3 billion from net gains on sale of assets/businesses and $1.0 billion related to an increase in accounts receivable and an increase in other current and non-current assets. Additional sources of operating cash flow of $12.3 billion resulted from an increase in accounts payable and accrued liabilities, a decrease in inventories and an increase in other current and non-current liabilities. The increase in accrued liabilities and non-current liabilities is primarily due to the 2017 U.S. tax legislation (TCJA). The U.S. tax of $10.1 billion is payable over 8 years. Additionally, foreign taxes of $3.4 billion, net were recorded in the deferred tax provision.

Investing activities use of $14.9 billion was for acquisitions, net of cash acquired of $35.2 billion (primarily the acquisitions of Actelion and AMO for approximately $29.6 billion and $4.3 billion, respectively) and additions to property, plant and equipment of $3.3 billion. This was partially offset by proceeds from the net sale of investments primarily marketable securities of $22.0 billion and $1.8 billion of proceeds from the disposal of assets/businesses (primarily the divestitures of Codman Neurosurgery and COMPEED®).

Financing activities use of $7.7 billion was primarily for dividends to shareholders of $8.9 billion, $6.4 billion for the repurchase of common stock and $0.2 billion of other financing. Financing activities also included sources of $6.8 billion from net proceeds of short and long-term debt and $1.1 billion of proceeds from stock options exercised/employee withholding tax on stock awards, net.

On October 13, 2015, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $10.0 billion of the Company's shares of common stock. As of July 2, 2017, $10.0 billion was repurchased under the program and the program was completed. Shares acquired are available for general corporate purposes.

As of December 31, 2017, the Company's notes payable and long-term debt was in excess of cash, cash equivalents and marketable securities. In 2017, the Company continued to have access to liquidity through the commercial paper market. Additionally, as a result of the TCJA, the Company has access to its cash outside the U.S. at a significantly reduced cost. The Company anticipates that operating cash flows, the ability to raise funds from external sources, borrowing capacity from existing committed credit facilities and access to the commercial paper markets will continue to provide sufficient resources to fund operating needs for the next twelve months. The Company monitors the global capital markets on an ongoing basis and from time to time may raise capital when market conditions are favorable. The Company filed a new shelf registration on February 27, 2017 which will enable it to issue debt securities on a timely basis. In the fiscal first and fourth quarters of 2017, the Company issued bonds for a total of $9.0 billion for general corporate purposes, including the completion of the stock repurchase program. For additional details on borrowings, see Note 7 to the Consolidated Financial Statements.

Financing and Market Risk

The Company uses financial instruments to manage the impact of foreign exchange rate changes on cash flows. Accordingly, the Company enters into forward foreign exchange contracts to protect the value of certain foreign currency assets and liabilities and to hedge future foreign currency transactions primarily related to product costs. Gains or losses on these contracts are offset by the gains or losses on the underlying transactions. A 10% appreciation of the U.S. Dollar from the December 31, 2017 market rates would increase the unrealized value of the Company’s forward contracts by $167 million. Conversely, a 10% depreciation of the U.S. Dollar from the December 31, 2017 market rates would decrease the unrealized value of the Company’s forward contracts by $197 million. In either scenario, the gain or loss on the forward contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated earnings and cash flows.

The Company hedges the exposure to fluctuations in currency exchange rates, and the effect on certain assets and liabilities in foreign currency, by entering into currency swap contracts. A 1% change in the spread between U.S. and foreign interest rates on the Company’s interest rate sensitive financial instruments would either increase or decrease the unrealized value of the Company’s swap contracts by approximately $69 million. In either scenario, at maturity, the gain or loss on the swap contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated cash flows.

The Company does not enter into financial instruments for trading or speculative purposes. Further, the Company has a policy of only entering into contracts with parties that have at least an investment grade credit rating. The counter-parties to these contracts are major financial institutions and there is no significant concentration of exposure with any one counter-party. Management believes the risk of loss is remote.

The Company invests in both fixed rate and floating rate interest earning securities which carry a degree of interest rate risk. The fair market value of fixed rate securities may be adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than predicted if interest rates fall. A 1% (100 basis points) change in spread on the Company’s interest rate sensitive investments would either increase or decrease the unrealized value of cash equivalents and current marketable securities by approximately $8 million.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2017, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 13, 2018. Interest charged on borrowings under the credit line agreement is based on either bids provided by banks, the prime rate or London Interbank Offered Rates (LIBOR), plus applicable margins. Commitment fees under the agreement are not material.

Total borrowings at the end of 2017 and 2016 were $34.6 billion and $27.1 billion, respectively. The increase in borrowings between 2017 and 2016 was a result of financing for the Company's share repurchase program and general corporate purposes. In 2017, net debt (cash and current marketable securities, net of debt) was $16.3 billion compared to net cash of $14.8 billion in 2016. Total debt represented 36.5% of total capital (shareholders’ equity and total debt) in 2017 and 27.8% of total capital in 2016. Shareholders’ equity per share at the end of 2017 was $22.43 compared to $26.02 at year-end 2016, a decrease of 13.8%.

A summary of borrowings can be found in Note 7 to the Consolidated Financial Statements.

Contractual Obligations and Commitments

The Company's contractual obligations are primarily for the recently enacted tax legislation, leases, debt and unfunded retirement plans. There are no other significant obligations. To satisfy these obligations, the Company will use cash from operations. The following table summarizes the Company's contractual obligations and their aggregate maturities as of December 31, 2017 (see Notes 7, 8, 10 and 16 to the Consolidated Financial Statements for further details):

(Dollars in Millions)	Tax Legislation (TCJA)	Debt Obligations	Interest on Debt Obligations	Unfunded Retirement Plans	Operating Leases	Total
2018	$ 1,614	1,499	1,002	88	227	4,430
2019	807	2,752	949	89	184	4,781
2020	807	1,105	883	94	143	3,032
2021	807	1,797	840	100	106	3,650
2022	1,513	2,189	796	108	76	4,682
After 2022	4,538	22,832	9,659	651	103	37,783
Total	**$ 10,086**	**32,174**	**14,129**	**1,130**	**839**	**58,358**

For tax matters, see Note 8 to the Consolidated Financial Statements. For other retirement plan and post-employment medical benefit information, see Note 10 to the Consolidated Financial Statements. The table does not include activity related to business combinations.

Dividends

The Company increased its dividend in 2017 for the 55th consecutive year. Cash dividends paid were $3.32 per share in 2017 compared with dividends of $3.15 per share in 2016, and $2.95 per share in 2015. The dividends were distributed as follows:

	2017	2016	2015
First quarter	$ 0.80	0.75	0.70
Second quarter	0.84	0.80	0.75
Third quarter	0.84	0.80	0.75
Fourth quarter	0.84	0.80	0.75
Total	**$ 3.32**	**3.15**	**2.95**

On January 2, 2018, the Board of Directors declared a regular quarterly cash dividend of $0.84 per share, payable on March 13, 2018, to shareholders of record as of February 27, 2018. The Company expects to continue the practice of paying regular cash dividends.

Other Information

Critical Accounting Policies and Estimates

Management's discussion and analysis of results of operations and financial condition are based on the Company's consolidated financial statements that have been prepared in accordance with accounting principles generally accepted in the U.S. (GAAP). The preparation of these financial statements requires that management make estimates and assumptions that affect the amounts reported for revenues, expenses, assets, liabilities and other related disclosures. Actual results may or may not differ from these estimates. The Company believes that the understanding of certain key accounting policies and estimates are essential in achieving more insight into the Company's operating results and financial condition. These key accounting policies include revenue recognition, income taxes, legal and self-insurance contingencies, valuation of long-lived assets, assumptions used to determine the amounts recorded for pensions and other employee benefit plans and accounting for stock based awards.

Revenue Recognition: The Company recognizes revenue from product sales when goods are shipped or delivered, and title and risk of loss pass to the customer. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns and discounts to customers are accounted for as reductions in sales in the same period the related sales are recorded. See Note 1 to the Consolidated Financial Statements for the Accounting Standards Update related to revenue which will be adopted in 2018.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including prices charged by competitors. Rebates, which include the Medicaid rebate provision, are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns are estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales return accruals.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual net trade sales during the fiscal reporting years 2017, 2016 and 2015.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the year incurred. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on estimated sales volumes for the incentive period and are recorded as products are sold. The Company also earns service revenue for co-promotion of certain products. For all years presented, service revenues were approximately 1% or less of the total revenues and are included in sales to customers. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue.

In addition, the Company enters into collaboration arrangements that contain multiple revenue generating activities. Amounts due from collaborative partners for these arrangements are recognized as each activity is performed or delivered, based on the relative selling price. Upfront fees received as part of these arrangements are deferred and recognized over the performance period. See Note 1 to the Consolidated Financial Statements for additional disclosures on collaborations.

Reasonably likely changes to assumptions used to calculate the accruals for rebates, returns and promotions are not anticipated to have a material effect on the financial statements. The Company currently discloses the impact of changes to assumptions in the quarterly or annual filing in which there is a material financial statement impact.

Below are tables that show the progression of accrued rebates, returns, promotions, reserve for doubtful accounts and reserve for cash discounts by segment of business for the fiscal years ended December 31, 2017 and January 1, 2017.

Consumer Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits	Balance at End of Period
2017				
Accrued rebates [1]	$ 136	638	(588)	186
Accrued returns	65	128	(125)	68
Accrued promotions	358	2,148	(2,025)	481
Subtotal	$ 559	2,914	(2,738)	735
Reserve for doubtful accounts	24	10	(3)	31
Reserve for cash discounts	25	205	(207)	23
Total	$ 608	3,129	(2,948)	789
2016				
Accrued rebates[1]	$ 139	615	(618)	136
Accrued returns	54	111	(100)	65
Accrued promotions	412	1,908	(1,962)	358
Subtotal	$ 605	2,634	(2,680)	559
Reserve for doubtful accounts	18	12	(6)	24
Reserve for cash discounts	17	209	(201)	25
Total	$ 640	2,855	(2,887)	608

(1) Includes reserve for customer rebates of $48 million at December 31, 2017 and $37 million at January 1, 2017, recorded as a contra asset.

Pharmaceutical Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits[2]	Balance at End of Period
2017				
Accrued rebates [1]	$ 3,420	16,447	(15,005)	4,862
Accrued returns	334	256	(228)	362
Accrued promotions	—	69	(34)	35
Subtotal	$ 3,754	16,772	(15,267)	5,259
Reserve for doubtful accounts	38	40	(1)	77
Reserve for cash discounts	58	714	(717)	55
Total	$ 3,850	17,526	(15,985)	5,391
2016				
Accrued rebates [1]	$ 3,451	12,306	(12,337)	3,420
Accrued returns	404	140	(210)	334
Accrued promotions	11	10	(21)	—
Subtotal	$ 3,866	12,456	(12,568)	3,754
Reserve for doubtful accounts	46	2	(10)	38
Reserve for cash discounts	63	613	(618)	58
Total	$ 3,975	13,071	(13,196)	3,850

(1) Includes reserve for customer rebates of $90 million at December 31, 2017 and $102 million at January 1, 2017, recorded as a contra asset.

(2) Includes adjustments

Medical Devices Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits	Balance at End of Period
2017				
Accrued rebates[1]	$ 1,500	6,407	(6,287)	1,620
Accrued returns	127	729	(704)	152
Accrued promotions	32	135	(84)	83
Subtotal	$ 1,659	7,271	(7,075)	1,855
Reserve for doubtful accounts	190	27	(34)	183
Reserve for cash discounts	16	389	(390)	15
Total	$ 1,865	7,687	(7,499)	2,053
2016				
Accrued rebates[1]	$ 1,189	5,700	(5,389)	1,500
Accrued returns	239	518	(630)	127
Accrued promotions	47	78	(93)	32
Subtotal	$ 1,475	6,296	(6,112)	1,659
Reserve for doubtful accounts	204	21	(35)	190
Reserve for cash discounts	20	430	(434)	16
Total	$ 1,699	6,747	(6,581)	1,865

(1) Includes reserve for customer rebates of $501 million at December 31, 2017 and $430 million at January 1, 2017, recorded as a contra asset.

Income Taxes: Income taxes are recorded based on amounts refundable or payable for the current year and include the results of any difference between U.S. GAAP accounting and tax reporting, recorded as deferred tax assets or liabilities. The Company estimates deferred tax assets and liabilities based on enacted tax regulations and rates. Future changes in tax laws and rates may affect recorded deferred tax assets and liabilities.

The Company has unrecognized tax benefits for uncertain tax positions. The Company follows U.S. GAAP, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Management believes that changes in these estimates would not have a material effect on the Company's results of operations, cash flows or financial position.

In the fourth quarter of 2017, the United States enacted the TCJA, which includes provisions for a tax on all previously undistributed earnings in foreign jurisdictions. The Company has provisionally booked a $10.1 billion charge on these undistributed earnings in 2017. Additionally, the Company has provisionally recorded a $4.5 billion deferred tax liability for foreign local and withholding taxes, offset by a $1.1 billion deferred tax asset for U.S. foreign tax credits, for repatriation of substantially all undistributed foreign earnings. The Company is currently evaluating the remaining undistributed foreign earnings for which it has not provided deferred taxes for foreign local and withholding tax, as these earnings are considered to be indefinitely reinvested. The amount of these unrecorded deferred taxes is not expected to be material.

See Note 8 to the Consolidated Financial Statements for further information regarding income taxes.

Legal and Self Insurance Contingencies: The Company records accruals for various contingencies, including legal proceedings and product liability claims as these arise in the normal course of business. The accruals are based on management's judgment as to the probability of losses and, where applicable, actuarially determined estimates. The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated.

The Company follows the provisions of U.S. GAAP when recording litigation related contingencies. A liability is recorded when a loss is probable and can be reasonably estimated. The best estimate of a loss within a range is accrued; however, if no estimate in the range is better than any other, the minimum amount is accrued.

See Notes 1 and 21 to the Consolidated Financial Statements for further information regarding product liability and legal proceedings.

Long-Lived and Intangible Assets: The Company assesses changes in economic conditions and makes assumptions regarding estimated future cash flows in evaluating the value of the Company's property, plant and equipment, goodwill and intangible assets. As these assumptions and estimates may change over time, it may or may not be necessary for the Company to record impairment charges.

Employee Benefit Plans: The Company sponsors various retirement and pension plans, including defined benefit, defined contribution and termination indemnity plans, which cover most employees worldwide. These plans are based on assumptions for the discount rate, expected return on plan assets, mortality rates, expected salary increases, health care cost trend rates and attrition rates. See Note 10 to the Consolidated Financial Statements for further details on these rates and the effect a rate change to the health care cost trend would have on the Company's results of operations.

Stock Based Compensation: The Company recognizes compensation expense associated with the issuance of equity instruments to employees for their services. Based on the type of equity instrument, the fair value is estimated on the date of grant using either the Black-Scholes option valuation model or a combination of both the Black-Scholes option valuation model and Monte Carlo valuation model, and is expensed in the financial statements over the service period. The input assumptions used in determining fair value are the expected life, expected volatility, risk-free rate and expected dividend yield. For performance share units the fair market value is calculated for each of the three component goals at the date of grant. The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award, discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. See Note 17 to the Consolidated Financial Statements for additional information.

New Accounting Pronouncements

Refer to Note 1 to the Consolidated Financial Statements for recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of December 31, 2017.

Economic and Market Factors

The Company is aware that its products are used in an environment where, for more than a decade, policymakers, consumers and businesses have expressed concerns about the rising cost of health care. In response to these concerns, the Company has a long-standing policy of pricing products responsibly. For the period 2007 - 2017, in the United States, the weighted average compound annual growth rate of the Company's net price increases for health care products (prescription and over-the-counter drugs, hospital and professional products) was below the U.S. Consumer Price Index (CPI).

The Company operates in certain countries where the economic conditions continue to present significant challenges. The Company continues to monitor these situations and take appropriate actions. Inflation rates continue to have an effect on worldwide economies and, consequently, on the way companies operate. The Company has accounted for operations in Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. In the face of increasing costs, the Company strives to maintain its profit margins through cost reduction programs, productivity improvements and periodic price increases.

In June 2016, the United Kingdom (U.K.) held a referendum in which voters approved an exit from the European Union (E.U.), commonly referred to as "Brexit" and in March 2017 the U.K. formally started the process for the U.K. to leave the E.U. Given the lack of comparable precedent, it is unclear what financial, trade, regulatory and legal implications the withdrawal of the U.K. from the E.U. will have. Brexit creates global political and economic uncertainty, which may cause, among other consequences, volatility in exchange rates and interest rates, additional cost containment by third-party payors and changes in regulations. However, the Company currently does not believe that these and other related effects will have a material impact on the Company's consolidated financial position or operating results. As of December 31, 2017, the business of the Company's U.K. subsidiaries represented less than 3% of both the Company's consolidated assets and fiscal twelve months revenues, respectively.

The Company is exposed to fluctuations in currency exchange rates. A 1% change in the value of the U.S. Dollar as compared to all foreign currencies in which the Company had sales, income or expense in 2017 would have increased or decreased the translation of foreign sales by approximately $360 million and income by $105 million.

Governments around the world consider various proposals to make changes to tax laws, which may include increasing or decreasing existing statutory tax rates. A change in statutory tax rate in any country would result in the revaluation of the Company's deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is enacted. This change would result in an expense or benefit recorded to the Company's Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries where it operates. Changes to the statutory tax rate may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted.

The Company faces various worldwide health care changes that may continue to result in pricing pressures that include health care cost containment and government legislation relating to sales, promotions and reimbursement of health care products.

Changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing health care insurance coverage, as a result of the current global economic downturn, may continue to impact the Company's businesses.

The Company also operates in an environment increasingly hostile to intellectual property rights. Firms have filed Abbreviated New Drug Applications or Biosimilar Biological Product Applications with the FDA or otherwise challenged the coverage and/or validity of the Company's patents, seeking to market generic or biosimilar forms of many of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the event the Company is not successful in defending the patent claims challenged in the resulting lawsuits, generic or biosimilar versions of the products at issue will be introduced to the market, resulting in the potential for substantial market share and revenue losses for those products, and which may result in a non-cash impairment charge in any associated intangible asset. There is also a risk that one or more competitors could launch a generic or biosimilar version of the product at issue following regulatory approval even though one or more valid patents are in place. For further information, see the discussion on "REMICADE® Related Cases" and "Litigation Against Filers of Abbreviated New Drug Applications" in Note 21 to the Consolidated Financial Statements.

Legal Proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability, intellectual property, commercial and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of business.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. The Company has accrued for certain litigation matters and continues to monitor each related legal issue and adjust accruals for new information and further developments in accordance with Accounting Standards Codification (ASC) 450-20-25. For these and other litigation and regulatory matters currently disclosed for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions. The ability to make such estimates and judgments can be affected by various factors, including whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; or there are numerous parties involved.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution of, or increase in accruals for, one or more of these matters in any reporting period may have a material adverse effect on the Company's results of operations and cash flows for that period.

See Note 21 to the Consolidated Financial Statements for further information regarding legal proceedings.

Common Stock Market Prices

The Company's Common Stock is listed on the New York Stock Exchange under the symbol JNJ. As of February 16, 2018, there were 147,484 record holders of Common Stock of the Company. The composite market price ranges for Johnson & Johnson Common Stock during 2017 and 2016 were:

	2017		2016	
	High	Low	High	Low
First quarter	$ 129.00	110.76	$ 109.56	94.28
Second quarter	137.00	120.95	121.54	107.88
Third quarter	137.08	129.05	126.07	117.04
Fourth quarter	144.35	130.02	122.50	109.32
Year-end close	$139.72		$115.21	

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK 814

The information called for by this item is incorporated herein by reference to "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition - Liquidity and Capital Resources - Financing and Market Risk" of this Report; and Note 1 "Summary of Significant Accounting Policies - Financial Instruments" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Audited Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
At December 31, 2017 and January 1, 2017
(Dollars in Millions Except Share and Per Share Amounts) (Note 1)

		2017	2016
Assets			
Current assets			
Cash and cash equivalents (Notes 1 and 2)	$	17,824	18,972
Marketable securities (Notes 1 and 2)		472	22,935
Accounts receivable trade, less allowances for doubtful accounts $291 (2016, $252)		13,490	11,699
Inventories (Notes 1 and 3)		8,765	8,144
Prepaid expenses and other receivables		2,537	3,282
Total current assets		**43,088**	**65,032**
Property, plant and equipment, net (Notes 1 and 4)		17,005	15,912
Intangible assets, net (Notes 1 and 5)		53,228	26,876
Goodwill (Notes 1 and 5)		31,906	22,805
Deferred taxes on income (Note 8)		7,105	6,148
Other assets		4,971	4,435
Total assets	**$**	**157,303**	**141,208**
Liabilities and Shareholders' Equity			
Current liabilities			
Loans and notes payable (Note 7)	$	3,906	4,684
Accounts payable		7,310	6,918
Accrued liabilities		7,304	5,635
Accrued rebates, returns and promotions		7,210	5,403
Accrued compensation and employee related obligations		2,953	2,676
Accrued taxes on income (Note 8)		1,854	971
Total current liabilities		**30,537**	**26,287**
Long-term debt (Note 7)		30,675	22,442
Deferred taxes on income (Note 8)		8,368	2,910
Employee related obligations (Notes 9 and 10)		10,074	9,615
Long-term taxes payable (Note 8)		8,472	—
Other liabilities		9,017	9,536
Total liabilities		**97,143**	**70,790**
Shareholders' equity			
Preferred stock — without par value (authorized and unissued 2,000,000 shares)		—	—
Common stock — par value $1.00 per share (Note 12) (authorized 4,320,000,000 shares; issued 3,119,843,000 shares)		3,120	3,120
Accumulated other comprehensive income (loss) (Note 13)		(13,199)	(14,901)
Retained earnings		101,793	110,551
		91,714	98,770
Less: common stock held in treasury, at cost (Note 12) (437,318,000 shares and 413,332,000 shares)		31,554	28,352
Total shareholders' equity		**60,160**	**70,418**
Total liabilities and shareholders' equity	**$**	**157,303**	**141,208**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EARNINGS
(Dollars and Shares in Millions Except Per Share Amounts) (Note 1)

		2017	2016	2015
Sales to customers	$	76,450	71,890	70,074
Cost of products sold		25,354	21,685	21,536
Gross profit		51,096	50,205	48,538
Selling, marketing and administrative expenses		21,420	19,945	21,203
Research and development expense		10,554	9,095	9,046
In-process research and development		408	29	224
Interest income		(385)	(368)	(128)
Interest expense, net of portion capitalized (Note 4)		934	726	552
Other (income) expense, net		183	484	(2,064)
Restructuring (Note 22)		309	491	509
Earnings before provision for taxes on income		17,673	19,803	19,196
Provision for taxes on income (Note 8)		16,373	3,263	3,787
Net earnings	**$**	**1,300**	**16,540**	**15,409**
Net earnings per share (Notes 1 and 15)				
Basic	**$**	**0.48**	**6.04**	**5.56**
Diluted	**$**	**0.47**	**5.93**	**5.48**
Cash dividends per share	**$**	**3.32**	**3.15**	**2.95**
Average shares outstanding (Notes 1 and 15)				
Basic		**2,692.0**	**2,737.3**	**2,771.8**
Diluted		**2,745.3**	**2,788.9**	**2,812.9**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Dollars in Millions) (Note 1)

	2017	2016	2015
Net earnings	$ 1,300	16,540	15,409
Other comprehensive income (loss), net of tax			
Foreign currency translation	1,696	(612)	(3,632)
Securities:			
Unrealized holding gain (loss) arising during period	159	(52)	471
Reclassifications to earnings	(338)	(141)	(124)
Net change	(179)	(193)	347
Employee benefit plans:			
Prior service credit (cost), net of amortization	2	21	(60)
Gain (loss), net of amortization	29	(862)	931
Effect of exchange rates	(201)	159	148
Net change	(170)	(682)	1,019
Derivatives & hedges:			
Unrealized gain (loss) arising during period	(4)	(359)	(115)
Reclassifications to earnings	359	110	(62)
Net change	355	(249)	(177)
Other comprehensive income (loss)	1,702	(1,736)	(2,443)
Comprehensive income	$ 3,002	14,804	12,966

The tax effects in other comprehensive income for the fiscal years ended 2017, 2016 and 2015 respectively: Securities; $96 million, $104 million and $187 million, Employee Benefit Plans; $83 million, $346 million and $519 million, Derivatives & Hedges; $191 million, $134 million and $95 million.

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY
(Dollars in Millions) (Note 1)

	Total	Retained Earnings	Accumulated Other Comprehensive Income	Common Stock Issued Amount	Treasury Stock Amount
Balance, December 28, 2014	**$ 69,752**	**97,245**	**(10,722)**	**3,120**	**(19,891)**
Net earnings	15,409	15,409			
Cash dividends paid	(8,173)	(8,173)			
Employee compensation and stock option plans	1,920	(577)			2,497
Repurchase of common stock	(5,290)				(5,290)
Other	(25)	(25)			
Other comprehensive income (loss), net of tax	(2,443)		(2,443)		
Balance, January 3, 2016	**71,150**	**103,879**	**(13,165)**	**3,120**	**(22,684)**
Net earnings	16,540	16,540			
Cash dividends paid	(8,621)	(8,621)			
Employee compensation and stock option plans	2,130	(1,181)			3,311
Repurchase of common stock	(8,979)				(8,979)
Other	(66)	(66)			
Other comprehensive income (loss), net of tax	(1,736)		(1,736)		
Balance, January 1, 2017	**70,418**	**110,551**	**(14,901)**	**3,120**	**(28,352)**
Net earnings	1,300	1,300			
Cash dividends paid	(8,943)	(8,943)			
Employee compensation and stock option plans	2,077	(1,079)			3,156
Repurchase of common stock	(6,358)				(6,358)
Other	(36)	(36)			
Other comprehensive income (loss), net of tax	1,702		1,702		
Balance, December 31, 2017	**$ 60,160**	**101,793**	**(13,199)**	**3,120**	**(31,554)**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Dollars in Millions) (Note 1)

		2017	2016	2015
Cash flows from operating activities				
Net earnings	$	1,300	16,540	15,409
Adjustments to reconcile net earnings to cash flows from operating activities:				
Depreciation and amortization of property and intangibles		5,642	3,754	3,746
Stock based compensation		962	878	874
Venezuela adjustments		—	—	122
Asset write-downs		795	283	624
Net gain on sale of assets/businesses		(1,307)	(563)	(2,583)
Deferred tax provision		2,406	(341)	(270)
Accounts receivable allowances		17	(11)	18
Changes in assets and liabilities, net of effects from acquisitions and divestitures:				
Increase in accounts receivable		(633)	(1,065)	(433)
Decrease/(Increase) in inventories		581	(249)	(449)
Increase in accounts payable and accrued liabilities		2,725	656	287
Increase in other current and non-current assets		(411)	(529)	(103)
Increase/(Decrease) in other current and non-current liabilities		8,979	(586)	2,327
Net cash flows from operating activities		**21,056**	**18,767**	**19,569**
Cash flows from investing activities				
Additions to property, plant and equipment		(3,279)	(3,226)	(3,463)
Proceeds from the disposal of assets/businesses, net		1,832	1,267	3,464
Acquisitions, net of cash acquired (Note 20)		(35,151)	(4,509)	(954)
Purchases of investments		(6,153)	(33,950)	(40,828)
Sales of investments		28,117	35,780	34,149
Other (primarily intangibles)		(234)	(123)	(103)
Net cash used by investing activities		**(14,868)**	**(4,761)**	**(7,735)**
Cash flows from financing activities				
Dividends to shareholders		(8,943)	(8,621)	(8,173)
Repurchase of common stock		(6,358)	(8,979)	(5,290)
Proceeds from short-term debt		869	111	2,416
Retirement of short-term debt		(1,330)	(2,017)	(1,044)
Proceeds from long-term debt, net of issuance costs		8,992	12,004	75
Retirement of long-term debt		(1,777)	(2,223)	(68)
Proceeds from the exercise of stock options/employee withholding tax on stock awards, net		1,062	1,189	1,005
Other		(188)	(15)	(57)
Net cash used by financing activities		**(7,673)**	**(8,551)**	**(11,136)**
Effect of exchange rate changes on cash and cash equivalents		337	(215)	(1,489)
(Decrease)/Increase in cash and cash equivalents		(1,148)	5,240	(791)
Cash and cash equivalents, beginning of year (Note 1)		18,972	13,732	14,523
Cash and cash equivalents, end of year (Note 1)	**$**	**17,824**	**18,972**	**13,732**

Supplemental cash flow data				
Cash paid during the year for:				
Interest	$	960	730	617
Interest, net of amount capitalized		866	628	515
Income taxes		3,312	2,843	2,865

Supplemental schedule of non-cash investing and financing activities				
Treasury stock issued for employee compensation and stock option plans, net of cash proceeds/ employee withholding tax on stock awards	$	2,062	2,043	1,486
Conversion of debt		16	35	16

Acquisitions				
Fair value of assets acquired	$	36,937	4,586	1,174
Fair value of liabilities assumed and noncontrolling interests		(1,786)	(77)	(220)
Net cash paid for acquisitions	**$**	**35,151**	**4,509**	**954**

See Notes to Consolidated Financial Statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Johnson & Johnson and its subsidiaries (the Company). Intercompany accounts and transactions are eliminated.

Description of the Company and Business Segments

The Company has approximately 134,000 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world and its primary focus is on products related to human health and well-being.

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. The Consumer segment includes a broad range of products used in the baby care, oral care, beauty, over-the-counter pharmaceutical, women's health and wound care markets. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on six therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, pulmonary hypertension, and cardiovascular and metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, cardiovascular, diabetes care and vision care fields, which are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

Accounting Standard adopted in 2016

During the fiscal second quarter of 2016, the Company adopted Accounting Standards Update (ASU) 2016-09 Compensation - Stock Compensation: Improvements to Employee Share Based Payment Accounting for the reporting of additional tax benefits on share-based compensation that vested or were exercised during the fiscal year. The update requires all excess tax benefits and deficiencies to be recognized as a reduction or an increase to the provision for taxes on income. Previously, the Company recorded these benefits directly to Retained Earnings. The tax benefit for the Company was $353 million for the fiscal year 2016. The standard does not permit retroactive presentation of this benefit to prior fiscal years on the Consolidated Statement of Earnings.

New Accounting Standards

Recently Adopted Accounting Standards

ASU 2016-07: Simplifying the Transition to the Equity Method of Accounting

The amendments in the update eliminate the requirement that when an investment qualifies for the use of the equity method as a result of an increase in the level of ownership interest or degree of influence, an investor must adjust the investment, results of operations, and retained earnings retroactively on a step by step basis as if the equity method had been in effect during all previous periods that the investment had been held. The amendments in this update are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. The amendments should be applied prospectively upon their effective date to increases in the level of ownership interest or degree of influence that result in the application of the equity method. The adoption of this standard did not have a material impact on the presentation of the Company's consolidated financial statements.

ASU 2015-11: Simplifying the Measurement of Inventory

This update requires inventory to be measured at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. This update is effective for the Company for all annual and interim periods beginning after December 15, 2016. The amendments in this update should be applied prospectively. This update did not have any material impact on the Company's consolidated financial statements.

Recently Issued Accounting Standards

Not Adopted as of December 31, 2017

ASU 2018-02: Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income

This update allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Job Act enacted in December 2017. This update will be effective for the Company for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early adoption is permitted. The Company does not expect this standard to have a material impact on the Company's consolidated financial statements.

ASU 2017-12: Targeted Improvements to Accounting for Hedging Activities
This update makes more financial and nonfinancial hedging strategies eligible for hedge accounting. It also amends the presentation and disclosure requirements and changes how companies assess effectiveness. This update will be effective for the Company for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted upon its issuance. The Company is currently assessing the impact of the future adoption of this standard on its financial statements.

ASU 2017-07: Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost
This update requires that an employer disaggregate the service cost component from the other components of net periodic benefit cost ("NPBC"). In addition, only the service cost component will be eligible for capitalization. This update is effective for the Company for all annual and interim periods beginning after December 15, 2017. Early adoption is permitted as of the beginning of an annual period for which financial statements (interim or annual) have not been issued or made available for issuance. The amendments in this Update should be applied retrospectively for the presentation of the service cost component and the other components of NPBC in the income statement and prospectively, on and after the effective date, for the capitalization of the service cost component of NPBC in assets. The Company is assessing the retroactive restatement methodology and impact to the individual line items on Consolidated Statement of Earnings. The Company does not expect there to be a material impact to net earnings.

ASU 2017-01: Clarifying the Definition of a Business
This update narrows the definition of a business by providing a screen to determine when an integrated set of assets and activities is not a business. The screen specifies that an integrated set of assets and activities is not a business if substantially all of the fair value of the gross assets acquired or disposed of is concentrated in a single or a group of similar identifiable assets. This update will be effective for the Company for annual periods beginning after December 15, 2017, including interim periods within those annual periods. Early adoption is permitted. This update should be applied prospectively. The Company does not expect this standard to have a material impact on the Company's consolidated financial statements.

ASU 2016-16: Income Taxes: Intra-Entity Transfers of Assets Other Than Inventory
This update removes the current exception in US GAAP prohibiting entities from recognizing current and deferred income tax expenses or benefits related to transfer of assets, other than inventory, within the consolidated entity. The current exception to defer the recognition of any tax impact on the transfer of inventory within the consolidated entity until it is sold to a third party remains unaffected. The amendments in this update are effective for public entities for annual reporting periods beginning after December 15, 2017. The results from a preliminary assessment indicate that the adoption of the standard will not have a significant impact on the Company's financial results. The Company expects to record net adjustments to deferred taxes of approximately $2.0 billion, a decrease to Other Assets of approximately $0.7 billion and an increase to retained earnings of approximately $1.3 billion.

ASU 2016-02: Leases
This update requires the recognition of lease assets and lease liabilities on the balance sheet for all lease obligations and disclosing key information about leasing arrangements. This update requires the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under current generally accepted accounting principles. This update will be effective for the Company for all annual and interim periods beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. The Company anticipates that most of its operating leases will result in the recognition of additional assets and the corresponding liabilities on its Consolidated Balance Sheets, however does not expect the standard to have a material impact on the financial position. The actual impact will depend on the Company's lease portfolio at the time of adoption. The Company continues to assess all implications of the standard and related financial disclosures.

ASU 2016-01: Financial Instruments: Recognition and Measurement of Financial Assets and Financial Liabilities
The amendments in this update supersede the guidance to classify equity securities with readily determinable fair values into different categories (that is, trading or available-for-sale) and require equity securities to be measured at fair value with changes in the fair value recognized through net income. The standard amends financial reporting by providing relevant information about an entity's equity investments and reducing the number of items that are recognized in other comprehensive income. This update will be effective for the Company for annual periods beginning after December 15, 2017, and interim periods within those annual periods. The adoption of this standard will not have a material impact on the Company's consolidated financial statements.

ASU 2014-09: Revenue from Contracts with Customers
The amendments replace substantially all current U.S. GAAP guidance on this topic and eliminate industry-specific guidance. Early adoption of this standard is permitted but not before the original effective date for all annual periods and interim reporting

periods beginning after December 15, 2017. The Company will adopt the standard using the modified retrospective method. The adoption of this standard will not have a material impact on the Company's consolidated financial statements including the additional disclosure requirements.

Cash Equivalents

The Company classifies all highly liquid investments with stated maturities of three months or less from date of purchase as cash equivalents and all highly liquid investments with stated maturities of greater than three months from the date of purchase as current marketable securities. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating. The Company invests its cash primarily in government securities and obligations, corporate debt securities, money market funds and reverse repurchase agreements (RRAs).

RRAs are collateralized by deposits in the form of Government Securities and Obligations for an amount not less than 102% of their value. The Company does not record an asset or liability as the Company is not permitted to sell or repledge the associated collateral. The Company has a policy that the collateral has at least an A (or equivalent) credit rating. The Company utilizes a third party custodian to manage the exchange of funds and ensure that collateral received is maintained at 102% of the value of the RRAs on a daily basis. RRAs with stated maturities of greater than three months from the date of purchase are classified as marketable securities.

Investments

Investments classified as held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings. Investments classified as available-for-sale are carried at estimated fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income. Available-for-sale securities available for current operations are classified as current assets otherwise, they are classified as long term. Management determines the appropriate classification of its investment in debt and equity securities at the time of purchase and re-evaluates such determination at each balance sheet date. The Company periodically reviews its investments in equity securities for impairment and adjusts these investments to their fair value when a decline in market value is deemed to be other than temporary. If losses on these securities are considered to be other than temporary, the loss is recognized in earnings.

Property, Plant and Equipment and Depreciation

Property, plant and equipment are stated at cost. The Company utilizes the straight-line method of depreciation over the estimated useful lives of the assets:

Building and building equipment	20 - 30 years
Land and leasehold improvements	10 - 20 years
Machinery and equipment	2 - 13 years

The Company capitalizes certain computer software and development costs, included in machinery and equipment, when incurred in connection with developing or obtaining computer software for internal use. Capitalized software costs are amortized over the estimated useful lives of the software, which generally range from 3 to 8 years.

The Company reviews long-lived assets to assess recoverability using undiscounted cash flows. When certain events or changes in operating or economic conditions occur, an impairment assessment may be performed on the recoverability of the carrying value of these assets. If the asset is determined to be impaired, the loss is measured based on the difference between the asset’s fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows.

Revenue Recognition

The Company recognizes revenue from product sales when the goods are shipped or delivered and title and risk of loss pass to the customer. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns and discounts to customers are accounted for as reductions in sales in the same period the related sales are recorded.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including prices charged by competitors. Rebates, which include Medicaid, are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns are generally estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales returns accruals.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company’s accounting policies, the Company generally issues credit to customers for

returned goods. The Company's sales returns reserves are accounted for in accordance with U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual sales to customers during the fiscal reporting years 2017, 2016 and 2015.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the year incurred. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. The Company also earns service revenue for co-promotion of certain products and includes it in sales to customers. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue.

Shipping and Handling

Shipping and handling costs incurred were $1,042 million, $974 million and $996 million in 2017, 2016 and 2015, respectively, and are included in selling, marketing and administrative expense. The amount of revenue received for shipping and handling is less than 0.5% of sales to customers for all periods presented.

Inventories

Inventories are stated at the lower of cost or net realizable value determined by the first-in, first-out method.

Intangible Assets and Goodwill

The authoritative literature on U.S. GAAP requires that goodwill and intangible assets with indefinite lives be assessed annually for impairment. The Company completed the annual impairment test for 2017 in the fiscal fourth quarter. Future impairment tests will be performed annually in the fiscal fourth quarter, or sooner if warranted. Purchased in-process research and development is accounted for as an indefinite lived intangible asset until the underlying project is completed, at which point the intangible asset will be accounted for as a definite lived intangible asset, or abandoned, at which point the intangible asset will be written off or partially impaired.

Intangible assets that have finite useful lives continue to be amortized over their useful lives, and are reviewed for impairment when warranted by economic conditions. See Note 5 for further details on Intangible Assets and Goodwill.

Financial Instruments

As required by U.S. GAAP, all derivative instruments are recorded on the balance sheet at fair value. Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value, with Level 1 having the highest priority and Level 3 having the lowest. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The Company documents all relationships between hedged items and derivatives. The overall risk management strategy includes reasons for undertaking hedge transactions and entering into derivatives. The objectives of this strategy are: (1) minimize foreign currency exposure's impact on the Company's financial performance; (2) protect the Company's cash flow from adverse movements in foreign exchange rates; (3) ensure the appropriateness of financial instruments; and (4) manage the enterprise risk associated with financial institutions. See Note 6 for additional information on Financial Instruments.

Product Liability

Accruals for product liability claims are recorded, on an undiscounted basis, when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated based on existing information and actuarially determined estimates where applicable. The accruals are adjusted periodically as additional information becomes available. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated.

As a result of cost and availability factors, effective November 1, 2005, the Company ceased purchasing third-party product liability insurance. The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated.

Research and Development

Research and development expenses are expensed as incurred. Upfront and milestone payments made to third parties in connection with research and development collaborations are expensed as incurred up to the point of regulatory approval.

Payments made to third parties subsequent to regulatory approval are capitalized and amortized over the remaining useful life of the related product. Amounts capitalized for such payments are included in other intangibles, net of accumulated amortization.

The Company enters into collaborative arrangements, typically with other pharmaceutical or biotechnology companies, to develop and commercialize drug candidates or intellectual property. These arrangements typically involve two (or more) parties who are active participants in the collaboration and are exposed to significant risks and rewards dependent on the commercial success of the activities. These collaborations usually involve various activities by one or more parties, including research and development, marketing and selling and distribution. Often, these collaborations require upfront, milestone and royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development. Amounts due from collaborative partners related to development activities are generally reflected as a reduction of research and development expense because the performance of contract development services is not central to the Company's operations. In general, the income statement presentation for these collaborations is as follows:

Nature/Type of Collaboration	Statement of Earnings Presentation
Third-party sale of product	Sales to customers
Royalties/milestones paid to collaborative partner (post-regulatory approval)*	Cost of products sold
Royalties received from collaborative partner	Other income (expense), net
Upfront payments & milestones paid to collaborative partner (pre-regulatory approval)	Research and development expense
Research and development payments to collaborative partner	Research and development expense
Research and development payments received from collaborative partner	Reduction of Research and development expense

* Milestones are capitalized as intangible assets and amortized to cost of products sold over the useful life.

For all years presented, there was no individual project that represented greater than 5% of the total annual consolidated research and development expense.

The Company has a number of products and compounds developed in collaboration with strategic partners including XARELTO®, co-developed with Bayer HealthCare AG and IMBRUVICA®, developed in collaboration and co-marketed with Pharmacyclics LLC, an AbbVie company.

Advertising

Costs associated with advertising are expensed in the year incurred and are included in selling, marketing and administrative expenses. Advertising expenses worldwide, which comprised television, radio, print media and Internet advertising, were $2.5 billion, $2.4 billion and $2.5 billion in 2017, 2016 and 2015, respectively.

Income Taxes

Income taxes are recorded based on amounts refundable or payable for the current year and include the results of any difference between U.S. GAAP accounting and tax reporting, recorded as deferred tax assets or liabilities. The Company estimates deferred tax assets and liabilities based on enacted tax regulations and rates. Future changes in tax laws and rates may affect recorded deferred tax assets and liabilities in the future.

The Company has unrecognized tax benefits for uncertain tax positions. The Company follows U.S. GAAP which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Management believes that changes in these estimates would not have a material effect on the Company's results of operations, cash flows or financial position.

In the fourth quarter of 2017, the United States enacted the TCJA, which includes provisions for a tax on all previously undistributed earnings in foreign jurisdictions. The Company has provisionally booked a $10.1 billion charge on these undistributed earnings in 2017. Additionally, the Company has provisionally recorded a $4.5 billion deferred tax liability for foreign local and withholding taxes, offset by a $1.1 billion deferred tax asset for U.S. foreign tax credits, for repatriation of substantially all undistributed foreign earnings. The Company is currently evaluating the remaining undistributed foreign earnings for which it has not provided deferred taxes for foreign local and withholding tax, as these earnings are considered to be indefinitely reinvested. The amount of these unrecorded deferred taxes is not expected to be material.

See Note 8 for further information regarding income taxes.

Net Earnings Per Share
Basic earnings per share is computed by dividing net earnings available to common shareholders by the weighted average number of common shares outstanding for the period. Diluted earnings per share reflects the potential dilution that could occur if securities were exercised or converted into common stock using the treasury stock method.

Use of Estimates
The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the amounts reported. Estimates are used when accounting for sales discounts, rebates, allowances and incentives, product liabilities, income taxes, withholding taxes, depreciation, amortization, employee benefits, contingencies and intangible asset and liability valuations. Actual results may or may not differ from those estimates.

The Company follows the provisions of U.S. GAAP when recording litigation related contingencies. A liability is recorded when a loss is probable and can be reasonably estimated. The best estimate of a loss within a range is accrued; however, if no estimate in the range is better than any other, the minimum amount is accrued.

Annual Closing Date
The Company follows the concept of a fiscal year, which ends on the Sunday nearest to the end of the month of December. Normally each fiscal year consists of 52 weeks, but every five or six years the fiscal year consists of 53 weeks, and therefore includes additional shipping days, as was the case in 2015, and will be the case again in 2020.

Reclassification
Certain prior period amounts have been reclassified to conform to current year presentation.

2. Cash, Cash Equivalents and Current Marketable Securities
At the end of 2017 and 2016, cash, cash equivalents and current marketable securities were comprised of:

(Dollars in Millions)	2017			
	Carrying Amount	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	$ 2,929	2,929	$ 2,929	—
U.S. Gov't Securities[1]	—	—	—	—
Other Sovereign Securities[1]	279	279	219	60
U.S. Reverse repurchase agreements	4,025	4,025	4,025	—
Other Reverse repurchase agreements	—	—	—	—
Corporate debt securities[1]	289	289	244	45
Money market funds	4,288	4,288	4,288	—
Time deposits[1]	1,176	1,176	1,175	1
Subtotal	$ 12,986	12,986	12,880	106
Gov't Securities	$ 4,864	4,864	4,833	31
Other Sovereign Securities	186	186	80	106
Corporate debt securities	260	260	31	229
Subtotal available for sale[2]	$ 5,310	5,310	4,944	366
Total cash, cash equivalents and current marketable securities			**$ 17,824**	**472**

In 2017, the carrying amount was the same as the estimated fair value.

(Dollars in Millions)	2016					
	Carrying Amount	Unrecognized Gain	Unrecognized Loss	Estimated Fair Value	Cash Equivalents	Current Marketable Securities
Cash	$ 1,979	—	—	1,979	1,979	—
U.S. Gov't Securities[1]	10,832	—	(1)	10,831	2,249	8,583
Other Sovereign Securities[1]	1,299	—	—	1,299	120	1,179
U.S. Reverse repurchase agreements	6,103	—	—	6,103	6,103	—
Other Reverse repurchase agreements	240	—	—	240	240	—
Corporate debt securities[1]	754	—	—	754	—	754
Money market funds	7,187	—	—	7,187	7,187	—
Time deposits[1]	1,094	—	—	1,094	1,094	—
Subtotal	$ 29,488	—	(1)	29,487	18,972	10,516
		Unrealized Gain	Unrealized Loss			
Gov't Securities	$ 10,277	5	(51)	10,231	—	10,231
Other Sovereign Securities	90	—	—	90		90
Corporate debt securities	1,777	1	(12)	1,766	—	1,766
Equity investments	34	298	—	332		332
Subtotal available for sale[2]	$ 12,178	304	(63)	12,419	—	12,419
Total cash, cash equivalents and current marketable securities					**$ 18,972**	**22,935**

[1] Held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings.
[2] Available for sale securities are reported at fair value with unrealized gains and losses reported net of taxes in other comprehensive income.

Fair value of government securities and obligations and corporate debt securities were estimated using quoted broker prices and significant other observable inputs.

The contractual maturities of the available for sale debt securities at December 31, 2017 are as follows:

(Dollars in Millions)	Cost Basis	Fair Value
Due within one year	$ 5,214	5,214
Due after one year through five years	96	96
Due after five years through ten years	—	—
Total debt securities	$ 5,310	5,310

The Company invests its excess cash in both deposits with major banks throughout the world and other high-quality money market instruments. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating.

3. Inventories

At the end of 2017 and 2016, inventories were comprised of:

(Dollars in Millions)		2017	2016
Raw materials and supplies	$	1,140	952
Goods in process		2,317	2,185
Finished goods		5,308	5,007
Total inventories	**$**	**8,765**	**8,144**

4. Property, Plant and Equipment

At the end of 2017 and 2016, property, plant and equipment at cost and accumulated depreciation were:

(Dollars in Millions)		2017	2016
Land and land improvements	$	829	753
Buildings and building equipment		11,240	10,112
Machinery and equipment		25,949	23,554
Construction in progress		3,448	3,354
Total property, plant and equipment, gross	$	41,466	37,773
Less accumulated depreciation		24,461	21,861
Total property, plant and equipment, net	**$**	**17,005**	**15,912**

The Company capitalizes interest expense as part of the cost of construction of facilities and equipment. Interest expense capitalized in 2017, 2016 and 2015 was $94 million, $102 million and $102 million, respectively.

Depreciation expense, including the amortization of capitalized interest in 2017, 2016 and 2015 was $2.6 billion, $2.5 billion and $2.5 billion, respectively.

Upon retirement or other disposal of property, plant and equipment, the costs and related amounts of accumulated depreciation or amortization are eliminated from the asset and accumulated depreciation accounts, respectively. The difference, if any, between the net asset value and the proceeds are recorded in earnings.

5. Intangible Assets and Goodwill

At the end of 2017 and 2016, the gross and net amounts of intangible assets were:

(Dollars in Millions)		2017	2016
Intangible assets with definite lives:			
Patents and trademarks — gross	$	36,427	10,521
Less accumulated amortization		7,223	5,076
Patents and trademarks — net	**$**	**29,204**	**5,445**
Customer relationships and other intangibles — gross	$	20,204	17,615
Less accumulated amortization		7,463	6,515
Customer relationships and other intangibles — net	**$**	**12,741**	**11,100**
Intangible assets with indefinite lives:			
Trademarks	$	7,082	6,888
Purchased in-process research and development		4,201	3,443
Total intangible assets with indefinite lives	**$**	**11,283**	**10,331**
Total intangible assets — net	**$**	**53,228**	**26,876**

Goodwill as of December 31, 2017 and January 1, 2017, as allocated by segment of business, was as follows:

(Dollars in Millions)	Consumer	Pharmaceutical	Medical Devices	Total
Goodwill at January 3, 2016	$ 7,240	2,889	11,500	21,629
Goodwill, related to acquisitions	1,362	—	210	1,572
Goodwill, related to divestitures	(63)	(12)	—	(75)
Currency translation/other	(276)	(37)	(8)	(321)
Goodwill at January 1, 2017	$ 8,263	2,840	11,702	22,805
Goodwill, related to acquisitions	102	6,161	2,200	8,463
Goodwill, related to divestitures	(74)	(1)	(102)	(177)
Currency translation/other	584	109	122	815
Goodwill at December 31, 2017	**$ 8,875**	**9,109**	**13,922**	**31,906**

The weighted average amortization periods for patents and trademarks and customer relationships and other intangible assets are 12 years and 23 years, respectively. The amortization expense of amortizable assets included in cost of products sold was $3.0 billion, $1.2 billion and $1.2 billion before tax, for the fiscal years ended December 31, 2017, January 1, 2017 and January 3, 2016, respectively. The estimated amortization expense for the five succeeding years approximates $4.4 billion before tax, per year. Intangible asset write-downs are included in Other (income) expense, net.

The primary driver of the increase to intangible assets and goodwill is related to the Actelion acquisition in the fiscal second quarter of 2017, which resulted in the recording of $25.0 billion to intangible assets and $6.2 billion to goodwill. The intangible assets and goodwill amounts related to the Actelion acquisition are based on the preliminary purchase price allocation. Additionally, the Abbott Medical Optics (AMO) acquisition in the fiscal first quarter of 2017, resulted in the recording of $2.3 billion to intangible assets and $1.7 billion to goodwill. The intangible assets and goodwill amounts related to the AMO acquisition are based on the final purchase price allocation.

See Note 20 to the Consolidated Financial Statements for additional details related to acquisitions and divestitures.

6. Fair Value Measurements

The Company uses forward foreign exchange contracts to manage its exposure to the variability of cash flows, primarily related to the foreign exchange rate changes of future intercompany products and third-party purchases of materials denominated in a foreign currency. The Company uses cross currency interest rate swaps to manage currency risk primarily related to borrowings. The Company also uses equity collar contracts to manage exposure to market risk associated with certain equity investments. All three types of derivatives are designated as cash flow hedges.

Additionally, the Company uses interest rate swaps as an instrument to manage interest rate risk related to fixed rate borrowings. These derivatives are designated as fair value hedges. The Company uses forward foreign exchange contracts designated as net investment hedges. Additionally, the Company uses forward foreign exchange contracts to offset its exposure to certain foreign currency assets and liabilities. These forward foreign exchange contracts are not designated as hedges and therefore, changes in the fair values of these derivatives are recognized in earnings, thereby offsetting the current earnings effect of the related foreign currency assets and liabilities.

The Company does not enter into derivative financial instruments for trading or speculative purposes, or that contain credit risk related contingent features. During the fiscal second quarter of 2017, the Company entered into credit support agreements (CSA) with certain derivative counterparties establishing collateral thresholds based on respective credit ratings and netting agreements. As of December 31, 2017, the total amount of collateral paid under the credit support agreements (CSA) amounted to $162 million net. For equity collar contracts, the Company pledged the underlying hedged marketable equity securities to the counter-party as collateral. On an ongoing basis, the Company monitors counter-party credit ratings. The Company considers credit non-performance risk to be low, because the Company primarily enters into agreements with commercial institutions that have at least an investment grade credit rating. Refer to the table on significant financial assets and liabilities measured at fair value contained in this footnote for receivables and payables with these commercial institutions. As of December 31, 2017, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of $34.5 billion, $2.3 billion, and $1.1 billion respectively. As of January 1, 2017, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps, interest rate swaps and equity collar contracts of $36.0 billion, $2.3 billion, $1.8 billion, and $0.3 billion respectively.

All derivative instruments are recorded on the balance sheet at fair value. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The designation as a cash flow hedge is made at the entrance date of the derivative contract. At inception, all derivatives are expected to be highly effective. Changes in the fair value of a derivative that is designated as a cash flow hedge and is highly effective are recorded in accumulated other comprehensive income until the underlying transaction affects earnings, and are then reclassified to earnings in the same account as the hedged transaction. Gains and losses associated with interest rate swaps and changes in fair value of hedged debt attributable to changes in interest rates are recorded to interest expense in the period in which they occur. Gains and losses on net investment hedges are accounted for through the currency translation account. On an ongoing basis, the Company assesses whether each derivative continues to be highly effective in offsetting changes of hedged items. If and when a derivative is no longer expected to be highly effective, hedge accounting is discontinued. Hedge ineffectiveness, if any, is included in current period earnings in Other (income) expense, net for forward foreign exchange contracts, cross currency interest rate swaps, net investment hedges and equity collar contracts. For interest rate swaps designated as fair value hedges, hedge ineffectiveness, if any, is included in current period earnings within interest expense. For the current reporting period, hedge ineffectiveness associated with interest rate swaps was not material.

During the fiscal second quarter of 2016, the Company designated its Euro denominated notes issued in May 2016 with due dates ranging from 2022 to 2035 as a net investment hedge of the Company's investments in certain of its international subsidiaries that use the Euro as their functional currency in order to reduce the volatility caused by changes in exchange rates.

The change in the carrying value due to remeasurement of these Euro notes resulted in a $597 million unrealized pretax loss for the fiscal year ended December 31, 2017, reflected in foreign currency translation adjustment, within the Consolidated Statements of Comprehensive Income. The change in the carrying value due to remeasurement of these Euro notes resulted in a cumulative $222 million unrealized pretax loss from hedge inception through the fiscal year ended December 31, 2017, reflected in foreign currency translation adjustment, within the Consolidated Statements of Comprehensive Income.

As of December 31, 2017, the balance of deferred net gains on derivatives included in accumulated other comprehensive income was $70 million after-tax. For additional information, see the Consolidated Statements of Comprehensive Income and Note 13. The Company expects that substantially all of the amounts related to forward foreign exchange contracts will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months, excluding interest rate contracts, net investment hedges and equity collar contracts. The amount ultimately realized in earnings may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity of the derivative.

The following table is a summary of the activity related to derivatives designated as cash flow hedges for the fiscal years ended December 31, 2017 and January 1, 2017:

(Dollars in Millions)	Gain/(Loss) Recognized In Accumulated OCI[1]		Gain/(Loss) Reclassified From Accumulated OCI Into Income[1]		Gain/(Loss) Recognized In Other Income/Expense[2]	
Cash Flow Hedges by Income Statement Caption	**2017**	**2016**	**2017**	**2016**	**2017**	**2016**
Sales to customers [3]	$ 49	(65)	(31)	(47)	(1)	(1)
Cost of products sold [3]	96	(212)	(159)	(3)	(10)	(15)
Research and development expense [3]	(199)	(76)	(165)	(90)	5	—
Interest (income)/Interest expense, net [4]	110	66	83	37	—	—
Other (income) expense, net [3][5]	(60)	(72)	(87)	(7)	—	2
Total	**$ (4)**	**(359)**	**(359)**	**(110)**	**(6)**	**(14)**

All amounts shown in the table above are net of tax.

(1) Effective portion

(2) Ineffective portion

(3) Forward foreign exchange contracts

(4) Cross currency interest rate swaps

(5) Includes equity collar contracts

For the fiscal years ended December 31, 2017 and January 1, 2017, a loss of $5 million and $56 million, respectively, was recognized in Other (income) expense, net, relating to forward foreign exchange contracts not designated as hedging instruments.

Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described below with Level 1 having the highest priority and Level 3 having the lowest.

The fair value of a derivative financial instrument (i.e., forward foreign exchange contracts, interest rate contracts) is the aggregation by currency of all future cash flows discounted to its present value at the prevailing market interest rates and subsequently converted to the U.S. Dollar at the current spot foreign exchange rate. The Company does not believe that fair values of these derivative instruments materially differ from the amounts that could be realized upon settlement or maturity, or that the changes in fair value will have a material effect on the Company's results of operations, cash flows or financial position. The Company also holds equity investments which are classified as Level 1 and debt securities which are classified as Level 2. The Company did not have any other significant financial assets or liabilities which would require revised valuations under this standard that are recognized at fair value.

The following three levels of inputs are used to measure fair value:

Level 1 — Quoted prices in active markets for identical assets and liabilities.

Level 2 — Significant other observable inputs.

Level 3 — Significant unobservable inputs.

The Company's significant financial assets and liabilities measured at fair value as of December 31, 2017 and January 1, 2017 were as follows:

	2017				2016
(Dollars in Millions)	Level 1	Level 2	Level 3	Total	Total [1]
Derivatives designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts [7]	$ —	342	—	342	747
Interest rate contracts [2][4][7]	—	7	—	7	31
Total	—	**349**	—	**349**	**778**
Liabilities:					
Forward foreign exchange contracts [7]	—	314	—	314	723
Interest rate contracts [3][4][7]	—	15	—	15	382
Equity collar contracts	—	—	—	—	57
Total	—	**329**	—	**329**	**1,162**
Derivatives not designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts [7]	—	38	—	38	34
Liabilities:					
Forward foreign exchange contracts [7]	—	38	—	38	57
Available For Sale Other Investments:					
Equity investments[5]	751	—	—	751	1,209
Debt securities[6]	$ —	5,310	—	5,310	12,087

(1) 2016 assets and liabilities are all classified as Level 2 with the exception of equity investments of $1,209 million, which are classified as Level 1.
(2) Includes $7 million and $23 million of non-current assets for the fiscal years ending December 31, 2017 and January 1, 2017, respectively.
(3) Includes $9 million and $382 million of non-current liabilities for the fiscal years ending December 31, 2017 and January 1, 2017, respectively.
(4) Includes cross currency interest rate swaps and interest rate swaps.

(5) Classified as non-current other assets. The carrying amount of the equity investments were $394 million and $520 million as of December 31, 2017 and January 1, 2017, respectively. The unrealized gains were $367 million and $757 million as of December 31, 2017 and January 1, 2017, respectively. The unrealized losses were $10 million and $68 million as of December 31, 2017 and January 1, 2017, respectively.
(6) Classified as cash equivalents and current marketable securities.
(7) Includes collateral exchanged on the credit support agreements on derivatives.

See Notes 2 and 7 for financial assets and liabilities held at carrying amount on the Consolidated Balance Sheet.

7. Borrowings

The components of long-term debt are as follows:

(Dollars in Millions)	2017	Effective Rate %	2016	Effective Rate %
5.55% Debentures due 2017	$ —	—	1,000	5.55
1.125% Notes due 2017	—	—	699	1.15
5.15% Debentures due 2018	900	5.18	899	5.18
1.65% Notes due 2018	597	1.70	600	1.70
4.75% Notes due 2019 (1B Euro 1.1947)[2]/(1B Euro 1.0449)[3]	1,192 [2]	5.83	1,041 [3]	5.83
1.875% Notes due 2019	496	1.93	499	1.93
0.89% Notes due 2019	300	1.75	299	1.20
1.125% Notes due 2019	699	1.13	699	1.13
3% Zero Coupon Convertible Subordinated Debentures due 2020	60	3.00	84	3.00
2.95% Debentures due 2020	547	3.15	546	3.15
1.950% Notes due 2020	499	1.99	—	—
3.55% Notes due 2021	448	3.67	447	3.67
2.45% Notes due 2021	349	2.48	348	2.48
1.65% Notes due 2021	998	1.65	997	1.65
0.250% Notes due 2022 (1B Euro 1.1947)[2]/(1B Euro 1.0449)[3]	1,191 [2]	0.26	1,041 [3]	0.26
2.25% Notes due 2022	995	2.31	—	—
6.73% Debentures due 2023	250	6.73	249	6.73
3.375% Notes due 2023	806	3.17	807	3.17
2.05% Notes due 2023	498	2.09	497	2.09
0.650% Notes due 2024 (750MM Euro 1.1947)[2]/(750MM Euro 1.0449)[3]	891 [2]	0.68	779 [3]	0.68
5.50% Notes due 2024 (500MM GBP 1.3444)[2]/(500MM GBP 1.2237)[3]	666 [2]	6.75	605 [3]	6.75
2.625% Notes due 2025	747	2.63	—	—
2.45% Notes due 2026	1,990	2.47	1,989	2.47
2.95% Notes due 2027	995	2.96	—	—
1.150% Notes due 2028 (750MM Euro 1.1947)[2]/(750MM Euro 1.0449)[3]	887 [2]	1.21	775 [3]	1.21
2.900% Notes due 2028	1,492	2.91	—	—
6.95% Notes due 2029	296	7.14	296	7.14
4.95% Debentures due 2033	498	4.95	497	4.95
4.375% Notes due 2033	856	4.24	857	4.24
1.650% Notes due 2035 (1.5B Euro 1.1947)[2]/(1.5B Euro 1.0449)[3]	1,774 [2]	1.68	1,549 [3]	1.68
3.55% Notes due 2036	987	3.59	987	3.59
5.95% Notes due 2037	991	5.99	990	5.99
3.625% Notes due 2037	1,486	3.64	—	—
5.85% Debentures due 2038	696	5.85	695	5.85
3.400% Notes due 2038	990	3.42	—	—
4.50% Debentures due 2040	538	4.63	537	4.63
4.85% Notes due 2041	296	4.89	296	4.89
4.50% Notes due 2043	495	4.52	495	4.52

3.70% Notes due 2046	1,971	3.74	1,970	3.74
3.75% Notes due 2047	990	3.76	—	—
3.500% Notes due 2048	742	3.52	—	—
Other	75	—	77	—
Subtotal	**32,174** (4)	**3.19%** (1)	**24,146** (4)	**3.33** (1)
Less current portion	1,499		1,704	
Total long-term debt	**$ 30,675**		**22,442**	

(1) Weighted average effective rate.
(2) Translation rate at December 31, 2017.
(3) Translation rate at January 1, 2017.
(4) The excess of the fair value over the carrying value of debt was $2.0 billion in 2017 and $1.6 billion in 2016.

Fair value of the long-term debt was estimated using market prices, which were corroborated by quoted broker prices and significant other observable inputs.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2017, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 13, 2018. Interest charged on borrowings under the credit line agreements is based on either bids provided by banks, the prime rate or London Interbank Offered Rates (LIBOR), plus applicable margins. Commitment fees under the agreements are not material.

Throughout 2017, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $3.9 billion at the end of 2017, of which $2.3 billion was borrowed under the Commercial Paper Program, $1.5 billion is the current portion of the long term debt, and the remainder principally represents local borrowing by international subsidiaries.

Throughout 2016, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $4.7 billion at the end of 2016, of which $2.7 billion was borrowed under the Commercial Paper Program, $1.7 billion is the current portion of the long term debt, and the remainder principally represents local borrowing by international subsidiaries.

Aggregate maturities of long-term obligations commencing in 2018 are:

(Dollars in Millions)

2018	2019	2020	2021	2022	After 2022
$1,499	2,752	1,105	1,797	2,189	22,832

8. Income Taxes

Tax Cuts and Jobs Act (TCJA) and SEC Staff Accounting Bulletin 118 (SAB 118)

On December 22, 2017, the United States enacted into law new U.S. tax legislation, referred to as the TCJA. This law includes provisions for a comprehensive overhaul of the corporate income tax code, including a reduction of the statutory corporate tax rate from 35% to 21%, effective on January 1, 2018. This new legislation also eliminated or reduced certain corporate income tax deductions as well as introduced new provisions that taxed certain foreign income not previously taxed by the United States. The TCJA also includes a provision for a tax on all previously undistributed earnings of U.S. companies located in foreign jurisdictions. Undistributed earnings in the form of cash and cash equivalents is taxed at a rate of 15.5% and all other earnings are taxed at a rate of 8.0%. This tax is payable over 8 years and will not accrue interest.

In December 2017, the SEC provided regulatory guidance for accounting of the impacts of the TCJA, referred to as SAB 118. Under the guidance in SAB 118, the income tax effects, which the accounting under ASC 740 is incomplete, are reported as a provisional amount based on a reasonable estimate. The reasonable estimate is subject to adjustment during a "measurement period", not to exceed one year, until the accounting is complete. The estimate is also subject to the finalization of management's analysis related to certain matters, such as developing interpretations of the provision of the TCJA, changes to certain estimates and amounts related to the earnings and profits of certain subsidiaries and the filing of tax returns.

As a result of the enactment of the TCJA, the Company recorded a provisional tax cost of $13.0 billion in the fourth quarter of 2017. This provisional charge was assessed as of January 18, 2018 and consisted of:

- a $10.1 billion charge on previously undistributed foreign earnings as of December 31, 2017
- a $4.5 billion deferred tax liability for foreign local and withholding taxes, offset by a $1.1 billion deferred tax asset for U.S. foreign tax credits, for repatriation of substantially all those earnings

- a $0.6 billion tax benefit relating to the remeasurement of U.S. deferred tax assets and liabilities and the impact of the TCJA on tax reserves; and
- a $0.1 billion charge for U.S. state and local taxes on the repatriation of these foreign earnings.

In determining this charge, the Company utilized the most recent information and guidance available related to the calculation of the tax liability and the impact to its deferred tax assets and liabilities, including those recorded for foreign local and withholding taxes that the Company assessed as of January 18, 2018. The provisional charge may require further adjustments and changes to the Company's estimates as new guidance is made available. Revisions to the provisional charge may be material to the Company's financial results.

The TCJA also includes provisions for a tax on global intangible low-taxed income (GILTI). GILTI is described as the excess of a U.S. shareholder's total net foreign income over a deemed return on tangible assets, as provided by the TCJA. In January 2018, in response to inquiries by companies, the FASB issued guidance that allows companies to elect as an accounting policy whether to treat the GILTI tax as a period cost or to recognize deferred tax assets and liabilities when basis differences exist that are expected to affect the amount of GILTI inclusion upon reversal. The Company has provisionally elected to treat GILTI as a period expense pending further analysis of this new tax provision.

The provision for taxes on income consists of:

(Dollars in Millions)	2017	2016	2015
Currently payable:			
U.S. taxes	$ 11,969	1,896	2,748
International taxes	1,998	1,708	1,309
Total currently payable	13,967	3,604	4,057
Deferred:			
U.S. taxes	(1,956)	294	37
International taxes	4,362	(635)	(307)
Total deferred	2,406	(341)	(270)
Provision for taxes on income	**$ 16,373**	**3,263**	**3,787**

A comparison of income tax expense at the U.S. statutory rate of 35% in 2017, 2016 and 2015, to the Company's effective tax rate is as follows:

(Dollars in Millions)	2017	2016	2015
U.S.	$ 4,865	7,457	8,179
International	12,808	12,346	11,017
Earnings before taxes on income:	$ 17,673	19,803	19,196
Tax rates:			
U.S. statutory rate	35.0 %	35.0	35.0
International operations [1]	(12.8)	(17.2)	(15.4)
Research and orphan drug tax credits	(0.4)	(0.4)	(0.2)
U.S. state and local	0.6	(0.1)	0.4
U.S. manufacturing deduction	(0.8)	(0.6)	(0.6)
U.S. tax on international income	0.7	1.3	0.2
Tax benefits on share based compensation	(2.1)	(1.8)	—
U.S. tax benefit on asset/business disposals	(0.8)	—	—
All other	(0.1)	0.3	0.3
TCJA impact	73.3 [2]	—	—
Effective Rate	92.6 %	16.5 %	19.7 %

(1) For all periods presented the Company has subsidiaries operating in Puerto Rico under various tax incentives. In 2017, International operations reflects the impacts of operations in jurisdictions with statutory tax rates different than the United States, particularly Ireland, Switzerland and Puerto Rico, which is a

favorable impact on the effective tax rate as compared with the 35.0% U.S. statutory rate. The 2017 amount also includes tax cost related to the revaluation of deferred tax balances related to the change in the Belgian statutory tax rate increasing the tax provision by approximately 3.4%.
(2) Includes U.S. state and local taxes provisionally recorded as part TCJA provisional charge which was approximately 0.6% of the total effective tax rate

The 2017 effective tax rate increased by 76.1% as compared to 2016, primarily driven by the enactment of the TCJA in the United States in December 2017. The enactment of the TCJA resulted in a provisional tax charge in the fourth quarter of 2017, of approximately $13.0 billion or approximately 73.3 percentage point increase to the effective tax rate.

The remainder of the increase in the tax rate for 2017 was related to the remeasurement of the Company's deferred tax assets in Belgium, as a result of changes in the Belgian statutory corporate tax rate enacted in December 2017, offset by a tax benefit for the closure of the Company's Animas insulin pump business.

The decrease in the 2016 effective tax rate, as compared to 2015 was primarily attributable to the Company adopting a new accounting standard for the reporting of additional tax benefits on share-based compensation that vested or were exercised during the fiscal year. The remainder of the change in the effective tax rate was primarily related to the lower earnings before taxes in the United States and the settlement of several uncertain tax positions in 2016 versus 2015.

The decrease in the 2015 effective tax rate, as compared to 2014 was primarily attributable to the increases in taxable income in lower tax jurisdictions relative to higher tax jurisdictions and a tax benefit resulting from a restructuring of international affiliates.

The items noted above reflect the key drivers of the rate reconciliation.

Temporary differences and carryforwards for 2017 and 2016 were as follows:

	2017 Deferred Tax		2016 Deferred Tax	
(Dollars in Millions)	**Asset**	**Liability**	**Asset**	**Liability**
Employee related obligations	$ 2,259		2,958	
Stock based compensation	507		749	
Depreciation		(9)		(219)
Non-deductible intangibles		(6,506)		(6,672)
International R&D capitalized for tax	1,307		1,264	
Reserves & liabilities	1,718		1,857	
Income reported for tax purposes	1,316		1,309	
Net operating loss carryforward international	762		717	
Undistributed foreign earnings	1,101	(4,457)		
Miscellaneous international	755	(194)	1,135	(15)
Miscellaneous U.S.	177		155	
Total deferred income taxes	**$ 9,902**	**(11,166)**	**10,144**	**(6,906)**

The Company has wholly-owned international subsidiaries that have cumulative net losses. The Company believes that it is more likely than not that these subsidiaries will realize future taxable income sufficient to utilize these deferred tax assets.

The following table summarizes the activity related to unrecognized tax benefits:

(Dollars in Millions)	**2017**	**2016**	**2015**
Beginning of year	$ 3,041	3,080	2,465
Increases related to current year tax positions	332	348	570
Increases related to prior period tax positions	232	11	182
Decreases related to prior period tax positions	(416) (1)	(338)	(79)
Settlements	(2)	(37)	(4)
Lapse of statute of limitations	(36)	(23)	(54)
End of year	**$ 3,151**	**3,041**	**3,080**

(1) $347 million of this decrease is related to the TCJA

The unrecognized tax benefits of $3.2 billion at December 31, 2017, if recognized, would affect the Company's annual effective tax rate. The Company conducts business and files tax returns in numerous countries and currently has tax audits in progress with a number of tax authorities. The IRS has completed its audit for the tax years through 2009 and is currently auditing the tax years 2010-2012. In other major jurisdictions where the Company conducts business, the years remain open generally back to the year 2004. The Company believes it is possible that audits may be completed by tax authorities in some

jurisdictions over the next twelve months. However, the Company is not able to provide a reasonably reliable estimate of the timing of any other future tax payments relating to uncertain tax positions.

The Company classifies liabilities for unrecognized tax benefits and related interest and penalties as long-term liabilities. Interest expense and penalties related to unrecognized tax benefits are classified as income tax expense. The Company recognized after tax interest expense of $60 million, $7 million and $44 million in 2017, 2016 and 2015, respectively. The total amount of accrued interest was $436 million and $344 million in 2017 and 2016, respectively.

9. Employee Related Obligations

At the end of 2017 and 2016, employee related obligations recorded on the Consolidated Balance Sheets were:

(Dollars in Millions)	2017	2016
Pension benefits	$ 5,343	4,710
Postretirement benefits	2,331	2,733
Postemployment benefits	2,250	2,050
Deferred compensation	475	534
Total employee obligations	10,399	10,027
Less current benefits payable	325	412
Employee related obligations — non-current	**$ 10,074**	**9,615**

Prepaid employee related obligations of $526 million and $227 million for 2017 and 2016, respectively, are included in Other assets on the Consolidated Balance Sheets.

10. Pensions and Other Benefit Plans

The Company sponsors various retirement and pension plans, including defined benefit, defined contribution and termination indemnity plans, which cover most employees worldwide. The Company also provides post-retirement benefits, primarily health care, to all eligible U.S. retired employees and their dependents.

Many international employees are covered by government-sponsored programs and the cost to the Company is not significant.

Retirement plan benefits for employees are primarily based on the employee's compensation during the last three to five years before retirement and the number of years of service. Due to an amendment of the formula used to calculate benefits of the U.S. Defined Benefit Plan that occurred in 2014, benefits for employees hired on or after January 1, 2015, are primarily calculated using employee compensation over total years of service.

International subsidiaries have plans under which funds are deposited with trustees, annuities are purchased under group contracts, or reserves are provided.

The Company does not typically fund retiree health care benefits in advance, but may do so at its discretion. The Company also has the right to modify these plans in the future.

In 2017 and 2016 the Company used December 31, 2017 and December 31, 2016, respectively, as the measurement date for all U.S. and international retirement and other benefit plans.

Net periodic benefit costs for the Company's defined benefit retirement plans and other benefit plans for 2017, 2016 and 2015 include the following components:

	Retirement Plans			Other Benefit Plans		
(Dollars in Millions)	2017	2016	2015	2017	2016	2015
Service cost	$ 1,080	949	1,037	247	224	257
Interest cost	927	927	988	159	158	186
Expected return on plan assets	(2,041)	(1,962)	(1,809)	(6)	(6)	(7)
Amortization of prior service cost (credit)	2	1	2	(30)	(34)	(33)
Recognized actuarial losses	609	496	745	138	135	201
Curtailments and settlements	17	11	8	—	—	—
Net periodic benefit cost	**$ 594**	**422**	**971**	**508**	**477**	**604**

Amounts expected to be recognized in net periodic benefit cost in the coming year for the Company's defined benefit retirement plans and other postretirement plans:

(Dollars in Millions)	
Amortization of net transition obligation	$ —
Amortization of net actuarial losses	931
Amortization of prior service credit	30

Unrecognized gains and losses for the U.S. pension plans are amortized over the average remaining future service for each plan. For plans with no active employees, they are amortized over the average life expectancy. The amortization of gains and losses for the other U.S. benefit plans is determined by using a 10% corridor of the greater of the market value of assets or the accumulated postretirement benefit obligation. Total unamortized gains and losses in excess of the corridor are amortized over the average remaining future service.

Prior service costs/benefits for the U.S. pension plans are amortized over the average remaining future service of plan participants at the time of the plan amendment. Prior service cost/benefit for the other U.S. benefit plans is amortized over the average remaining service to full eligibility age of plan participants at the time of the plan amendment.

The following table represents the weighted-average actuarial assumptions:

	Retirement Plans			Other Benefit Plans		
Worldwide Benefit Plans	**2017**	**2016**	**2015**	**2017**	**2016**	**2015**
Net Periodic Benefit Cost						
Service cost discount rate	3.59%	3.98	3.78	4.63	4.77	4.31
Interest cost discount rate	3.98%	4.24	3.78	3.94	4.10	4.31
Rate of increase in compensation levels	4.01%	4.02	4.05	4.31	4.32	4.11
Expected long-term rate of return on plan assets	8.43%	8.55	8.53			
Benefit Obligation						
Discount rate	3.30%	3.78	4.11	3.78	4.42	4.63
Rate of increase in compensation levels	3.99%	4.02	4.01	4.30	4.29	4.28

The Company's discount rates are determined by considering current yield curves representing high quality, long-term fixed income instruments. The resulting discount rates are consistent with the duration of plan liabilities. For the fiscal year 2016, the Company changed its methodology in determining service and interest cost from the single weighted average discount rate approach to duration specific spot rates along that yield curve to the plans' liability cash flows, which management has concluded is a more precise estimate. Prior to this change in methodology, the Company measured service and interest costs utilizing a single weighted-average discount rate derived from the yield curve used to measure the plan obligations. The Company has accounted for this change as a change in accounting estimate and, accordingly, has accounted for it on a prospective basis. This change does not impact the benefit obligation and did not have a material impact to the 2016 full year results.

The expected rates of return on plan asset assumptions represent the Company's assessment of long-term returns on diversified investment portfolios globally. The assessment is determined using projections from external financial sources, long-term historical averages, actual returns by asset class and the various asset class allocations by market.

The following table displays the assumed health care cost trend rates, for all individuals:

Health Care Plans	2017	2016
Health care cost trend rate assumed for next year	6.33%	6.32%
Rate to which the cost trend rate is assumed to decline (ultimate trend)	4.55%	4.50%
Year the rate reaches the ultimate trend rate	2038	2038

A one-percentage-point change in assumed health care cost trend rates would have the following effect:

(Dollars in Millions)	One-Percentage-Point Increase	One-Percentage-Point Decrease
Health Care Plans		
Total interest and service cost	$ 29	(23)
Post-retirement benefit obligation	$ 355	(291)

The following table sets forth information related to the benefit obligation and the fair value of plan assets at year-end 2017 and 2016 for the Company's defined benefit retirement plans and other post-retirement plans:

	Retirement Plans		Other Benefit Plans	
(Dollars in Millions)	**2017**	**2016**	**2017**	**2016**
Change in Benefit Obligation				
Projected benefit obligation — beginning of year	$ 28,116	25,855	4,605	4,669
Service cost	1,080	949	247	224
Interest cost	927	927	159	158
Plan participant contributions	60	54	—	—
Amendments	(7)	(48)	(17)	—
Actuarial (gains) losses	2,996	2,302	(166)	(73)
Divestitures & acquisitions	201	(24)	88	—
Curtailments, settlements & restructuring	(35)	(25)	2	—
Benefits paid from plan*	(1,050)	(1,210)	(351)	(378)
Effect of exchange rates	933	(664)	15	5
Projected benefit obligation — end of year	**$ 33,221**	**28,116**	**4,582**	**4,605**
Change in Plan Assets				
Plan assets at fair value — beginning of year	$ 23,633	22,254	75	74
Actual return on plan assets	4,274	2,286	12	7
Company contributions	664	838	545	372
Plan participant contributions	60	54	—	—
Settlements	(32)	(25)	—	—
Divestitures & acquisitions	173	(24)	—	—
Benefits paid from plan assets*	(1,050)	(1,210)	(351)	(378)
Effect of exchange rates	682	(540)	—	—
Plan assets at fair value — end of year	**$ 28,404**	**23,633**	**281**	**75**
Funded status — end of year	**$ (4,817)**	**(4,483)**	**(4,301)**	**(4,530)**
Amounts Recognized in the Company's Balance Sheet consist of the following:				
Non-current assets	$ 526	227	—	—
Current liabilities	(92)	(86)	(228)	(315)
Non-current liabilities	(5,251)	(4,624)	(4,073)	(4,215)
Total recognized in the consolidated balance sheet — end of year	**$ (4,817)**	**(4,483)**	**(4,301)**	**(4,530)**
Amounts Recognized in Accumulated Other Comprehensive Income consist of the following:				
Net actuarial loss	$ 8,140	7,749	1,500	1,804
Prior service cost (credit)	(25)	(12)	(137)	(150)
Unrecognized net transition obligation	—	—	—	—
Total before tax effects	**$ 8,115**	**7,737**	**1,363**	**1,654**
Accumulated Benefit Obligations — end of year	**$ 29,793**	**25,319**		

*In 2016, the Company offered a voluntary lump-sum payment option below a pre-determined threshold for certain eligible former employees who are vested participants of the U.S. Qualified Defined Benefit Pension Plan. The distribution of the lump-sums was completed by the end of fiscal 2017. The amounts distributed in 2017 and 2016 were approximately $127 million and $420 million, respectively. These distributions from the plan did not have a material impact on the Company's financial position.

(Dollars in Millions)	Retirement Plans 2017	Retirement Plans 2016	Other Benefit Plans 2017	Other Benefit Plans 2016
Amounts Recognized in Net Periodic Benefit Cost and Other Comprehensive Income				
Net periodic benefit cost	**$ 594**	**422**	**508**	**477**
Net actuarial (gain) loss	740	1,965	(169)	(72)
Amortization of net actuarial loss	(609)	(496)	(138)	(135)
Prior service cost (credit)	(7)	(48)	(17)	—
Amortization of prior service (cost) credit	(2)	(1)	30	34
Effect of exchange rates	256	(218)	3	(1)
Total loss/(income) recognized in other comprehensive income, before tax	**$ 378**	**1,202**	**(291)**	**(174)**
Total recognized in net periodic benefit cost and other comprehensive income	**$ 972**	**1,624**	**217**	**303**

The Company plans to continue to fund its U.S. Qualified Plans to comply with the Pension Protection Act of 2006. International Plans are funded in accordance with local regulations. Additional discretionary contributions are made when deemed appropriate to meet the long-term obligations of the plans. For certain plans, funding is not a common practice, as funding provides no economic benefit. Consequently, the Company has several pension plans that are not funded.

In 2017, the Company contributed $72 million and $592 million to its U.S. and international pension plans, respectively.

The following table displays the funded status of the Company's U.S. Qualified & Non-Qualified pension plans and international funded and unfunded pension plans at December 31, 2017 and December 31, 2016, respectively:

	U.S. Plans				International Plans			
	Qualified Plans		Non-Qualified Plans		Funded Plans		Unfunded Plans	
(Dollars in Millions)	2017	2016	2017	2016	2017	2016	2017	2016
Plan Assets	$ 18,681	16,057	—	—	9,723	7,576	—	—
Projected Benefit Obligation	19,652	16,336	2,257	1,905	10,863	9,502	449	373
Accumulated Benefit Obligation	17,654	14,759	1,849	1,568	9,893	8,663	397	329
Over (Under) Funded Status								
Projected Benefit Obligation	$ (971)	(279)	(2,257)	(1,905)	(1,140)	(1,926)	(449)	(373)
Accumulated Benefit Obligation	1,027	1,298	(1,849)	(1,568)	(170)	(1,087)	(397)	(329)

Plans with accumulated benefit obligations in excess of plan assets have an accumulated benefit obligation, projected benefit obligation and plan assets of $3.8 billion, $4.6 billion and $0.7 billion, respectively, at the end of 2017, and $8.8 billion, $9.9 billion and $5.6 billion, respectively, at the end of 2016.

The following table displays the projected future benefit payments from the Company's retirement and other benefit plans:

(Dollars in Millions)	2018	2019	2020	2021	2022	2023-2027
Projected future benefit payments						
Retirement plans	$ 970	1,007	1,057	1,131	1,190	7,062
Other benefit plans	$ 322	312	306	301	297	1,395

The following table displays the projected future minimum contributions to the unfunded retirement plans. These amounts do not include any discretionary contributions that the Company may elect to make in the future.

(Dollars in Millions)	2018	2019	2020	2021	2022	2023-2027
Projected future contributions	$ 88	89	94	100	108	651

Each pension plan is overseen by a local committee or board that is responsible for the overall administration and investment of the pension plans. In determining investment policies, strategies and goals, each committee or board considers factors including, local pension rules and regulations; local tax regulations; availability of investment vehicles (separate accounts, commingled accounts, insurance funds, etc.); funded status of the plans; ratio of actives to retirees; duration of liabilities; and other relevant factors including: diversification, liquidity of local markets and liquidity of base currency. A majority of the Company's pension funds are open to new entrants and are expected to be on-going plans. Permitted investments are primarily liquid and/or listed, with little reliance on illiquid and non-traditional investments such as hedge funds.

The Company's retirement plan asset allocation at the end of 2017 and 2016 and target allocations for 2018 are as follows:

	Percent of Plan Assets		Target Allocation
	2017	2016	2018
Worldwide Retirement Plans			
Equity securities	76%	75%	73%
Debt securities	24	25	27
Total plan assets	**100%**	**100%**	**100%**

Determination of Fair Value of Plan Assets

The Plan has an established and well-documented process for determining fair values. Fair value is based upon quoted market prices, where available. If listed prices or quotes are not available, fair value is based upon models that primarily use, as inputs, market-based or independently sourced market parameters, including yield curves, interest rates, volatilities, equity or debt prices, foreign exchange rates and credit curves.

While the Plan believes its valuation methods are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

Valuation Hierarchy

The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described in the table below with Level 1 having the highest priority and Level 3 having the lowest.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Following is a description of the valuation methodologies used for the investments measured at fair value.

- *Short-term investment funds* — Cash and quoted short-term instruments are valued at the closing price or the amount held on deposit by the custodian bank. Other investments are through investment vehicles valued using the Net Asset Value (NAV) provided by the administrator of the fund. The NAV is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding. The NAV is a quoted price in a market that is not active and classified as Level 2.
- *Government and agency securities* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified within Level 1 of the valuation hierarchy. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows. When quoted market prices for a security are not available in an active market, they are classified as Level 2.
- *Debt instruments* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified as Level 1. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows and are classified as Level 2. Level 3 debt instruments are priced based on unobservable inputs.
- *Equity securities* — Equity securities are valued at the closing price reported on the major market on which the individual securities are traded. Substantially all common stock is classified within Level 1 of the valuation hierarchy.
- *Commingled funds* — These investment vehicles are valued using the NAV provided by the fund administrator. The NAV is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding. Assets in the Level 2 category have a quoted market price.

- *Insurance contracts* — The instruments are issued by insurance companies. The fair value is based on negotiated value and the underlying investments held in separate account portfolios as well as considering the credit worthiness of the issuer. The underlying investments are government, asset-backed and fixed income securities. In general, insurance contracts are classified as Level 3 as there are no quoted prices nor other observable inputs for pricing.
- *Other assets* — Other assets are represented primarily by limited partnerships and real estate investments, as well as commercial loans and commercial mortgages that are not classified as corporate debt. Other assets that are exchange listed and actively traded are classified as Level 1, while inactively traded assets are classified as Level 2.

The following table sets forth the Retirement Plans' investments measured at fair value as of December 31, 2017 and December 31, 2016:

	Quoted Prices in Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs[a] (Level 3)		Investments Measured at Net Asset Value		Total Assets	
(Dollars in Millions)	**2017**	**2016**	**2017**	**2016**	**2017**	**2016**	**2017**	**2016**	**2017**	**2016**
Short-term investment funds	$ 429	145	427	652	—	—	—	—	856	797
Government and agency securities	—	—	3,094	2,655	—	—	—	—	3,094	2,655
Debt instruments	—	—	2,013	1,237	—	—	—	—	2,013	1,237
Equity securities	13,848	11,433	—	12	—	—	—	—	13,848	11,445
Commingled funds	—	—	1,780	1,316	57	—	6,158	5,767	7,995	7,083
Insurance contracts	—	—	—	—	199	24	—	—	199	24
Other assets	—	—	121	—	—	—	278	392	399	392
Investments at fair value	**$ 14,277**	**11,578**	**7,435**	**5,872**	**256**	**24**	**6,436**	**6,159**	**28,404**	**23,633**

[a] The activity for the Level 3 assets is not significant for all years presented.

The Company's Other Benefit Plans are unfunded except for U.S. commingled funds (Level 2) of $81 million and $75 million and U.S. short-term investment funds (Level 2) of $200 million and $0 at December 31, 2017 and December 31, 2016, respectively.

The fair value of Johnson & Johnson Common Stock directly held in plan assets was $938 million (3.3% of total plan assets) at December 31, 2017 and $847 million (3.6% of total plan assets) at December 31, 2016.

11. Savings Plan

The Company has voluntary 401(k) savings plans designed to enhance the existing retirement programs covering eligible employees. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which he/she is eligible. Total Company matching contributions to the plans were $214 million, $191 million and $187 million in 2017, 2016 and 2015, respectively.

12. Capital and Treasury Stock
Changes in treasury stock were:

(Amounts in Millions Except Treasury Stock Shares in Thousands)	Treasury Stock Shares	Treasury Stock Amount
Balance at December 28, 2014	336,620	$ 19,891
Employee compensation and stock option plans	(24,413)	(2,497)
Repurchase of common stock	52,474	5,290
Balance at January 3, 2016	364,681	22,684
Employee compensation and stock option plans	(30,839)	(3,311)
Repurchase of common stock	79,490	8,979
Balance at January 1, 2017	413,332	28,352
Employee compensation and stock option plans	(25,508)	(3,156)
Repurchase of common stock	49,494	6,358
Balance at December 31, 2017	437,318	$ 31,554

Aggregate shares of common stock issued were approximately 3,119,843,000 shares at the end of 2017, 2016 and 2015.

Cash dividends paid were $3.32 per share in 2017, compared with dividends of $3.15 per share in 2016, and $2.95 per share in 2015.

On October 13, 2015, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $10.0 billion of the Company's shares of common stock. This share repurchase program was completed as of July 2, 2017.

On July 21, 2014, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's shares of common stock. This share repurchase program was completed on April 28, 2015.

13. Accumulated Other Comprehensive Income (Loss)
Components of other comprehensive income (loss) consist of the following:

(Dollars in Millions)	Foreign Currency Translation	Gain/(Loss) On Securities	Employee Benefit Plans	Gain/ (Loss) On Derivatives & Hedges	Total Accumulated Other Comprehensive Income (Loss)
December 28, 2014	$ (4,803)	257	(6,317)	141	(10,722)
Net 2015 changes	(3,632)	347	1,019	(177)	(2,443)
January 3, 2016	(8,435)	604	(5,298)	(36)	(13,165)
Net 2016 changes	(612)	(193)	(682)	(249)	(1,736)
January 1, 2017	(9,047)	411	(5,980)	(285)	(14,901)
Net 2017 changes	1,696	(179)	(170)	355	1,702
December 31, 2017	$ (7,351)	232	(6,150)	70	(13,199)

Amounts in accumulated other comprehensive income are presented net of the related tax impact. Foreign currency translation is not adjusted for income taxes where it relates to permanent investments in international subsidiaries. For additional details on comprehensive income see the Consolidated Statements of Comprehensive Income.

Details on reclassifications out of Accumulated Other Comprehensive Income:
Gain/(Loss) On Securities - reclassifications released to Other (income) expense, net.
Employee Benefit Plans - reclassifications are included in net periodic benefit cost. See Note 10 for additional details.
Gain/(Loss) On Derivatives & Hedges - reclassifications to earnings are recorded in the same account as the hedged transaction. See Note 6 for additional details.

14. International Currency Translation

For translation of its subsidiaries operating in non-U.S. Dollar currencies, the Company has determined that the local currencies of its international subsidiaries are the functional currencies except those in highly inflationary economies, which are defined as those which have had compound cumulative rates of inflation of 100% or more during the past three years, or where a substantial portion of its cash flows are not in the local currency. For the majority of the Company's subsidiaries the local currency is the functional currency.

In consolidating international subsidiaries, balance sheet currency effects are recorded as a component of accumulated other comprehensive income. This equity account includes the results of translating certain balance sheet assets and liabilities at current exchange rates and some accounts at historical rates, except for those located in highly inflationary economies. The translation of balance sheet accounts for highly inflationary economies are reflected in the operating results.

A rollforward of the changes during 2017, 2016 and 2015 for foreign currency translation adjustments is included in Note 13.

Net currency transaction gains and losses included in Other (income) expense were losses of $216 million, $289 million and $104 million in 2017, 2016 and 2015, respectively.

15. Earnings Per Share

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal years ended December 31, 2017, January 1, 2017 and January 3, 2016:

(In Millions Except Per Share Amounts)	2017	2016	2015
Basic net earnings per share	$ 0.48	6.04	5.56
Average shares outstanding — basic	2,692.0	2,737.3	2,771.8
Potential shares exercisable under stock option plans	139.7	142.4	141.5
Less: shares repurchased under treasury stock method	(87.3)	(92.1)	(102.6)
Convertible debt shares	0.9	1.3	2.2
Adjusted average shares outstanding — diluted	2,745.3	2,788.9	2,812.9
Diluted net earnings per share	$ 0.47	5.93	5.48

The diluted net earnings per share calculation included the dilutive effect of convertible debt that is offset by the related reduction in interest expense of $1 million after-tax for year 2017, $2 million for year 2016 and $3 million for year 2015.

The diluted net earnings per share calculation for 2017, 2016 and 2015 included all shares related to stock options, as the exercise price of all options was less than the average market value of the Company's stock.

16. Rental Expense and Lease Commitments

Rentals of space, vehicles, manufacturing equipment and office and data processing equipment under operating leases were approximately $372 million, $330 million and $316 million in 2017, 2016 and 2015, respectively.

The approximate minimum rental payments required under operating leases that have initial or remaining non-cancelable lease terms in excess of one year at December 31, 2017 are:

(Dollars in Millions)

2018	2019	2020	2021	2022	After 2022	Total
$227	184	143	106	76	103	839

Commitments under capital leases are not significant.

17. Common Stock, Stock Option Plans and Stock Compensation Agreements

At December 31, 2017, the Company had 2 stock-based compensation plans. The shares outstanding are for contracts under the Company's 2005 Long-Term Incentive Plan and the 2012 Long-Term Incentive Plan. The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan. Under the 2012 Long-Term Incentive Plan, the Company may issue up to 650 million shares of common stock, plus any shares canceled, expired, forfeited, or not issued from the 2005 Long-Term Incentive Plan subsequent to April 26, 2012. Shares available for future grants under the 2012 Long-Term Incentive Plan were 389 million at the end of 2017.

The compensation cost that has been charged against income for these plans was $962 million, $878 million and $874 million for 2017, 2016 and 2015, respectively. The total income tax benefit recognized in the income statement for share-based compensation costs was $275 million, $256 million and $253 million for 2017, 2016 and 2015, respectively. An additional tax

benefit of $353 million was recognized in 2016 due to the adoption of a new accounting standard for the reporting of additional tax benefits on share-based compensation. The total unrecognized compensation cost was $798 million, $749 million and $744 million for 2017, 2016 and 2015, respectively. The weighted average period for this cost to be recognized was 1.76 years, 1.09 years and 0.98 years for 2017, 2016, and 2015, respectively. Share-based compensation costs capitalized as part of inventory were insignificant in all periods.

The Company settles employee benefit equity issuances with treasury shares. Treasury shares are replenished throughout the year for the number of shares used to settle employee benefit equity issuances.

Stock Options

Stock options expire 10 years from the date of grant and vest over service periods that range from 6 months to 4 years. All options are granted at the average of the high and low prices of the Company's Common Stock on the New York Stock Exchange on the date of grant.

The fair value of each option award was estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the following table. For 2017, 2016 and 2015 grants, expected volatility represents a blended rate of 10-year weekly historical overall volatility rate, and a 5-week average implied volatility rate based on at-the-money traded Johnson & Johnson options with a life of 2 years. For all grants, historical data is used to determine the expected life of the option. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant.

The average fair value of options granted was $13.38, $10.01 and $10.68, in 2017, 2016 and 2015, respectively. The fair value was estimated based on the weighted average assumptions of:

	2017	2016	2015
Risk-free rate	2.25%	1.51%	1.77%
Expected volatility	15.30%	15.76%	15.48%
Expected life (in years)	7.0	7.0	7.0
Expected dividend yield	2.90%	3.10%	2.90%

A summary of option activity under the Plan as of December 31, 2017, January 1, 2017 and January 3, 2016, and changes during the years ending on those dates is presented below:

(Shares in Thousands)	Outstanding Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (Dollars in Millions)
Shares at December 28, 2014	115,712	$ 70.37	$ 4,014
Options granted	20,484	100.06	
Options exercised	(16,683)	62.53	
Options canceled/forfeited	(2,996)	82.22	
Shares at January 3, 2016	116,517	76.41	3,065
Options granted	22,491	101.87	
Options exercised	(22,547)	65.66	
Options canceled/forfeited	(3,006)	92.83	
Shares at January 1, 2017	113,455	83.16	3,636
Options granted	19,287	115.67	
Options exercised	(18,975)	70.87	
Options canceled/forfeited	(2,461)	101.40	
Shares at December 31, 2017	**111,306**	**$ 90.48**	**$ 5,480**

The total intrinsic value of options exercised was $1,060 million, $980 million and $644 million in 2017, 2016 and 2015, respectively.

The following table summarizes stock options outstanding and exercisable at December 31, 2017:

(Shares in Thousands)	Outstanding			Exercisable	
Exercise Price Range	Options	Average Life[1]	Average Exercise Price	Options	Average Exercise Price
$52.13-$62.20	12,148	1.7	$60.37	12,148	$60.37
$62.62-$65.62	9,548	3.0	$63.91	9,547	$63.91
$66.07-$72.54	14,816	5.0	$72.53	14,816	$72.53
$90.44-$100.48	35,035	6.6	$95.48	15,843	$90.49
$101.87-$115.67	39,759	8.6	$108.35	67	$105.91
	111,306	**6.3**	**$90.48**	**52,421**	**$73.61**

[1] Average contractual life remaining in years.

Stock options outstanding at January 1, 2017 and January 3, 2016 were 113,455 and an average life of 6.2 years and 116,517 and an average life of 5.9 years, respectively. Stock options exercisable at January 1, 2017 and January 3, 2016 were 50,414 at an average price of $65.77 and 48,345 at an average price of $62.26, respectively.

Restricted Share Units and Performance Share Units

The Company grants restricted share units which vest over service periods that range from 6 months to 3 years. The Company also grants performance share units, which are paid in shares of Johnson & Johnson Common Stock after the end of a three-year performance period. Whether any performance share units vest, and the amount that does vest, is tied to the completion of service periods that range from 6 months to 3 years and the achievement, over a three-year period, of three equally-weighted goals that directly align with or help drive long-term total shareholder return: operational sales, adjusted operational earnings per share, and relative total shareholder return. The number of shares actually earned at the end of the three-year period will vary, based only on actual performance, from 0% to 200% of the target number of performance share units granted. In the fourth quarter of 2017, the Company modified the restricted share units that are scheduled to vest between January 1, 2018 and March 15, 2018. This modification guaranteed a minimum aggregate value, below the market value of the total expected payout amount, for all awards expected to vest during this period. The amount that was committed was not material to the Company's overall financial position.

A summary of the restricted share units and performance share units activity under the Plans as of December 31, 2017 is presented below:

(Shares in Thousands)	Outstanding Restricted Share Units	Outstanding Performance Share Units
Shares at January 1, 2017	21,061	2,415
Granted	7,248	1,276
Issued	(7,205)	(1,361)
Canceled/forfeited/adjusted	(943)	295
Shares at December 31, 2017	20,161	2,625

The average fair value of the restricted share units granted was $107.69, $92.45 and $91.65 in 2017, 2016 and 2015, respectively, using the fair market value at the date of grant. The fair value of restricted share units was discounted for dividends, which are not paid on the restricted share units during the vesting period. The fair value of restricted share units issued was $596.5 million, $587.7 million and $597.6 million in 2017, 2016 and 2015, respectively.

The weighted average fair value of the performance share units granted was $114.13, $105.30 and $93.54 in 2017, 2016 and 2015, calculated using the weighted average fair market value for each of the three component goals at the date of grant.

The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. The fair value of performance share units issued was $132.5 million, $127.7 million and $16.7 million in 2017, 2016 and 2015, respectively.

18. **Segments of Business and Geographic Areas**

(Dollars in Millions)	Sales to Customers 2017	2016	2015
Consumer —			
United States	$ 5,565	5,420	5,222
International	8,037	7,887	8,285
Total	**13,602**	**13,307**	**13,507**
Pharmaceutical —			
United States	21,474	20,125	18,333
International	14,782	13,339	13,097
Total	**36,256**	**33,464**	**31,430**
Medical Devices —			
United States	12,824	12,266	12,132
International	13,768	12,853	13,005
Total	**26,592**	**25,119**	**25,137**
Worldwide total	**$ 76,450**	**71,890**	**70,074**

(Dollars in Millions)	Income Before Tax 2017 [3]	2016 [4]	2015 [5]	Identifiable Assets 2017	2016
Consumer	$ 2,524	2,441	1,787	$ 25,030	23,971
Pharmaceutical	11,083	12,827	11,734	59,450	27,477
Medical Devices	5,392	5,578	6,826	45,413	39,773
Total	18,999	20,846	20,347	129,893	91,221
Less: Expense not allocated to segments [1]	1,326	1,043	1,151		
General corporate [2]				27,410	49,987
Worldwide total	**$ 17,673**	**19,803**	**19,196**	**$ 157,303**	**141,208**

(Dollars in Millions)	Additions to Property, Plant & Equipment 2017	2016	2015	Depreciation and Amortization 2017	2016	2015
Consumer	$ 485	486	544	$ 674	608	559
Pharmaceutical	936	927	1,063	2,416	886	929
Medical Devices	1,566	1,472	1,631	2,216	1,928	1,945
Segments total	2,987	2,885	3,238	5,306	3,422	3,433
General corporate	292	341	225	336	332	313
Worldwide total	**$ 3,279**	**3,226**	**3,463**	**$ 5,642**	**3,754**	**3,746**

(Dollars in Millions)	Sales to Customers 2017	2016	2015	Long-Lived Assets [6] 2017	2016
United States	$ 39,863	37,811	35,687	$ 38,556	36,934
Europe	17,126	15,770	15,995	56,677	21,996
Western Hemisphere excluding U.S.	6,041	5,734	6,045	2,990	2,961
Asia-Pacific, Africa	13,420	12,575	12,347	2,773	2,512
Segments total	76,450	71,890	70,074	100,996	64,403
General corporate				1,143	1,190
Other non long-lived assets				55,164	75,615
Worldwide total	**$ 76,450**	**71,890**	**70,074**	**$ 157,303**	**141,208**

See Note 1 for a description of the segments in which the Company operates.

Export sales are not significant. In 2017, the Company had two wholesalers distributing products for all three segments that represented approximately 14.0% and 10.0% of the total consolidated revenues. In 2016, the Company had two wholesalers distributing products for all three segments that represented approximately 13.5% and 10.7% of the total consolidated revenues. In 2015, the Company had one wholesaler distributing products for all three segments that represented approximately 12.5% of the total consolidated revenues.

(1) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.

(2) General corporate includes cash, cash equivalents and marketable securities.

(3) The Pharmaceutical segment includes $797 million for Actelion acquisition related costs, an in-process research and development expense of $396 million and net litigation expense of $117 million. The Medical Devices segment includes net litigation expense of $1,139 million, a restructuring related charge of $760 million, an asset impairment of $215 million primarily related to the insulin pump business and $140 million for AMO acquisition related costs. The Medical Devices segment includes a gain of $0.7 billion from the divestiture of Codman Neurosurgery. The Consumer segment includes a gain of $0.5 billion from the divestiture of COMPEED®.

(4) Includes net litigation expense of $806 million and a restructuring related charge of $685 million in the Medical Devices segment. The Pharmaceutical segment includes a positive adjustment of $0.5 billion to previous reserve estimates, an in-process research and development expense of $29 million, and gains from the divestitures of the controlled substance raw material and active pharmaceutical ingredient (API) business and certain anesthetic products in Europe.

(5) The Medical Devices segment includes a restructuring related charge of $590 million, an intangible asset write-down of $346 million related to Acclarent, Synthes integration costs of $196 million and $148 million expense for the cost associated with the DePuy ASR™ Hip program. Includes $224 million of in-process research and development expense, comprised of $214 million and $10 million in the Pharmaceutical and Medical Devices segments, respectively. Includes net litigation expense of $141 million comprised of $136 million in the Pharmaceutical segment and $5 million in the Medical Devices segment, which included the gain from the litigation settlement agreement with Guidant for $600 million. The Medical Devices Segment includes a gain of $1.3 billion from the divestiture of the Cordis business. The Pharmaceutical segment includes a gain of $981 million from the U.S. divestiture of NUCYNTA® and a positive adjustment of $0.5 billion to previous reserve estimates, including Managed Medicaid rebates. The Consumer segment includes a gain of $229 million from the divestiture of SPLENDA® brand.

(6) Long-lived assets include property, plant and equipment, net for 2017, and 2016 of $17,005 and $15,912, respectively, and intangible assets and goodwill, net for 2017 and 2016 of $85,134 and $49,681, respectively.

19. Selected Quarterly Financial Data (unaudited)

Selected unaudited quarterly financial data for the years 2017 and 2016 are summarized below:

	2017				2016			
(Dollars in Millions Except Per Share Data)	First Quarter [1]	Second Quarter [2]	Third Quarter [3]	Fourth Quarter [4]	First Quarter [5]	Second Quarter [6]	Third Quarter [7]	Fourth Quarter [8]
Segment sales to customers								
Consumer	$ 3,228	3,478	3,356	3,540	3,195	3,419	3,261	3,432
Pharmaceutical	8,245	8,635	9,695	9,681	8,178	8,654	8,400	8,232
Medical Devices	6,293	6,726	6,599	6,974	6,109	6,409	6,159	6,442
Total sales	17,766	18,839	19,650	20,195	17,482	18,482	17,820	18,106
Gross profit	12,380	13,016	12,748	12,952	12,153	13,146	12,334	12,572
Earnings before provision for taxes on income	5,575	4,748	4,790	2,560	5,294	4,904	5,281	4,324
Net earnings (loss)	4,422	3,827	3,764	(10,713)	4,457	3,997	4,272	3,814
Basic net earnings (loss) per share	$ 1.63	1.42	1.40	(3.99)	1.62	1.46	1.56	1.41
Diluted net earnings (loss) per share	$ 1.61	1.40	1.37	(3.99)	1.59	1.43	1.53	1.38

(1) The first quarter of 2017 includes a restructuring charge of $121 million after-tax ($161 million before-tax) and an AMO acquisition related cost of $251 million after-tax ($38 million before-tax).

(2) The second quarter of 2017 includes a net litigation expense of $352 million after-tax ($493 million before-tax), Actelion acquisition related costs of $199 million after-tax ($213 million before-tax) a restructuring charge of $101 million after-tax ($128 million before-tax) and an asset impairment charge of $125 million after-tax ($182 million before-tax).

(3) The third quarter of 2017 includes a net litigation expense of $97 million after-tax ($118 million before-tax), Actelion acquisition related costs of $255 million after-tax ($367 million before-tax) and a restructuring charge of $136 million after-tax ($187 million before-tax).

(4) The fourth quarter of 2017 includes a net litigation expense of $506 million after-tax ($645 million before-tax), Actelion acquisition related costs of $313 million after-tax ($217 million before-tax), a restructuring charge of $237 million after-tax ($284 million before-tax), an in-process research and development expense of $266 million after-tax ($408 million before-tax) and an after-tax benefit of $116 million related to the insulin pump business. Additionally, the fourth quarter of 2017 includes a provisional charge of $13.6 billion for recently enacted tax legislation.

(5) The first quarter of 2016 includes a restructuring charge of $120 million after-tax ($137 million before-tax) and net litigation expense of $56 million after-tax ($66 million before-tax).

(6) The second quarter of 2016 includes a restructuring charge of $97 million after-tax ($141 million before-tax) and net litigation expense of $493 million after-tax ($600 million before-tax).

(7) The third quarter of 2016 includes a restructuring charge of $76 million after-tax ($109 million before-tax) and net litigation expense of $46 million after-tax ($55 million before-tax).

(8) The fourth quarter of 2016 includes a restructuring charge of $251 million after-tax ($298 million before-tax) and net litigation expense of $80 million after-tax ($96 million before-tax).

20. Business Combinations and Divestitures

Certain businesses were acquired for $35,151 million in cash and $1,786 million of liabilities assumed during 2017. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2017 acquisitions primarily included: Actelion Ltd an established leading franchise of differentiated, innovative products for pulmonary arterial hypertension (PAH); Abbott Medical Optics (AMO), a wholly-owned subsidiary of Abbott Laboratories, which included ophthalmic products related to: cataract surgery, laser refractive surgery and consumer eye health; Neuravi Limited, a privately-held medical device company that develops and markets medical devices for neurointerventional therapy; TearScience Inc., a manufacturer of products dedicated to treating meibomian gland dysfunction; Sightbox, Inc., a privately-held company that developed a subscription vision care service that connects consumers with eye care professionals and a supply of contact lenses; Torax Medical, Inc., a privately-held medical device company that manufactures and markets the LINX™ Reflux Management System for the surgical treatment of gastroesophageal reflux disease and Megadyne Medical Products, Inc., a privately-held medical device company that develops, manufactures and markets electrosurgical tools.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $34,379 million and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately $1,139 million has been identified as the value of IPR&D primarily associated with the acquisition of Actelion Ltd. The value of the IPR&D was calculated using cash flow projections discounted for the inherent risk in the projects.

During 2017, the Company completed the acquisition of Actelion Ltd through an all cash tender offer in Switzerland for $280 per share, amounting to $29.6 billion, net of cash acquired. As part of the transaction, immediately prior to the completion of the acquisition, Actelion spun out its drug discovery operations and early-stage clinical development assets into a newly created Swiss biopharmaceutical company, Idorsia Ltd. The shares of Idorsia are listed on the SIX Swiss Exchange (SIX). The Company currently holds 9.9% of the shares of Idorsia and has rights to an additional 22.1% of Idorsia equity through a convertible loan with a principal amount of approximately $0.5 billion. The convertible loan may be converted into Idorsia shares as follows: (i) up to an aggregate shareholding of 16% of Idorsia shares as a result of certain shareholders holding more than 20% of the issued Idorsia shares, and (ii) up to the balance of the remaining amount within 20 business days of the maturity date of the convertible loan, which has a 10 year term, or if Idorsia undergoes a change of control transaction. The investment in Idorsia was recorded as a cost method investment in Other assets in the Company's consolidated Balance Sheet. The Company also exercised the option acquired on ACT-132577, a product within Idorsia being developed for resistant hypertension currently in phase 2 of clinical development. The Company has also entered into an agreement to provide Idorsia with a Swiss franc denominated credit facility of approximately $250 million. As of December 31, 2017, Idorsia has not made any draw-downs under the credit facility. Actelion has entered into a transitional services agreement with Idorsia. Actelion has established a leading franchise of differentiated, innovative products for pulmonary arterial hypertension (PAH) that are highly complementary to the existing portfolio of the Company. The addition of Actelion’s specialty in-market medicines and late-stage products is consistent with the Company's efforts to grow in attractive and complementary therapeutic areas and serve patients with serious illnesses and significant unmet medical need.

The Company is still finalizing the allocation of the purchase price to the individual assets acquired and liabilities assumed. The allocation of the purchase price included in the current period balance sheet is based on the best estimate of management and is preliminary and subject to change. To assist management in the allocation, the Company engaged valuation specialists to prepare appraisals. The Company will finalize the amounts recognized as the information necessary to complete the analysis is obtained. The Company expects to finalize these amounts as soon as possible but no later than one year from the acquisition date.

The following table presents the preliminary amounts recognized for assets acquired and liabilities assumed for Actelion as of the acquisition date as well as the adjustments made up to December 31, 2017:

(Dollars in Millions)		June 16, 2017	December 31, 2017
Cash & Cash equivalents	$	469	469
Inventory[1]		759	759
Accounts Receivable		485	485
Other current assets		93	93
Property, plant and equipment		104	104
Goodwill		5,986	6,161
Intangible assets		25,010	25,010
Deferred Taxes		3	99
Other non-current assets		19	19
Total Assets Acquired		32,928	33,199
Current liabilities		531	956
Deferred Taxes		1,960	1,776
Other non-current liabilities		383	413
Total Liabilities Assumed		2,874	3,145
Net Assets Acquired	$	30,054	30,054

[1] Includes adjustment of $642 million to write-up the acquired inventory to its estimated fair value.

Subsequent to the date of acquisition there was an adjustment of $0.2 billion to the deferred taxes and $0.4 billion to the current liabilities with the offset to goodwill.

The assets acquired are recorded in the Pharmaceutical segment. The acquisition of Actelion resulted in approximately $6.2 billion of goodwill. The goodwill is primarily attributable to synergies expected to arise from the acquisition. The goodwill is not expected to be deductible for tax purposes.

The purchase price allocation to the identifiable intangible assets is as follows:

(Dollars in Millions)		
Intangible assets with definite lives:		
Patents and trademarks	$	24,230
Total amortizable intangibles		24,230
In-process research and development		780
Total intangible assets	**$**	**25,010**

The patents and trademarks acquired are comprised of developed technology with a weighted average life of 9 years and was primarily based on the patent life of the marketed products. The intangible assets with definite lives were assigned asset lives ranging from 4 to 10 years. The in-process research and development intangible assets were valued for technology programs for unapproved products.

The value of the IPR&D was calculated using probability adjusted cash flow projections discounted for the risk inherent in such projects. The discount rate applied was 9%.

The acquisition was accounted for using the acquisition method and, accordingly, the results of operations of Actelion were reported in the Company's financial statements beginning on June 16, 2017, the date of acquisition. For the year ended December 31, 2017 total sales and a net loss for Actelion from the date of acquisition were $1.4 billion and $1.4 billion, respectively.

The following table provides pro forma results of operations for the fiscal year ended December 31, 2017 and January 1, 2017, as if Actelion had been acquired as of January 4, 2016. The pro forma results include the effect of certain purchase accounting adjustments such as the estimated changes in depreciation and amortization expense on the acquired tangible and intangible assets. However, pro forma results do not include any anticipated cost savings or other effects of the planned

integration of Actelion. Accordingly, such amounts are not necessarily indicative of the results if the acquisition had occurred on the dates indicated or which may occur in the future.

	Unaudited Pro forma Consolidated Results	
(Dollars in Millions Except Per Share Data)	2017	2016
Net Sales	77,681	74,339
Net Earnings	1,509	13,916
Diluted Net Earnings per Common Share	0.55	4.99

In 2017, the Company recorded Actelion acquisition related costs before tax of approximately $0.8 billion, which was recorded in Other (income)/expense and Cost of products sold.

During 2017, the Company acquired Abbott Medical Optics (AMO), a wholly-owned subsidiary of Abbott Laboratories, for $4.3 billion, net of cash acquired. The acquisition included ophthalmic products related to: cataract surgery, laser refractive surgery and consumer eye health. The net purchase price was primarily recorded as amortizable intangible assets for $2.3 billion and goodwill for $1.7 billion. The weighted average life of total amortizable intangibles, the majority being customer relationships, is approximately 14.4 years. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not deductible for tax purposes. The intangible assets and goodwill amounts are based on the final purchase price allocation. The assets acquired were recorded in the Medical Devices segment.

Certain businesses were acquired for $4,509 million in cash and $77 million of liabilities assumed during 2016. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2016 acquisitions primarily included: Vogue International LLC, a privately-held company focused on the marketing, development and distribution of salon-influenced and nature inspired hair care and other personal products; NeuWave Medical, Inc., a privately-held medical device company that manufactures and markets minimally invasive soft tissue microwave ablation systems; NeoStrata Company, Inc., a global leader in dermocosmetics, and the global rights for the commercialization of RHINOCORT® allergy spray outside the United States.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $4,077 million and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

The net purchase price for Vogue International LLC of $3.3 billion was primarily recorded as amortizable intangible assets for $2.3 billion and goodwill for $1.1 billion. The weighted average life for the $2.3 billion of total amortizable intangibles is approximately 22 years. The trademark asset values were determined to have definite lives ranging from 10 to 22 years, with the majority being 22 years. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is expected to be deductible for tax purposes. The assets acquired were recorded in the Consumer segment.

Certain businesses were acquired for $954 million in cash and $220 million of liabilities assumed during 2015. The assumed liabilities primarily represent the fair value of the contingent consideration of $210 million. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2015 acquisitions primarily included: XO1 Limited, a privately-held biopharmaceutical company developing an anti-thrombin antibody and Novira Therapeutics, Inc., a privately held clinical-stage biopharmaceutical company developing innovative therapies for curative treatment of chronic hepatitis B virus infection.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $1,173 million and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately $839 million has been identified as the value of IPR&D primarily associated with the acquisitions of XO1 Limited and Novira Therapeutics, Inc. The value of the IPR&D was calculated using cash flow projections discounted for the inherent risk in the projects.

The IPR&D related to the acquisition of XO1 Limited of $360 million is associated with a recombinant human antibody developed to mimic the activity of a human antibody which appears to produce an anticoagulated state without predisposition to bleeding. A probability of success factor of 36.0% was used to reflect inherent clinical and regulatory risk. The discount rate applied was 11.75%.

The IPR&D related to the acquisition of Novira Therapeutics, Inc. of $396 million is associated with its lead candidate NVR 3-778 which is an investigational small molecule, direct-acting antiviral, for oral administration in patients with HBV that inhibits the HBV core or capsid protein. A probability of success factor of 51.0% was used to reflect inherent clinical and regulatory risk. The discount rate applied was 16.0%. During 2017, the Company recorded a charge for the impairment of the IPR&D related to the acquisition of Novira Therapeutics, Inc. The impairment was the result of the cancellation of product development due to safety concerns.

In 2012, the Company completed the acquisition of Synthes, Inc. for a purchase price of $20.2 billion in cash and stock. In connection with the acquisition of Synthes, Inc. the Company entered into two accelerated share repurchase (ASR) agreements. In 2013, the Company settled the remaining liabilities under the ASR agreements. While the Company believes that the transactions under each ASR agreement and a series of related internal transactions were consummated in a tax efficient manner in accordance with applicable law, it is possible that the Internal Revenue Service could assert one or more contrary positions to challenge the transactions from a tax perspective. If challenged, an amount up to the total purchase price for the Synthes shares could be treated as subject to applicable U.S. tax at approximately the statutory rate to the Company, plus interest.

With the exception of the Actelion Ltd acquisition, supplemental pro forma information for 2017, 2016 and 2015 in accordance with U.S. GAAP standards related to business combinations, and goodwill and other intangible assets, is not provided, as the impact of the aforementioned acquisitions did not have a material effect on the Company's results of operations, cash flows or financial position.

During the fiscal first quarter of 2017, the Company announced it is engaging in a process to evaluate potential strategic options for the Johnson & Johnson Diabetes Care Companies, specifically LifeScan, Inc., Animas Corporation, and Calibra Medical, Inc. Strategic options may include the formation of operating partnerships, joint ventures or strategic alliances, a sale of the businesses, or other alternatives either separately or together. During the fiscal second quarter of 2017, the Company recorded an impairment charge of $0.2 billion, primarily related to the insulin pump business. During the fiscal fourth quarter of 2017, the Company announced its decision to exit the Animas insulin pump business. The Company is continuing to evaluate potential strategic options for LifeScan, Inc. and determine the best opportunity to drive future growth and maximize shareholder value. There were no assets held for sale as of December 31, 2017 related to the announcement.

During 2017, the Company divestitures primarily included: the Codman Neurosurgery business, to Integra LifeSciences Holdings Corporation and the divestiture of COMPEED® to HRA Pharma. In 2017, the pre-tax gains on the divestitures were approximately $1.3 billion.

During 2016, the Company divestitures included: the controlled substance raw material and active pharmaceutical ingredient (API) business; certain anesthetic products in Europe; and certain non-strategic Consumer brands. In 2016, the pre-tax gains on the divestitures were approximately $0.6 billion.

During 2015, the Company divestitures included: the Cordis business to Cardinal Health; the SPLENDA® brand to Heartland Food Products Group; and the U.S. license rights to NUCYNTA® (tapentadol), NUCYNTA® ER (tapentadol extended-release tablets), and NUCYNTA® (tapentadol) oral solution. In 2015, the pre-tax gains on the divestitures were approximately $2.6 billion.

21. Legal Proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability, intellectual property, commercial and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of their business.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of December 31, 2017, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions. The ability to make such estimates and judgments can be affected by various factors, including whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; or there are numerous parties involved.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution of, or increase in accruals for, one or more of these matters in any reporting period may have a material adverse effect on the Company's results of operations and cash flows for that period.

PRODUCT LIABILITY

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While the Company believes it has substantial defenses, it is not feasible to predict the ultimate outcome of litigation. The Company has

established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

The most significant of these cases include: the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System; the PINNACLE® Acetabular Cup System; pelvic meshes; RISPERDAL®; XARELTO®; body powders containing talc, primarily JOHNSONS® Baby Powder; and INVOKANA®. As of December 31, 2017, in the U.S. there were approximately 2,000 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, 10,000 with respect to the PINNACLE® Acetabular Cup System, 53,600 with respect to pelvic meshes, 13,700 with respect to RISPERDAL®, 22,900 with respect to XARELTO®, 6,610 with respect to body powders containing talc; and 1,100 with respect to INVOKANA®.

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System used in hip replacement surgery. Claims for personal injury have been made against DePuy and Johnson & Johnson. The number of pending lawsuits is expected to fluctuate as certain lawsuits are settled or dismissed and additional lawsuits are filed. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada, Australia, Ireland, Germany and Italy. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR Hip System plaintiffs to establish a program to settle claims with eligible ASR Hip patients in the United States who had surgery to replace their ASR Hips, known as revision surgery, as of August 31, 2013. DePuy reached additional agreements in February 2015 and March 2017, which further extended the settlement program to include ASR Hip patients who had revision surgeries after August 31, 2013 and prior to February 15, 2017. This settlement program has resolved more than 10,000 claims, with more expected from the recent extension, therefore bringing to resolution significant ASR Hip litigation activity in the United States. However, lawsuits in the United States remain, and the settlement program does not address litigation outside of the United States. In Australia, a class action settlement was reached that resolved the claims of the majority of ASR Hip patients in that country. The Company continues to receive information with respect to potential additional costs associated with this recall on a worldwide basis. The Company has established accruals for the costs associated with the United States settlement program and DePuy ASR™ Hip-related product liability litigation.

Claims for personal injury have also been made against DePuy Orthopaedics, Inc. and Johnson & Johnson relating to the PINNACLE® Acetabular Cup System used in hip replacement surgery. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Texas. Litigation has also been filed in some state courts and in countries outside of the United States, primarily in the United Kingdom. In the United Kingdom, a trial is ongoing regarding common issues of liability and a decision is expected in the first half of 2018. The Company has established an accrual for defense costs in connection with product liability litigation associated with the PINNACLE® Acetabular Cup System.

Claims for personal injury have been made against Ethicon, Inc. (Ethicon) and Johnson & Johnson arising out of Ethicon's pelvic mesh devices used to treat stress urinary incontinence and pelvic organ prolapse. The Company continues to receive information with respect to potential costs and additional cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Southern District of West Virginia. The Company has settled or otherwise resolved a majority of the United States cases and the costs associated with these settlements are reflected in the Company's accruals. In addition, class actions and individual personal injury cases or claims have been commenced in various countries outside of the United States, including claims and cases in the United Kingdom, the Netherlands and Belgium, and class actions in Israel, Australia and Canada, seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices. In Australia, a trial of class action issues is ongoing and a decision is expected in 2018. The Company has established accruals with respect to product liability litigation associated with Ethicon's pelvic mesh products.

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and Johnson & Johnson arising out of the use of RISPERDAL®, indicated for the treatment of schizophrenia, acute manic or mixed episodes associated with bipolar I disorder and irritability associated with autism, and related compounds. Lawsuits have been primarily filed in state courts in Pennsylvania, California, and Missouri. Other actions are pending in various courts in the United States and Canada. Product

liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has established an accrual with respect to product liability litigation associated with RISPERDAL®.

Claims for personal injury arising out of the use of XARELTO®, an oral anticoagulant, have been made against Janssen Pharmaceuticals, Inc. (JPI); Johnson & Johnson; and JPI's collaboration partner for XARELTO® Bayer AG and certain of its affiliates. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Eastern District of Louisiana. In addition, cases have been filed in state courts across the United States. Many of these cases have been consolidated into a state mass tort litigation in Philadelphia, Pennsylvania; and there are coordinated proceedings in Delaware, California and Missouri. Class action lawsuits also have been filed in Canada. The Company has established an accrual for defense costs in connection with product liability litigation associated with XARELTO®.

Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSONS® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the District of New Jersey. The Company has established an accrual for defense costs in connection with product liability litigation associated with body powders containing talc.

Claims for personal injury have been made against a number of Johnson & Johnson companies, including Janssen Pharmaceuticals, Inc. and Johnson & Johnson, arising out of the use of INVOKANA®, a prescription medication indicated to improve glycemic control in adults with Type 2 diabetes. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the District of New Jersey. Cases have also been filed in state courts in Pennsylvania, California and New Jersey. Class action lawsuits have been filed in Canada. The Company has established an accrual with respect to product liability litigation associated with INVOKANA®.

INTELLECTUAL PROPERTY

Certain subsidiaries of Johnson & Johnson are subject, from time to time, to legal proceedings and claims related to patent, trademark and other intellectual property matters arising out of their businesses. Many of these matters involve challenges to the coverage and/or validity of the patents on various products and allegations that certain of the Company's products infringe the patents of third parties. Although these subsidiaries believe that they have substantial defenses to these challenges and allegations with respect to all significant patents, there can be no assurance as to the outcome of these matters. A loss in any of these cases could adversely affect the ability of these subsidiaries to sell their products, result in loss of sales due to loss of market exclusivity, require the payment of past damages and future royalties, and may result in a non-cash impairment charge for any associated intangible asset. The most significant of these matters are described below.

Medical Devices

In June 2009, Rembrandt Vision Technologies, L.P. (Rembrandt) filed a patent infringement lawsuit against Johnson & Johnson Vision Care, Inc. (JJVCI) in the United States District Court for the Eastern District of Texas alleging that JJVCI's manufacture and sale of its ACUVUE® ADVANCE and ACUVUE OASYS® Hydrogel Contact Lenses infringed Rembrandt's United States Patent No. 5,712,327 and seeking monetary relief. The case was transferred to the United States District Court for the Middle District of Florida, where a trial in May 2012 resulted in a verdict of non-infringement that was subsequently upheld on appeal. In July 2014, Rembrandt sought a new trial based on alleged new evidence, which the District Court denied. In April 2016, the Court of Appeals overturned that ruling and remanded the case to the District Court for a new trial. A new trial was held in August 2017, and the jury returned a verdict of non-infringement in favor of JJVCI. Rembrandt has appealed the verdict to the United States Court of Appeals for the Federal Circuit.

In March 2013, Medinol Ltd. (Medinol) filed a patent infringement lawsuit against Cordis Corporation (Cordis) and Johnson & Johnson in the United States District Court for the Southern District of New York alleging that Cordis's sales of the CYPHER™ and CYPHER SELECT™ stents made in the United States since 2005 willfully infringed four of Medinol's patents directed to the geometry of articulated stents. Medinol is seeking damages and attorneys' fees. After trial in January 2014, the District Court dismissed the case, finding Medinol unreasonably delayed bringing its claims (the laches defense). In September 2014,

the District Court denied a motion by Medinol to vacate the judgment and grant it a new trial. Medinol appealed the decision to the United States Court of Appeals for the Federal Circuit, then dismissed the appeal in order to file a petition for review with the United States Supreme Court. In March 2017, the United States Supreme Court held that the laches defense is not available in patent cases and remanded this case to the United States Court of Appeals for the Federal Circuit to consider Medinol's appeal of whether Medinol is entitled to seek a new trial. Cordis was divested in 2015, and the Company retained any liability that may result from this case.

In November 2016, MedIdea, L.L.C. (MedIdea) filed a patent infringement lawsuit against DePuy Orthopaedics, Inc. in the United States District Court for the Northern District of Illinois alleging infringement by the ATTUNE® Knee System. MedIdea alleges infringement of United States Patent Nos. 6,558,426 ('426); 8,273,132; 8,721,730 and 9,492,280 relating to posterior stabilized knee systems. Specifically, MedIdea alleges that the SOFCAM™ Contact feature of the ATTUNE® posterior stabilized knee products infringes the patents-in-suit. MedIdea is seeking monetary damages and injunctive relief. In June 2017, the case was transferred to the United States District Court for the District of Massachusetts. In December 2017, DePuy Synthes Products, Inc. filed a Petition for Inter Partes Review with the United States Patent and Trademark Office, seeking to invalidate the '426 patent.

In December 2016, Ethicon Endo-Surgery, Inc. and Ethicon Endo-Surgery, LLC (now known as Ethicon LLC) sued Covidien, Inc. in the United States District Court for the District of Massachusetts seeking a declaration that United States Patent Nos. 6,585,735 (the '735 patent); 7,118,587; 7,473,253; 8,070,748 and 8,241,284 (the '284 patent), are either invalid or not infringed by Ethicon's ENSEAL® X1 Large Jaw Tissue Sealer product. In April 2017, Covidien LP, Covidien Sales LLC, and Covidien AG (collectively, Covidien) answered and counterclaimed, denying the allegations, asserting willful infringement of the '735 patent, the '284 patent and United States Patent Nos. 8,323,310; 9,084,608; 9,241,759 and 9,113,882, and seeking damages and an injunction. Covidien filed a motion for preliminary injunction, which was denied in October 2017. Trial is scheduled for September, 2019.

In November 2017, Board of Regents, The University of Texas System and Tissuegen, Inc. filed a lawsuit in the United States District Court for the Western District of Texas against Ethicon, Inc. and Ethicon US, LLC alleging the manufacture and sale of VICRYL® Plus Antibacterial Sutures and MONOCRYL® Plus Antibacterial Sutures infringe plaintiffs' United States Patent Nos. 6,596,296 and 7,033,603 directed to implantable polymer drug releasing biodegradable fibers containing a therapeutic agent.

Pharmaceutical

In April 2016, MorphoSys AG, a German biotech company, filed a patent infringement lawsuit against Janssen Biotech, Inc. (JBI), Genmab U.S. Inc. and Genmab A/S (collectively, Genmab) in the United States District Court for the District of Delaware. MorphoSys alleges that JBI's manufacture and sale of DARZALEX® (daratumumab) willfully infringes MorphoSys' United States Patent Nos. 8,263,746, 9,200,061 and 9,785,590. MorphoSys is seeking money damages. JBI licenses patents and the commercial rights to DARZALEX® from Genmab. Trial in the case is scheduled to commence in February 2019.

In August 2016, Sandoz Ltd and Hexal AG (collectively, Sandoz) filed a lawsuit in the English High Court against G.D. Searle LLC (a Pfizer company) and Janssen Sciences Ireland UC (JSI) alleging that Searle's supplementary protection certificate SPC/GB07/038 (SPC), which is exclusively licensed to JSI, is invalid and should be revoked. Janssen-Cilag Limited sells PREZISTA® (darunavir) in the United Kingdom pursuant to this license. In October 2016, Searle and JSI counterclaimed against Sandoz for threatened infringement of the SPC based on statements of its plans to launch generic darunavir in the United Kingdom. Sandoz admitted that its generic darunavir product would infringe the SPC if it is found valid. Searle and JSI are seeking an order enjoining Sandoz from marketing its generic darunavir before the expiration of the SPC. Following a trial in April 2017, the Court entered a decision holding that the SPC is valid and granting a final injunction. Sandoz has appealed the Court's decision and the injunction will be stayed pending the appeal. In January 2018, the Court referred the issue on appeal to the Court of Justice for the European Union (CJEU) and stayed the proceedings pending the CJEU's ruling on the issue.

REMICADE® Related Cases

United States Proceedings
In September 2013, Janssen Biotech, Inc. (JBI) and NYU Langone Medical Center (NYU) received an Office Action from the United States Patent and Trademark Office (USPTO) rejecting the claims in United States Patent No. 6,284,471 relating to REMICADE® (infliximab) (the '471 patent) in a reexamination proceeding instituted by a third party. The '471 patent expires in September 2018 and is co-owned by JBI and NYU, with NYU having granted JBI an exclusive license to NYU's rights under the patent. Following several office actions by the patent examiner, including two further rejections, and responses by

JBI, the USPTO issued a further action maintaining its rejection of the ’471 patent. JBI filed a notice of appeal to the USPTO’s Patent Trial and Appeal Board (the Board), which issued a decision in November 2016 upholding the examiner's rejection. In January 2018, the United States Court of Appeals for the Federal Circuit affirmed the Board's decision.

In August 2014, Celltrion Healthcare Co. Ltd. and Celltrion Inc. (collectively, Celltrion) filed an application with the United States Food and Drug Administration (FDA) for approval to make and sell its own infliximab biosimilar. In March 2015, JBI filed a lawsuit in the United States District Court for the District of Massachusetts against Celltrion and Hospira Healthcare Corporation (Hospira), which has exclusive marketing rights for Celltrion's infliximab biosimilar in the United States, seeking, among other things, a declaratory judgment that their biosimilar product infringes or potentially infringes several JBI patents, including the ’471 patent and United States Patent No. 7,598,083 (the ’083 patent). In August 2016, the District Court granted both Celltrion's and Hospira's motions for summary judgment of invalidity of the ’471 patent. JBI appealed those decisions to the United States Court of Appeals for the Federal Circuit. In January 2018, the Federal Circuit dismissed the appeal as moot based on its affirmance of the Board’s reexamination decision.

In June 2016, JBI filed two additional patent infringement lawsuits asserting the ’083 patent, one against Celltrion and Hospira in the United States District Court for the District of Massachusetts and the other against HyClone Laboratories, Inc., the manufacturer of the cell culture media that Celltrion uses to make its biosimilar product, in the United States District Court for the District of Utah. Although the ’083 patent is already asserted in the existing lawsuit against Celltrion, the additional lawsuit expands the claims to include the sale in the United States of Celltrion's biosimilar product manufactured with cell culture media made in the United States. This additional lawsuit against Celltrion has been consolidated with the existing lawsuit discussed above. Hospira has moved to dismiss all counts of the lawsuit related to the ’083 patent as to it. Celltrion's motion to dismiss all counts of the lawsuit related to the ’083 patent for failure to join all the co-owners of the '083 patent as plaintiffs was denied in October 2017. Trial is scheduled to begin in July 2018. The litigation against HyClone in Utah is stayed pending the outcome of the Massachusetts actions.

The FDA approved Celltrion’s infliximab biosimilar for sale in the United States in April 2016. Hospira's parent company, Pfizer Inc., launched Celltrion's infliximab biosimilar in the United States in late 2016.

In April 2017, JBI received notice that the FDA approved a marketing application submitted by Samsung Bioepis Co. Ltd. (Samsung) for the sale of its infliximab biosimilar in the United States. In May 2017, JBI filed a patent infringement lawsuit against Samsung in the United States District Court for the District of New Jersey alleging that the sale of its biosimilar product may infringe three of JBI’s patents. In July 2017, Samsung launched its biosimilar product (commercialized by Merck) in the United States. In November 2017, JBI voluntarily dismissed this lawsuit.

Litigation Against Filers of Abbreviated New Drug Applications (ANDAs)

The following summarizes lawsuits pending against generic companies that have filed Abbreviated New Drug Applications (ANDAs) with the FDA, or undertaken similar regulatory processes outside of the United States, seeking to market generic forms of products sold by various subsidiaries of Johnson & Johnson prior to expiration of the applicable patents covering those products. These ANDAs typically include allegations of non-infringement, invalidity and unenforceability of the applicable patents. In the event the subsidiaries are not successful in these actions, or the statutory 30-month stays of the ANDAs expire before the United States District Court rulings are obtained, the third-party companies involved will have the ability, upon approval of the FDA, to introduce generic versions of the products at issue to the market, resulting in the potential for substantial market share and revenue losses for those products, and which may result in a non-cash impairment charge in any associated intangible asset. In addition, from time to time, subsidiaries may settle these actions and such settlements can involve the introduction of generic versions of the products at issue to the market prior to the expiration of the relevant patents. The inter partes review (IPR) process with the United States Patent and Trademark Office (USPTO), created under the 2011 America Invents Act, is also being used by generic companies in conjunction with these ANDAs and lawsuits to challenge patents held by the Company’s subsidiaries.

ZYTIGA®

In July 2015, Janssen Biotech, Inc., Janssen Oncology, Inc. and Janssen Research & Development, LLC (collectively, Janssen) and BTG International Ltd. (BTG) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against a number of generic companies (and certain of their affiliates and/or suppliers) who filed ANDAs seeking approval to market a generic version of ZYTIGA® 250mg before the expiration of United States Patent No. 8,822,438 (the ’438 patent). The generic companies currently include Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC (collectively, Amneal); Apotex Inc. and Apotex Corp. (collectively, Apotex); Citron Pharma LLC (Citron); Dr. Reddy’s Laboratories, Ltd. and Dr. Reddy’s Laboratories, Inc. (collectively, Dr. Reddy’s); Mylan Pharmaceuticals Inc. and Mylan Inc.

(collectively, Mylan); Par Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc. (collectively, Par); Sun Pharmaceutical Industries Ltd. and Sun Pharmaceuticals Industries, Inc. (collectively, Sun); Teva Pharmaceuticals USA, Inc. (Teva); Wockhardt Bio A.G.; Wockhardt USA LLC and Wockhardt Ltd. (collectively, Wockhardt); West-Ward Pharmaceutical Corp. (West-Ward) and Hikma Pharmaceuticals, LLC (Hikma). In February 2018, the court heard oral arguments on a motion for summary judgment of non-infringement filed by certain defendants. The parties await a decision. If the decision is unfavorable, the stay could be lifted and a generic version of ZYTIGA® could enter the market.

Janssen and BTG also initiated patent infringement lawsuits in the United States District Court for the District of New Jersey against Amerigen Pharmaceuticals Limited (Amerigen) in May 2016, and Glenmark Pharmaceuticals, Inc. in June 2016, each of whom filed an ANDA seeking approval to market its generic version of ZYTIGA® before the expiration of the ’438 patent.

In August 2015, Janssen and BTG filed an additional jurisdictional protective lawsuit against the Mylan defendants in the United States District Court for the Northern District of West Virginia, which has been stayed.

In August 2017, Janssen and BTG initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva, who filed an ANDA seeking approval to market a generic version of ZYTIGA® 500mg before the expiration of the ’438 patent.

In January 2018, Janssen dismissed its lawsuit against Sun after it withdrew its ANDA.

In each of the above lawsuits, Janssen is seeking an order enjoining the defendants from marketing their generic versions of ZYTIGA® before the expiration of the ’438 patent.

Several generic companies including Amerigen, Argentum Pharmaceuticals LLC (Argentum), Mylan, Wockhardt, Actavis, Amneal, Dr. Reddy’s, Sun, Teva, West-Ward and Hikma filed Petitions for Inter Partes Review (IPR) with the USPTO, seeking to invalidate the ’438 patent. In January 2018, the USPTO issued decisions invalidating the '438 patent, and Janssen is appealing this decision. The IPR decisions are not binding on the district court in the pending litigation.

In October 2017, Janssen Inc. and Janssen Oncology, Inc. (collectively, Janssen) initiated two Notices of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Teva Canada Limited (Teva) and the Minister of Health in Canada in response to Teva's filing Abbreviated New Drug Submissions (ANDS) and seeking approval to market generic versions of ZYTIGA® 250mg and ZYTIGA® 500mg before the expiration of Canadian Patent No. 2,661,422.

In November 2017, Janssen initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex Inc. (Apotex) and the Minister of Health in Canada in response to Apotex’s filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of ZYTIGA® before the expiration of Canadian Patent No. 2,661,422.

In each of these Notices of Application, Janssen is seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance with respect to Teva's and Apotex's ANDS before the expiration of Janssen's patent.

COMPLERA®

In August and September 2015, Janssen Pharmaceutica NV and Janssen Sciences Ireland UC (collectively, Janssen) and Gilead Sciences, Inc. and Gilead Sciences Ireland UC (collectively, Gilead) initiated patent infringement lawsuits in the United States District Courts for the District of Delaware and the District of West Virginia, respectively, against Mylan, Inc. and Mylan Pharmaceuticals, Inc. (collectively, Mylan), who filed an ANDA seeking approval to market a generic version of COMPLERA® before the expiration of United States Patent Nos. 8,841,310, 7,125,879 and 8,101,629. In July 2017, the West Virginia lawsuit was dismissed without prejudice by stipulation of the parties.

In the Delaware lawsuit, Janssen and Gilead amended their complaint to add claims for patent infringement with respect to United States Patent Nos. 8,080,551; 7,399,856; 7,563,922; 8,101,752 and 8,618,291. In November 2017, the parties entered into a settlement agreement.

XARELTO®

Beginning in October 2015, Janssen Pharmaceuticals, Inc. (JPI) and Bayer Pharma AG and Bayer Intellectual Property GmbH (collectively, Bayer) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of XARELTO® before expiration

of Bayer's United States Patent Nos. 7,157,456 , 7,585,860 and 7,592,339 relating to XARELTO®. JPI is the exclusive sublicensee of the asserted patents. The following generic companies are named defendants: Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. (collectively, Aurobindo); Breckenridge Pharmaceutical, Inc. (Breckenridge); InvaGen Pharmaceuticals Inc. (InvaGen); Micro Labs USA Inc. and Micro Labs Ltd (collectively, Micro); Mylan Pharmaceuticals Inc. (Mylan); Prinston Pharmaceuticals, Inc.; Sigmapharm Laboratories, LLC (Sigmapharm); Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. (collectively, Torrent). All defendants except Mylan and Sigmapharm have agreed to have their cases stayed and to be bound by the outcome of any final judgment rendered against any of the other defendants. Trial is scheduled for March 2018.

Beginning in April 2017, JPI and Bayer Intellectual Property GmbH and Bayer AG (collectively, Bayer AG) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of XARELTO® before expiration of Bayer AG's United States Patent No. 9,539,218 ('218) relating to XARELTO®. The following generic companies are named defendants: Alembic Pharmaceuticals Limited, Alembic Global Holding SA and Alembic Pharmaceuticals, Inc.; Aurobindo; Breckenridge; InvaGen; Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, Lupin); Micro; Mylan; Sigmapharm; Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals U.S.A., Inc. (collectively, Taro) and Torrent. Lupin has counterclaimed for a declaratory judgment of noninfringement and invalidity of United States Patent No. 9,415,053, but Lupin dismissed its counterclaims after it was provided a covenant not to sue on that patent. Aurobindo, Taro, Torrent and Micro have agreed to have their cases stayed and to be bound by the outcome of any final judgment rendered against any of the other defendants. The '218 cases have been consolidated for discovery and trial, and are currently set for trial in April 2019.

In each of these lawsuits, JPI is seeking an order enjoining the defendants from marketing their generic versions of XARELTO® before the expiration of the relevant patents.

PREZISTA®

In September 2017, Janssen Sciences Ireland UC and Janssen Products, L.P. (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc. (collectively, Aurobindo), who filed an ANDA seeking approval to market a generic version of PREZISTA® before the expiration of United States Patent Nos. 8,518,987; 7,700,645; 7,126,015; and 7,595,408. In January 2018, the parties entered into a settlement agreement.

In November 2017, Janssen Inc. initiated Notices of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex Inc. (Apotex) and the Minister of Health in Canada in response to Apotex's filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of PREZISTA® before the expiration of Canadian Patent Nos. 2,485,834 and 2,336,160, which is owned by the United States and the Board of Trustees of the University of Illinois. Janssen is seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance with respect to Apotex's ANDS before the expiration of the relevant patents.

RISPERDAL CONSTA®

In November 2016, the United States Patent and Trademark Office (USPTO) instituted an Inter Partes Review filed by Luye Pharma Group Ltd., Luye Pharma (USA) Ltd., Sandong Luye Pharmaceutical Co., Ltd. and Nanjing Luye Pharmaceutical Co., Ltd., seeking to invalidate United States Patent No. 6,667,061 relating to RISPERDAL CONSTA®. Janssen Pharmaceuticals, Inc. markets RISPERDAL CONSTA® pursuant to a license from Alkermes Pharma Ireland Ltd. In November 2017, the USPTO issued a decision upholding the validity of the patent.

INVOKANA®/INVOKAMET®

Beginning in July 2017, Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Cilag GmbH International and Janssen Pharmaceutica NV (collectively, Janssen) and Mitsubishi Tanabe Pharma Corporation (MTPC) filed patent infringement lawsuits in the United States District Court for the District of New Jersey, the United States District Court for the District of Colorado and the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of INVOKANA® and/or INVOKAMET® before expiration of MTPC's United States Patent Nos. 7,943,582 and/or 8,513,202 relating to INVOKANA® and INVOKAMET®. Janssen is the exclusive licensee of the asserted patents. The following generic companies are named defendants: Apotex Inc. and Apotex Corp. (Apotex); Aurobindo Pharma USA Inc. (Aurobindo); Macleods Pharmaceuticals Ltd. and MacLeods Pharma USA, Inc.; InvaGen Pharmaceuticals, Inc. (InvaGen); Prinston Pharmaceuticals Inc.; Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories Ltd; Hetero USA, Inc., Hetero Labs Limited Unit-V and Hetero Labs Limited; MSN Laboratories Private Ltd. and MSN Pharmaceuticals, Inc.; Laurus Labs Ltd.; Indoco Remedies Ltd.; Zydus Pharmaceuticals (USA) Inc. (Zydus); Sandoz, Inc. (Sandoz); Teva Pharmaceuticals USA, Inc.; and Lupin Ltd. and Lupin Pharmaceuticals, Inc.

Beginning in July 2017, Janssen and MTPC filed patent infringement lawsuits in the United States District Court for the District of New Jersey and the United States District Court for the District of Colorado against Sandoz and InvaGen, who filed ANDAs seeking approval to market generic versions of INVOKANA® and/or INVOKAMET® before expiration of MTPC's United States Patent No. 7,943,788 (the '788 patent) relating to INVOKANA® and INVOKAMET® and against Zydus, who filed ANDAs seeking approval to market generic versions of INVOKANA® and INVOKAMET® before expiration of the '788 patent, MTPC's United States Patent No. 8,222,219 relating to INVOKANA® and INVOKAMET® and MTPC's United States Patent No. 8,785,403 relating to INVOKAMET®, and against Aurobindo, who filed an ANDA seeking approval to market a generic version of INVOKANA® before expiration of the '788 patent and the '219 patent relating to INVOKANA®. Janssen is the exclusive licensee of the asserted patents. In October 2017, the Colorado lawsuits against Sandoz were dismissed. In December 2017, the Delaware lawsuits against Apotex and Teva were dismissed.

In each of these lawsuits, Janssen and MTPC are seeking an order enjoining the defendants from marketing their generic versions of INVOKANA® and/or INVOKAMET® before the expiration of the relevant patents.

VELETRI®

In July 2017, Actelion Pharmaceuticals Ltd. (Actelion) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Sun Pharmaceutical Industries, Inc. and Sun Pharmaceutical Industries Limited (collectively, Sun Pharmaceutical), who filed an ANDA seeking approval to market a generic version of VELETRI® before the expiration of United States Patent No. 8,598,227. Actelion is seeking an order enjoining Sun Pharmaceutical from marketing its generic version of VELETRI® before the expiration of the patent. Trial is scheduled to commence in June 2019.

OPSUMIT®

In January 2018, Actelion Pharmaceuticals Ltd (Actelion) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Zydus Pharmaceuticals (USA) Inc. (Zydus) and Amneal Pharmaceuticals LLC (Amneal), who filed an ANDA seeking approval to market a generic version of OPSUMIT® before the expiration of United States Patent No. 7,094,781. In the lawsuit, Actelion is seeking an order enjoining Zydus and Amneal from marketing generic versions of OPSUMIT® before the expiration of the patent.

INVEGA SUSTENNA®

In January 2018, Janssen Pharmaceutica NV and Janssen Pharmaceuticals, Inc. (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva Pharmaceuticals USA, Inc. (Teva), who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of United States Patent No. 9,439,906. In the lawsuit, Janssen is seeking an order enjoining Teva from marketing a generic version of INVEGA SUSTENNA® before the expiration of the patent.

IMBRUVICA®

Beginning in January 2018, Pharmacyclics LLC (Pharmacyclics) and Janssen Biotech, Inc. (Janssen) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of IMBRUVICA® before expiration of Pharmacyclics' United States Patent Nos. 8,008,309, 7,514,444, 8,697,711, 8,735,403, 8,957,079, 9,181,257, 8,754,091, 8,497,277, 8,925,015, 8,476,284, 8,754,090, 8,999,999, 9,125,889, 9,801,881, 9,801,883, 9,814,721, 9,795,604, 9,296,753, 9,540,382, 9,713,617 and/or 9,725,455 relating to IMBRUVICA®. Janssen is the exclusive licensee of the asserted patents. The following generic companies are named defendants: Cipla Limited and Cipla USA Inc. (Cipla); Fresenius Kabi USA, LLC, Fresenius Kabi USA, Inc., and Fresenius Kabi Oncology Limited (Fresenius Kabi); Sandoz Inc. and Lek Pharmaceuticals d.d. (Sandoz); Shilpa Medicare Limited (Shilpa); Sun Pharma Global FZE and Sun Pharmaceutical Industries Limited (Sun); Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Limited (Teva); and Zydus Worldwide DMCC and Cadila Healthcare Limited (Zydus).
In each of the lawsuits, Pharmacyclics and Janssen are seeking an order enjoining the defendants from marketing generic versions of IMBRUVICA® before the expiration of the relevant patents.

GOVERNMENT PROCEEDINGS

Like other companies in the pharmaceutical and medical devices industries, Johnson & Johnson and certain of its subsidiaries are subject to extensive regulation by national, state and local government agencies in the United States and other countries in which they operate. As a result, interaction with government agencies is ongoing. The most significant litigation brought by, and investigations conducted by, government agencies are listed below. It is possible that criminal charges and substantial fines and/or civil penalties or damages could result from government investigations or litigation.

Average Wholesale Price (AWP) Litigation

Johnson & Johnson and several of its pharmaceutical subsidiaries (the J&J AWP Defendants), along with numerous other pharmaceutical companies, were named as defendants in a series of lawsuits in state and federal courts involving allegations that the pricing and marketing of certain pharmaceutical products amounted to fraudulent and otherwise actionable conduct because, among other things, the companies allegedly reported an inflated Average Wholesale Price (AWP) for the drugs at issue. Payors alleged that they used those AWPs in calculating provider reimbursement levels. The plaintiffs in these cases included three classes of private persons or entities that paid for any portion of the purchase of the drugs at issue based on AWP, and state government entities that made Medicaid payments for the drugs at issue based on AWP. Many of these cases, both federal actions and state actions removed to federal court, were consolidated for pre-trial purposes in a multi-district litigation in the United States District Court for the District of Massachusetts, where all claims against the J&J AWP Defendants were ultimately dismissed. The J&J AWP Defendants also prevailed in a case brought by the Commonwealth of Pennsylvania. Other AWP cases have been resolved through court order or settlement. Two cases remain pending. In a case brought by Illinois, the parties are awaiting assignment of a trial date. In New Jersey, a putative class action based upon AWP allegations is pending against Centocor, Inc. and Ortho Biotech Inc. (both now Janssen Biotech, Inc.), Johnson & Johnson and ALZA Corporation.

Opioids Litigation

Beginning in 2014 and continuing to the present, Johnson & Johnson and Janssen Pharmaceuticals, Inc. (JPI), along with other pharmaceutical companies, have been named in numerous lawsuits brought by certain state and local governments related to the marketing of opioids, including DURAGESIC®, NUCYNTA® and NUCYNTA® ER. To date, complaints against pharmaceutical companies, including Johnson & Johnson and JPI, have been filed in state court by the state Attorneys General in Louisiana, Mississippi, Missouri, New Mexico, Ohio and Oklahoma. Complaints against the manufacturers also have been filed in state or federal court by city, county and local government agencies in the following states: Arkansas; California; Connecticut; Florida; Georgia; Illinois; Kentucky; Louisiana; Mississippi; Missouri; Nevada; New Hampshire; New Jersey; New Mexico; New York; Ohio; Oklahoma; Oregon; Pennsylvania; Tennessee; Texas; Washington and West Virginia. These actions allege a variety of claims related to opioids marketing practices, including false advertising, unfair competition, public nuisance, consumer fraud violations, deceptive acts and practices, false claims and unjust enrichment. The suits generally seek penalties and/or injunctive and monetary relief. These cases are in early stages of litigation. In October 2017, Johnson & Johnson and JPI were both served with a motion to consolidate 66 pending matters into a federal Multi District Litigation in the Southern District of Ohio. In December 2017, the MDL was approved in the Northern District of Ohio and there are approximately 190 cases that have been transferred to the MDL.

Johnson & Johnson, JPI and other pharmaceutical companies have also received subpoenas or requests for information related to opioids marketing practices from the following state Attorneys General: Alaska, Indiana, New Hampshire, New Jersey, Tennessee and Washington. In September 2017, Johnson & Johnson and JPI were contacted by the Texas and Colorado Attorney General's Offices on behalf of approximately 38 states regarding a multi-state Attorney General investigation. The multi-state coalition served Johnson & Johnson and JPI with subpoenas as part of the investigation. Johnson & Johnson and JPI have also received requests for information from the ranking minority member of the United States Senate Committee on Homeland Security and Governmental Affairs regarding the sales, marketing, and educational strategies related to the promotion of opioids use.

Other

In August 2012, DePuy Orthopaedics, Inc., DePuy, Inc. (now DePuy Synthes, Inc.), and Johnson & Johnson Services, Inc. received an informal request from the United States Attorney's Office for the District of Massachusetts and the Civil Division of the United States Department of Justice (the United States) for the production of materials relating to the DePuy ASR™ XL Hip device. In July 2014, the United States notified the United States District Court for the District of Massachusetts that it had declined to intervene in a qui tam case filed pursuant to the False Claims Act against the companies. In February 2016, the District Court granted the companies' motion to dismiss with prejudice, unsealed the qui tam complaint, and denied the qui tam relators' request for leave to file a further amended complaint. The qui tam relators appealed the case to the United States Court of Appeals for the First Circuit. In July 2017, the First Circuit affirmed the District Court's dismissal in part, reversed in part, and affirmed the decision to deny the relators' request to file a third amended complaint. The relators' remaining claims are now pending before the District Court.

Since October 2013, a group of State Attorneys General have issued Civil Investigative Demands relating to the development, sales and marketing of several of DePuy Orthopaedics, Inc.'s hip products. The states are seeking monetary and injunctive relief, and DePuy Orthopaedics, Inc. has entered into a tolling agreement with the states. In July 2014, the Oregon Department of Justice, which was investigating these matters independently of the other states, announced a settlement of its ASR™ XL Hip device investigation with the State of Oregon.

In October 2012, Johnson & Johnson was contacted by the California Attorney General's office regarding a multi-state Attorney General investigation of the marketing of surgical mesh products for hernia and urogynecological purposes by Johnson & Johnson's subsidiary, Ethicon, Inc. (Ethicon). Johnson & Johnson and Ethicon have since entered into a series of tolling agreements with the 47 states and the District of Columbia participating in the multi-state investigation and have responded to Civil Investigative Demands served by certain of the participating states. The states are seeking monetary and injunctive relief. In May 2016, California and Washington filed civil complaints against Johnson & Johnson, Ethicon Inc. and Ethicon US, LLC alleging violations of their consumer protection statutes. Similar complaints were filed against the companies by Kentucky in August 2016 and by Mississippi in October 2017. Johnson & Johnson and Ethicon have entered into a new tolling agreement with the remaining 43 states and the District of Columbia.

In December 2012, Therakos, Inc. (Therakos), formerly a subsidiary of Johnson & Johnson and part of the Ortho-Clinical Diagnostics, Inc. (OCD) franchise, received a letter from the civil division of the United States Attorney's Office for the Eastern District of Pennsylvania informing Therakos that the United States Attorney's Office was investigating the sales and marketing of Uvadex® (methoxsalen) and the Uvar Xts® and Cellex® Systems during the period 2000 to the present. The United States Attorney's Office requested that OCD and Johnson & Johnson preserve documents that could relate to the investigation. Therakos was subsequently acquired by an affiliate of Gores Capital Partners III, L.P. in January 2013, and OCD was divested in June 2014. Following the divestiture of OCD, Johnson & Johnson retains OCD's portion of any liability that may result from the investigation for activity that occurred prior to the sale of Therakos. In March 2014 and March 2016, the United States Attorney's Office requested that Johnson & Johnson produce certain documents, and Johnson & Johnson is cooperating with those requests.

In June 2014, the Mississippi Attorney General filed a complaint in Chancery Court of The First Judicial District of Hinds County, Mississippi against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (now Johnson & Johnson Consumer Inc.) (JJCI). The complaint alleges that defendants failed to disclose alleged health risks associated with female consumers' use of talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product no longer sold by JJCI) and seeks injunctive and monetary relief. The parties have agreed to adjourn the trial date and currently expect the trial to be re-scheduled to the fall of 2018.

In March 2016, Janssen Pharmaceuticals, Inc. (JPI) received a Civil Investigative Demand from the United States Attorney's Office for the Southern District of New York related to JPI's contractual relationships with pharmacy benefit managers over the

period from January 1, 2006 to the present with regard to certain of JPI's pharmaceutical products. The demand was issued in connection with an investigation under the False Claims Act.

In January 2017, Janssen Pharmaceuticals, Inc. (JPI) received a Civil Investigative Demand from the United States Department of Justice relating to allegations concerning the sales and marketing practices of OLYSIO®. In December 2017, Johnson & Johnson and JPI were served with a whistleblower lawsuit filed in the United States District Court for the Central District of California alleging the off-label promotion of OLYSIO® and additional products, including NUCYNTA®, XARELTO®, LEVAQUIN® and REMICADE®. At this time, the federal and state governments have declined to intervene and the lawsuit, which is related to the Civil Investigative Demand, is being prosecuted by a former company employee. JPI filed a motion to dismiss in the United States District Court for the Central District of California in January 2018.

In February 2017, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts seeking the production of records pertaining to payments to any 501(c)(3) charitable organization that provides financial assistance to Medicare patients. Multiple pharmaceutical companies have publicly reported receipt of subpoenas and ongoing inquiries similar to this one and the one described below.

Actelion Pharmaceuticals US, Inc. (Actelion US), received a subpoena in May 2016, with follow-up requests in June and December 2016, from the United States Attorney's Office for the District of Massachusetts. The subpoena seeks the production of records pertaining to Actelion US' payments to 501(c)(3) charitable organizations that provide financial assistance to Medicare patients.

In March 2017, Janssen Biotech, Inc. received a Civil Investigative Demand from the United States Department of Justice regarding a False Claims Act investigation concerning management and advisory services provided to rheumatology and gastroenterology practices that purchased REMICADE® or SIMPONI ARIA®.

In April and September 2017, Johnson & Johnson received subpoenas from the United States Attorney for the District of Massachusetts seeking documents broadly relating to pharmaceutical copayment support programs for DARZALEX®, OLYSIO®, REMICADE®, SIMPONI®, STELARA® and ZYTIGA®. The subpoenas also seek documents relating to Average Manufacturer Price and Best Price reporting to the Center for Medicare and Medicaid Services related to those products, as well as rebate payments to state Medicaid agencies.

In June 2017, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts seeking information regarding practices pertaining to the sterilization of DePuy Synthes, Inc. spinal implants at three hospitals in Boston as well as interactions of Company employees with physicians at these hospitals. Johnson & Johnson is producing documents in response to this subpoena.

From time to time, Johnson & Johnson has received requests from a variety of United States Congressional Committees to produce information relevant to ongoing congressional inquiries. It is the policy of Johnson & Johnson to cooperate with these inquiries by producing the requested information.

GENERAL LITIGATION

In June 2009, following the public announcement that Ortho-Clinical Diagnostics, Inc. (OCD) had received a grand jury subpoena from the United States Department of Justice, Antitrust Division, in connection with an investigation that has since been closed, multiple class action complaints were filed against OCD by direct purchasers seeking damages for alleged price fixing. These cases were consolidated for pre-trial purposes in the United States District Court for the Eastern District of Pennsylvania as In re Blood Reagent Antitrust Litigation. Following the appeal and reversal of its initial grant of a motion for class certification, on remand, the District Court in October 2015 again granted a motion by the plaintiffs for class certification. In July 2017, the Court issued an opinion granting in part and denying in part OCD's motion for summary judgment. The Court granted summary judgment concerning allegations of price fixing in 2005 and 2008, and denied summary judgment concerning allegations of price fixing in 2001. Trial has been set for June 2018. OCD was divested in 2014 and Johnson & Johnson retained any liability that may result from these cases.

In June 2011, DePuy Orthopaedics, Inc. (DePuy) filed suit against Orthopaedic Hospital (OH) in the United States District Court for the Northern District of Indiana seeking a declaratory judgment that DePuy did not owe OH royalties under a 1999 development agreement. In January 2012, OH filed a breach of contract case in California federal court, which was later consolidated with the Indiana case. In February 2014, OH brought suit for patent infringement relating to the same technology, and that action was also consolidated with the Indiana case. In August 2017, the court denied DePuy's motions for summary judgment. A trial date has not been set.

In September 2011, Johnson & Johnson, Johnson & Johnson Inc. and McNeil Consumer Healthcare Division of Johnson & Johnson Inc. received a Notice of Civil Claim filed by Nick Field in the Supreme Court of British Columbia, Canada (the BC Civil Claim). The BC Civil Claim is a putative class action brought on behalf of persons who reside in British Columbia and who purchased during the period between September 20, 2001 and in or about December 2010 one or more various McNeil infants' or children's over-the-counter medicines that were manufactured at the Fort Washington, Pennsylvania facility. The BC Civil Claim alleges that the defendants violated the BC Business Practices and Consumer Protection Act, and other Canadian statutes and common laws, by selling medicines that were allegedly not safe and/or effective or did not comply with Canadian Good Manufacturing Practices. The class certification hearing scheduled for October 2015 was adjourned, and the Court entered a Consent Order of Dismissal in November 2017 concluding this action. In addition, in April 2016, a putative class action was filed against Johnson & Johnson, Johnson & Johnson Sales and Logistics Company, LLC and McNeil PPC, Inc. (now known as Johnson & Johnson Consumer, Inc.) in New Jersey Superior Court, Camden County on behalf of persons who reside in the state of New Jersey who purchased various McNeil over-the-counter products from December 2008 through the present. The complaint alleges violations of the New Jersey Consumer Fraud Act. Following the grant of a motion to dismiss and the filing of an amended complaint, in May 2017, the Court denied a motion to dismiss the amended complaint. Discovery is underway.

In May 2014, two purported class actions were filed in federal court, one in the United States District Court for the Central District of California and one in the United States District Court for the Southern District of Illinois, against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (now Johnson & Johnson Consumer Inc.) (JJCI) alleging violations of state consumer fraud statutes based on nondisclosure of alleged health risks associated with talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product no longer sold by JJCI). Both cases seek injunctive relief and monetary damages; neither includes a claim for personal injuries. In October 2016, both cases were transferred to the United States District Court for the District Court of New Jersey as part of a newly created federal multi-district litigation. In July 2017, the Court granted Johnson & Johnson's and JJCI's motion to dismiss one of the cases. The plaintiff has appealed. In September 2017, the plaintiff in the second case voluntarily dismissed their complaint.

In August 2014, United States Customs and Border Protection (US CBP) issued a Penalty Notice against Janssen Ortho LLC (Janssen Ortho), assessing penalties for the alleged improper classification of darunavir ethanolate (the active pharmaceutical ingredient in PREZISTA®) in connection with its importation into the United States. In October 2014, Janssen Ortho submitted a Petition for Relief in response to the Penalty Notice. In May 2015, US CBP issued an Amended Penalty Notice assessing substantial penalties and Janssen Ortho filed a Petition for Relief in July 2015.

In March and April 2015, over 30 putative class action complaints were filed by contact lens patients in a number of courts around the United States against Johnson & Johnson Vision Care, Inc. (JJVCI) and other contact lens manufacturers, distributors, and retailers, alleging vertical and horizontal conspiracies to fix the retail prices of contact lenses. The complaints allege that the manufacturers reached agreements with each other and certain distributors and retailers concerning the prices at which some contact lenses could be sold to consumers. The plaintiffs are seeking damages and injunctive relief. All of the class action cases were transferred to the United States District Court for the Middle District of Florida in June 2015. The plaintiffs filed a consolidated class action complaint in November 2015. In June 2016, the Court denied motions to dismiss filed by JJVCI and other defendants. Discovery is ongoing. In March 2017, the plaintiffs filed a motion for class certification.

In August 2015, two third-party payors filed a purported class action in the United States District Court for the Eastern District of Louisiana against Janssen Research & Development, LLC, Janssen Ortho LLC, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Johnson & Johnson (as well as certain Bayer entities), alleging that the defendants improperly marketed and promoted XARELTO® as safer and more effective than less expensive alternative medications while failing to fully disclose its risks. The complaint seeks damages.

In May 2017, a purported class action was filed in the United States District Court for the Western District of Washington against Lifescan Inc., Johnson & Johnson, other diabetes test strip manufacturers and certain Pharmacy Benefit Managers (PBMs). The complaint alleges that consumers paid inflated prices for glucose monitor test strips as a consequence of undisclosed rebates and other incentives paid by manufacturers to PBMs. The complaint includes RICO, ERISA, and state consumer protection claims. The complaint seeks equitable relief and damages. In November 2017, the case was ordered transferred to United States District Court for the District of New Jersey.

In May 2017, Lonza Sales AG (Lonza) filed a Request for Arbitration with the London Court of International Arbitration against Janssen Research & Development, LLC (Janssen). Lonza alleges that Janssen breached a 2005 agreement between the parties by sublicensing certain Lonza technology used in the manufacture of daratumumab without Lonza's consent. Lonza seeks monetary damages.

In September 2017, Strategic Products Group, Inc. (SPG) filed an antitrust complaint against Lifescan, Inc. and Lifescan Scotland, Ltd. (collectively, Lifescan) in the United States District Court for the Northern District of Florida (Pensacola Division). SPG, the exclusive distributor of Unistrip blood glucose meter test strips, alleges that Lifescan has monopolized or is attempting to monopolize the market for blood glucose meter test strips compatible with certain Lifescan meters. The complaint seeks damages.

In September 2017, Pfizer, Inc. (Pfizer) filed an antitrust complaint against Johnson & Johnson and Janssen Biotech, Inc. (collectively Janssen) in United States District Court for the Eastern District of Pennsylvania. Pfizer alleges that Janssen has violated federal antitrust laws through its contracting strategies for REMICADE®. The complaint seeks damages and injunctive relief. In November 2017, Janssen moved to dismiss the complaint.

Beginning in September 2017, multiple purported class actions were filed against Johnson & Johnson and Janssen Biotech, Inc. (collectively Janssen) alleging that Janssen's REMICADE® contracting strategies violated federal and state antitrust and consumer laws and seeking damages and injunctive relief. In November 2017, the cases were consolidated for pre-trial purposes in United States District Court for the Eastern District of Pennsylvania as In re Remicade Antitrust Litigation.

In October 2017, certain United States service members and their families brought a complaint against a number of pharmaceutical and medical devices companies, including Johnson & Johnson and certain of its subsidiaries, alleging that the defendants violated the United States Anti-Terrorism Act. The complaint alleges that the defendants provided funding for terrorist organizations through their sales practices pursuant to pharmaceutical and medical device contracts with the Iraqi Ministry of Health.

Andover Healthcare, Inc. filed a Lanham act case against Johnson & Johnson Consumer Inc. in April 2017 in the United Stated District Court for the District of Massachusetts. Andover asserts that the claim "not made with natural rubber latex" on COACH® Sports Wrap, BAND-AID® Brand SECURE-FLEX® Wrap and BAND-AID® Brand HURT-FREE® Wrap is false. Andover seeks actual damages and pre-judgment interest thereon, disgorgement of profits, treble damages, attorney's fees and injunctive relief. The Court denied a motion to dismiss, an answer was filed and discovery is underway.

In February 2018, a securities class action lawsuit was filed against Johnson & Johnson in the United States District Court for the District of New Jersey alleging that Johnson & Johnson violated the federal Securities laws by failing to adequately disclose the alleged asbestos contamination in body powders containing talc, primarily JOHNSONS® Baby Powder. The lawsuit was assigned to the District Court Judge managing the personal injury multi-district litigation.

Johnson & Johnson or its subsidiaries are also parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the cost of past and/or future remediation.

22. Restructuring

The Company announced restructuring actions in its Medical Devices segment to better serve the needs of patients and customers in today's evolving healthcare marketplace. The Company is undertaking actions to strengthen its go-to-market model, accelerate the pace of innovation, further prioritize key platforms and geographies, and streamline operations while maintaining high quality standards.

The Company estimates that, in connection with its plans, it will record pre-tax restructuring related charges of approximately $2.0 billion to $2.4 billion. In 2017, the Company recorded a pre-tax charge of $760 million, of which $88 million was included in cost of products sold and $363 million was included in other (income) expense. See table below for additional details. Total project costs of $2.0 billion have been recorded since the restructuring has been announced.

Additionally, as part of the plan, the Company expects that the restructuring actions will result in position eliminations of approximately 4 to 6 percent of the Medical Devices segment's global workforce over the next 15 months. Approximately 2,400 positions have been eliminated of which 1,700 received separation payments since the restructuring announcement.

The Company estimates that approximately one-half of the cumulative pre-tax costs will result in cash outlays, including approximately $400 million of employee severance. Approximately one half of the cumulative pre-tax costs are non-cash, relating primarily to facility rationalization, inventory write-offs and intangible asset write-offs.

The following table summarizes the severance charges and the associated spending under this initiative through the fiscal year ended 2017:

(Dollars in Millions)		Severance	Asset Write-offs	Other**	Total
2015 restructuring charge	$	484	86	20	590
2015 activity			(86)	(3)	(89)
Reserve balance, January 3, 2016		484	—	17	501
2016 activity		(104)	—	(16)	(120)
Reserve balance, January 1, 2017		380	—	1	381
Current year activity:					
Charges			194	656	850
Cash payments		(61)		(619)	(680)
Settled non cash			(194)		(194)
Accrual adjustment		(90)			(90)
Reserve balance, December 31, 2017*	$	229	—	38	267

*Cash outlays for severance are expected to be substantially paid out over the next 18 months in accordance with the Company's plans and local laws.
**Other includes project expense such as salaries for employees supporting the initiative and consulting expenses.

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of Johnson & Johnson

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Johnson & Johnson and its subsidiaries as of December 31, 2017 and January 1, 2017, and the related consolidated statements of earnings, of comprehensive income, of equity, and of cash flows for each of the three years in the period ended December 31, 2017, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and January 1, 2017**,** and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017 based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Change in Accounting Principle

As discussed in Note 1 to the consolidated financial statements, the Company changed the manner in which it accounts for and presents certain elements of share based payments in 2016.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As described in Management's Report on Internal Control over Financial Reporting, management has excluded Abbott Medical Optics and Actelion Ltd. from its assessment of internal control over financial reporting as of December 31, 2017, because they were acquired by the Company in purchase business combinations during 2017. We have also excluded Abbott Medical Optics and Actelion Ltd. from our audit of internal control over financial reporting. Abbott Medical Optics and Actelion Ltd. are wholly-owned subsidiaries whose total assets and total revenues excluded from management's assessment and our audit of internal control over financial reporting represent approximately 1% and 1% of total assets, respectively and approximately 1% and 2% of total revenues, respectively, of the related consolidated financial statement amounts as of and for the year ended December 31, 2017.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

Florham Park, New Jersey
February 21, 2018

We have served as the Company's auditor since at least 1920. We have not determined the specific year we began serving as auditor of the Company.

Management's Report on Internal Control Over Financial Reporting

Under Section 404 of the Sarbanes-Oxley Act of 2002, management is required to assess the effectiveness of the Company's internal control over financial reporting as of the end of each fiscal year and report, based on that assessment, whether the Company's internal control over financial reporting is effective.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is designed to provide reasonable assurance as to the reliability of the Company's financial reporting and the preparation of external financial statements in accordance with generally accepted accounting principles.

Internal controls over financial reporting, no matter how well designed, have inherent limitations. Therefore, internal control over financial reporting determined to be effective can provide only reasonable assurance with respect to financial statement preparation and may not prevent or detect all misstatements. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management has assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2017. In making this assessment, the Company used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework (2013)." These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. The Company's assessment included extensive documenting, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

The Company acquired Abbott Medical Optics (AMO), a wholly-owned subsidiary of Abbott Laboratories and Actelion Ltd. and its consolidated subsidiaries (Actelion) in February and June 2017, respectively. Actelion's total assets, excluding intangible assets and goodwill, and total revenues represented approximately 1% and 2%, respectively, of the related consolidated financial statements as of and for the period ended December 31, 2017. AMO's total assets, excluding intangible assets and goodwill, and total revenues represented approximately 1% and 1%, respectively, of the related consolidated financial statements as of and for the period ended December 31, 2017. As the acquisitions occurred in the fiscal year 2017, the scope of the Company's assessment of the design and effectiveness of internal control over financial reporting for the fiscal year 2017 excluded the above mentioned acquisitions. This exclusion is in accordance with the SEC's general guidance that an assessment of a recently acquired business may be omitted from the scope in the year of acquisition.

Based on the Company's processes and assessment, as described above, management has concluded that, as of December 31, 2017, the Company's internal control over financial reporting was effective.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2017 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which appears herein.

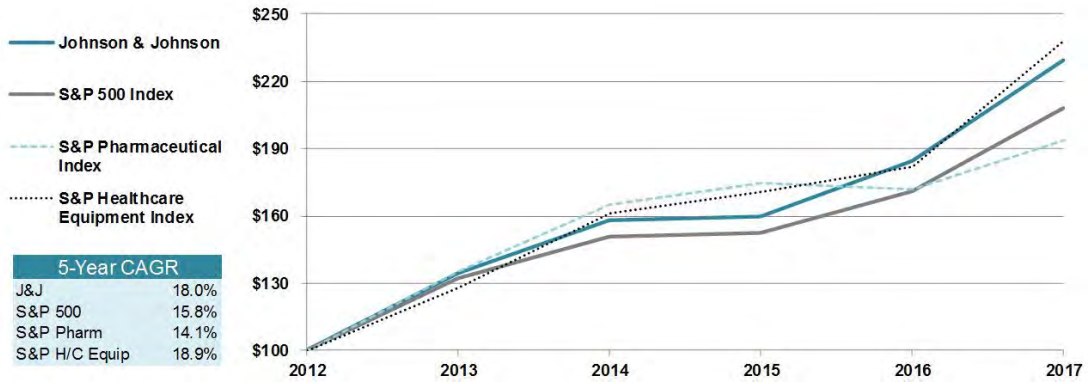
/s/ Alex Gorsky
Alex Gorsky
Chairman, Board of Directors
Chief Executive Officer

/s/ Dominic J. Caruso
Dominic J. Caruso
Executive Vice President, Chief Financial Officer

Shareholder Return Performance Graphs

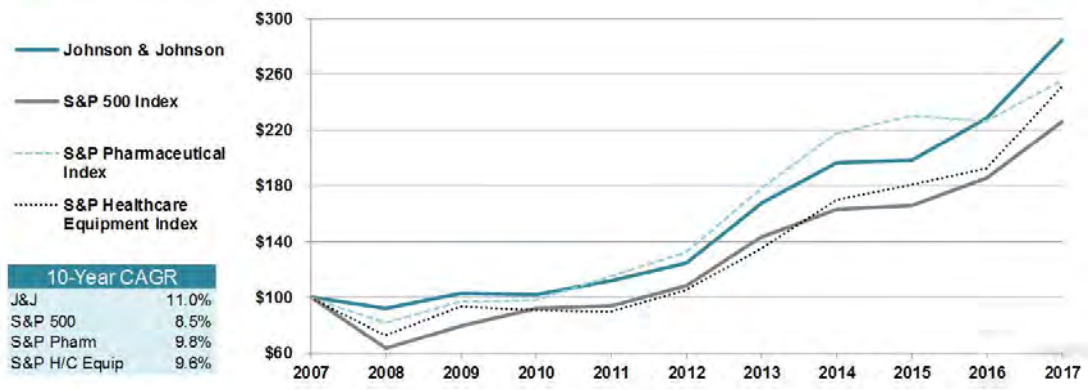
Set forth below are line graphs comparing the cumulative total shareholder return on the Company's Common Stock for periods of five years and ten years ending December 31, 2017, against the cumulative total return of the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index. The graphs and tables assume that $100 was invested on December 31, 2012 and December 31, 2007 in each of the Company's Common Stock, the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index and that all dividends were reinvested.

5 Year Shareholder Return Performance J&J vs. Indices



	2012	2013	2014	2015	2016	2017
Johnson & Johnson	$100.00	$134.62	$157.95	$159.78	$184.26	$229.23
S&P 500 Index	$100.00	$132.37	$150.48	$152.55	$170.78	$208.05
S&P Pharmaceutical Index	$100.00	$135.23	$165.27	$174.84	$172.10	$193.74
S&P Healthcare Equipment Index	$100.00	$127.69	$161.24	$170.88	$181.96	$238.17

10 Year Shareholder Return Performance J&J vs. Indices



	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Johnson & Johnson	$100.00	$92.23	$102.63	$102.03	$112.13	$124.27	$167.28	$196.28	$198.55	$228.97	$284.85
S&P 500 Index	$100.00	$63.00	$79.66	$91.66	$93.59	$108.56	$143.70	$163.36	$165.60	$185.40	$225.85
S&P Pharmaceutical Index	$100.00	$81.80	$97.03	$97.78	$115.15	$131.76	$178.18	$217.77	$230.37	$226.77	$255.27
S&P Healthcare Equipment Index	$100.00	$72.36	$93.19	$90.66	$89.94	$105.47	$134.67	$170.06	$180.22	$191.91	$251.20

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE 873

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures. At the end of the period covered by this Report, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Alex Gorsky, Chairman and Chief Executive Officer, and Dominic J. Caruso, Executive Vice President, Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Gorsky and Caruso concluded that, as of the end of the period covered by this Report, the Company's disclosure controls and procedures were effective

Reports on Internal Control Over Financial Reporting. The information called for by this item is incorporated herein by reference to "Management's Report on Internal Control Over Financial Reporting", and the attestation regarding internal controls over financial reporting included in the "Report of Independent Registered Public Accounting Firm" included in Item 8 of this Report.

Changes in Internal Control Over Financial Reporting. During the fiscal quarter ended December 31, 2017, there were no changes in the Company's internal control over financial reporting identified in connection with the evaluation required under Rules 13a-15 and 15d-15 under the Exchange Act that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

The Company is implementing a multi-year, enterprise-wide initiative to integrate, simplify and standardize processes and systems for the human resources, information technology, procurement, supply chain and finance functions. These are enhancements to support the growth of the Company's financial shared service capabilities and standardize financial systems. This initiative is not in response to any identified deficiency or weakness in the Company's internal control over financial reporting. In response to this initiative, the Company has and will continue to align and streamline the design and operation of its financial control environment.

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information called for by this item is incorporated herein by reference to the discussion of the Audit Committee under the caption "Item 1. Election of Directors - Board Committees"; and the material under the captions "Item 1. Election of Directors" and "Stock Ownership and Section 16 Compliance – Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement; and the material under the caption "Executive Officers of the Registrant" in Part I of this Report.

The Company's Code of Business Conduct, which covers all employees (including the Chief Executive Officer, Chief Financial Officer and Controller), meets the requirements of the SEC rules promulgated under Section 406 of the Sarbanes-Oxley Act of 2002. The Code of Business Conduct is available on the Company's website at *www.jnj.com/code-of-business-conduct*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code of Business Conduct or any waiver of the Code granted to the Chief Executive Officer, the Chief Financial Officer or the Controller will be posted on the Company's website at *www.investor.jnj.com/gov.cfm* within five business days (and retained on the website for at least one year).

In addition, the Company has adopted a Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers. The Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers is available on the Company's website at *www.investor.jnj.com/gov/boardconduct.cfm*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code or any waiver of the Code granted to any member of the Board of Directors or any executive officer will be posted

on the Company's website at *www.investor.jnj.com/gov.cfm* within five business days (and retained on the website for at least one year).

Item 11. EXECUTIVE COMPENSATION

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1. Election of Directors – Director Compensation," "Compensation Committee Report," "Compensation Discussion and Analysis" and "Executive Compensation Tables" in the Proxy Statement.

The material incorporated herein by reference to the material under the caption "Compensation Committee Report" in the Proxy Statement shall be deemed furnished, and not filed, in this Report and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, as a result of this furnishing, except to the extent that the Company specifically incorporates it by reference.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information called for by this item is incorporated herein by reference to the material under the caption "Item 1. Stock Ownership and Section 16 Compliance" in the Proxy Statement; and Note 17 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements in Item 8 of this Report.

Equity Compensation Plan Information

The following table provides certain information as of December 31, 2017 concerning the shares of the Company's Common Stock that may be issued under existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights	Weighted Average Exercise Price of Outstanding Options and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans[2][3]
Equity Compensation Plans Approved by Security Holders[1]	134,091,342	$75.11	389,083,761
Equity Compensation Plans Not Approved by Security Holders	-	-	-
Total	134,091,342	$75.11	389,083,761

(1) Included in this category are the following equity compensation plans which have been approved by the Company's shareholders: 2005 Long-Term Incentive Plan and 2012 Long-Term Incentive Plan.

(2) This column excludes shares reflected under the column "Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights."

(3) The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1. Election of Directors - Director Independence" and "Related Person Transactions" in the Proxy Statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information called for by this item is incorporated herein by reference to the material under the caption "Item 3. Ratification of Appointment of Independent Registered Public Accounting Firm" in the Proxy Statement.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this report:

1. *Financial Statements*

   Consolidated Balance Sheets at end of Fiscal Years 2017 and 2016

   Consolidated Statements of Earnings for Fiscal Years 2017, 2016 and 2015

   Consolidated Statements of Comprehensive Income for Fiscal Years 2017, 2016 and 2015

   Consolidated Statements of Equity for Fiscal Years 2017, 2016 and 2015

   Consolidated Statements of Cash Flows for Fiscal Years 2017, 2016 and 2015

   Notes to Consolidated Financial Statements

   Report of Independent Registered Public Accounting Firm

   All schedules are omitted because they are not applicable or the required information is included in the financial statements or notes.

2. *Exhibits* Required *to be Filed by Item 60l of Regulation S-K*

   The information called for by this item is incorporated herein by reference to the Exhibit Index in this Report.

Item 16. FORM 10-K SUMMARY

Registrants may voluntarily include a summary of information required by Form 10-K under this Item 16. The Company has elected not to include such summary information.

SIGNATURES

Pursuant to the requirements of Section 13 of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 21, 2018

JOHNSON & JOHNSON
(Registrant)

By /s/ A. Gorsky
A. Gorsky, Chairman, Board of Directors,
and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ A. Gorsky A. Gorsky	Chairman, Board of Directors Chief Executive Officer (Principal Executive Officer)	February 21, 2018
/s/ D. J. Caruso D. J. Caruso	Chief Financial Officer (Principal Financial Officer)	February 21, 2018
/s/ R. A. Kapusta R. A. Kapusta	Controller and Chief Accounting Officer (Principal Accounting Officer)	February 21, 2018
/s/ M. C. Beckerle M. C. Beckerle	Director	February 21, 2018
/s/ D. S. Davis D. S. Davis	Director	February 21, 2018
/s/ I. E. L. Davis I. E. L. Davis	Director	February 21, 2018

Signature	Title	Date
/s/ M. B. McClellan M. B. McClellan	Director	February 21, 2018
/s/ A. M. Mulcahy A. M. Mulcahy	Director	February 21, 2018
/s/ W. D. Perez W. D. Perez	Director	February 21, 2018
/s/ C. Prince C. Prince	Director	February 21, 2018
/s/ A. E. Washington A. E. Washington	Director	February 21, 2018
/s/ R. A. Williams R. A. Williams	Director	February 21, 2018

EXHIBIT INDEX

Reg. S-K Exhibit Table Item No.	Description of Exhibit
3(i)	Restated Certificate of Incorporation effective February 19, 2016 — Incorporated herein by reference to Exhibit 3(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.
3(ii)	By-Laws of the Company, as amended effective January 26, 2016 — Incorporated herein by reference to Exhibit 3.1 the Registrant's Form 8-K Current Report filed January 26, 2016.
4(a)	Upon the request of the Securities and Exchange Commission, the Registrant will furnish a copy of all instruments defining the rights of holders of long-term debt of the Registrant.
10(a)	2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 4 of the Registrant's S-8 Registration Statement filed with the Commission on May 10, 2005 (file no. 333-124785).*
10(b)	Form of Stock Option Certificate under the 2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 8-K Current Report filed January 13, 2012.*
10(c)	2012 Long-Term Incentive Plan — Incorporated herein by reference to Appendix A of the Registrant's Proxy Statement filed with the Commission on March 15, 2017 .*
10(d)	Form of Stock Option Certificate, Restricted Share Unit Certificate and Performance Share Unit Certificate under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.2, 10.3 and 10.4 of the Registrant's Form 10-Q Quarterly Report filed May 7, 2012.*
10(e)	Johnson & Johnson Executive Incentive Plan (as amended) — Incorporated herein by reference to Exhibit 10(f) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 31, 2000.*
10(f)	Domestic Deferred Compensation (Certificate of Extra Compensation) Plan — Incorporated herein by reference to Exhibit 10(g) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2003.*
10(g)	Amendments to the Certificate of Extra Compensation Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(h)	2009 Certificates of Long-Term Performance Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 27, 2009.*
10(i)	Amended and Restated Deferred Fee Plan for Directors — Incorporated herein by reference to Exhibit 10(k) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 1, 2012.*
10(j)	The Johnson & Johnson Executive Income Deferral Plan (Amended and Restated) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*
10(k)	Excess Savings Plan — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 29, 1996.*
10(l)	Amendments to the Johnson & Johnson Excess Savings Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(p) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2008.*
10(m)**	Excess Benefit Plan (Supplemental Retirement Plan) — Incorporated herein by reference to Exhibit 10(h) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 1993.*
10(n)	Amendments to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(r) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2008.*
10(o)	Amendment to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies, effective as of January 1, 2015 — Incorporated herein by reference to Exhibit 10(q) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2014.*
10(p)**	Executive Life Plan Agreement — Incorporated herein by reference to Exhibit 10(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 1993.*
10(q)	Executive Life Plan Agreement Closure Letter — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended March 29, 2015.*
10(r)	Employment Agreement for Dr. Paulus Stoffels - Incorporated herein by reference to Exhibit 10.2 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*
10(s)	Summary of Employment Arrangements for Sandra E. Peterson — Incorporated herein by reference to Exhibit 10(t) of the Registrant's Form 10-K Annual Report for the year ended December 30, 2012.*
10(t)	Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies, Amended and Restated as of October 1, 2014 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 28, 2014.*

Reg. S-K Exhibit Table Item No.	Description of Exhibit
10(u)	First Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended June 28, 2015.*
10(v)	Second Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10(x) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.*
12	Statement of Computation of Ratio of Earnings to Fixed Charges — Filed with this document.
21	Subsidiaries - Filed with this document.
23	Consent of Independent Registered Public Accounting Firm — Filed with this document.
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
32.1	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
32.2	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
101	XBRL (Extensible Business Reporting Language) The following materials from this Report for the fiscal year ended December 31, 2017, formatted in Extensive Business Reporting Language (XBRL): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Earnings, (iii) Consolidated Statements of Comprehensive Income, (iv) Consolidated Statements of Equity, (v) Consolidated Statements of Cash Flows, and (vi) Notes to the Consolidated Financial Statements.

* Management contract or compensatory plan.

** Paper filing.

A copy of any of the Exhibits listed above will be provided without charge to any shareholder submitting a written request specifying the desired exhibit(s) to the Secretary at the principal executive offices of the Company.

Exhibit “J16”

This is Exhibit “J16” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 30, 2018 **Commission file number 1-3215**

JOHNSON & JOHNSON

(Exact name of registrant as specified in its charter)

New Jersey	**22-1024240**
(State of incorporation)	(I.R.S. Employer Identification No.)
One Johnson & Johnson Plaza **New Brunswick, New Jersey**	**08933**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(732) 524-0400**

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT

Title of each class	Name of each exchange on which registered
Common Stock, Par Value $1.00	New York Stock Exchange
4.75% Notes Due November 2019	New York Stock Exchange
0.250% Notes Due January 2022	New York Stock Exchange
0.650% Notes Due May 2024	New York Stock Exchange
5.50% Notes Due November 2024	New York Stock Exchange
1.150% Notes Due November 2028	New York Stock Exchange
1.650% Notes Due May 2035	New York Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☑	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☐
Emerging growth company ☐	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $325 billion.

On February 15, 2019, there were 2,663,138,579 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Parts I and III:	Portions of registrant's proxy statement for its 2019 annual meeting of shareholders filed within 120 days after the close of the registrant's fiscal year (the "Proxy Statement"), are incorporated by reference to this report on Form 10-K (this "Report").

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and Johnson & Johnson's other publicly available documents contain "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Management and representatives of Johnson & Johnson and its subsidiaries (the "Company") also may from time to time make forward-looking statements. Forward-looking statements do not relate strictly to historical or current facts and reflect management's assumptions, views, plans, objectives and projections about the future. Forward-looking statements may be identified by the use of words such as "plans," "expects," "will," "anticipates," "estimates" and other words of similar meaning in conjunction with, among other things: discussions of future operations; expected operating results and financial performance; impact of planned acquisitions and dispositions; the Company's strategy for growth; product development; regulatory approvals; market position and expenditures.

Because forward-looking statements are based on current beliefs, expectations and assumptions regarding future events, they are subject to uncertainties, risks and changes that are difficult to predict and many of which are outside of the Company's control. Investors should realize that if underlying assumptions prove inaccurate, or known or unknown risks or uncertainties materialize, the Company's actual results and financial condition could vary materially from expectations and projections expressed or implied in its forward-looking statements. Investors are therefore cautioned not to rely on these forward-looking statements. Risks and uncertainties include, but are not limited to:

Risks Related to Product Development, Market Success and Competition

- Challenges and uncertainties inherent in innovation and development of new and improved products and technologies on which the Company's continued growth and success depend, including uncertainty of clinical outcomes, additional analysis of existing clinical data, obtaining regulatory approvals, health plan coverage and customer access, and initial and continued commercial success;
- Challenges to the Company's ability to obtain and protect adequate patent and other intellectual property rights for new and existing products and technologies in the United States and other important markets;
- The impact of patent expirations, typically followed by the introduction of competing biosimilars and generics and resulting revenue and market share losses;
- Increasingly aggressive and frequent challenges to the Company's patents by competitors and others seeking to launch competing generic, biosimilar or other products and increased receptivity of courts, the United States Patent and Trademark Office and other decision makers to such challenges, potentially resulting in loss of market exclusivity and rapid decline in sales for the relevant product sooner than expected;
- Competition in research and development of new and improved products, processes and technologies, which can result in product and process obsolescence;
- Competition to reach agreement with third parties for collaboration, licensing, development and marketing agreements for products and technologies;
- Competition based on cost-effectiveness, product performance, technological advances and patents attained by competitors; and
- Allegations that the Company's products infringe the patents and other intellectual property rights of third parties, which could adversely affect the Company's ability to sell the products in question and require the payment of money damages and future royalties.

Risks Related to Product Liability, Litigation and Regulatory Activity

- Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the United States Food and Drug Administration (or international counterparts), declining sales, reputational damage, increased litigation expense and share price impact;
- Impact, including declining sales and reputational damage, of significant litigation or government action adverse to the Company, including product liability claims and allegations related to pharmaceutical marketing practices and contracting strategies;
- Impact of an adverse judgment or settlement and the adequacy of reserves related to legal proceedings, including patent litigation, product liability, personal injury claims, securities class actions, government investigations, employment and other legal proceedings;
- Increased scrutiny of the health care industry by government agencies and state attorneys general resulting in investigations and prosecutions, which carry the risk of significant civil and criminal penalties, including, but not limited to, debarment from government business;

- Failure to meet compliance obligations in the McNEIL-PPC, Inc. Consent Decree or any other compliance agreements with governments or government agencies, which could result in significant sanctions;
- Potential changes to applicable laws and regulations affecting United States and international operations, including relating to: approval of new products; licensing and patent rights; sales and promotion of health care products; access to, and reimbursement and pricing for, health care products and services; environmental protection and sourcing of raw materials;
- Compliance with local regulations and laws that may restrict the Company's ability to manufacture or sell its products in relevant markets including, requirements to comply with medical device reporting regulations and other requirements such as the European Union's Medical Devices Regulation;
- Changes in domestic and international tax laws and regulations, including changes related to The Tax Cuts and Jobs Act in the United States, the Federal Act on Tax Reform and AHV Financing in Switzerland, increasing audit scrutiny by tax authorities around the world and exposures to additional tax liabilities potentially in excess of existing reserves; and
- Issuance of new or revised accounting standards by the Financial Accounting Standards Board and regulations by the Securities and Exchange Commission.

Risks Related to the Company's Strategic Initiatives and Healthcare Market Trends

- Pricing pressures resulting from trends toward health care cost containment, including the continued consolidation among health care providers and other market participants, trends toward managed care, the shift toward governments increasingly becoming the primary payers of health care expenses, significant new entrants to the health care markets seeking to reduce costs and government pressure on companies to voluntarily reduce costs and price increases;
- Restricted spending patterns of individual, institutional and governmental purchasers of health care products and services due to economic hardship and budgetary constraints;
- Challenges to the Company's ability to realize its strategy for growth including through externally sourced innovations, such as development collaborations, strategic acquisitions, licensing and marketing agreements, and the potential heightened costs of any such external arrangements due to competitive pressures;
- The potential that the expected strategic benefits and opportunities from any planned or completed acquisition or divestiture by the Company may not be realized or may take longer to realize than expected; and
- The potential that the expected benefits and opportunities related to past and ongoing restructuring actions may not be realized or may take longer to realize than expected.

Risks Related to Economic Conditions, Financial Markets and Operating Internationally

- Market conditions and the possibility that the Company's share repurchase program may be delayed, suspended or discontinued;
- Impact of inflation and fluctuations in interest rates and currency exchange rates and the potential effect of such fluctuations on revenues, expenses and resulting margins;
- Potential changes in export/import and trade laws, regulations and policies of the United States and other countries, including any increased trade restrictions or tariffs and potential drug reimportation legislation;
- The impact on international operations from financial instability in international economies, sovereign risk, possible imposition of governmental controls and restrictive economic policies, and unstable international governments and legal systems;
- Changes to global climate, extreme weather and natural disasters that could affect demand for the Company's products and services, cause disruptions in manufacturing and distribution networks, alter the availability of goods and services within the supply chain, and affect the overall design and integrity of the Company's products and operations; and
- The impact of armed conflicts and terrorist attacks in the United States and other parts of the world including social and economic disruptions and instability of financial and other markets.

Risks Related to Supply Chain and Operations

- Difficulties and delays in manufacturing, internally through third party providers or otherwise within the supply chain, that may lead to voluntary or involuntary business interruptions or shutdowns, product shortages, withdrawals or suspensions of products from the market, and potential regulatory action;
- Interruptions and breaches of the Company's information technology systems or those of the Company's vendors which, could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action;

- Reliance on global supply chains and production and distribution processes that are complex and subject to increasing regulatory requirements that may adversely affect supply, sourcing and pricing of materials used in the Company's products; and
- The potential that the expected benefits and opportunities related to restructuring actions contemplated for the global supply chain may not be realized or may take longer to realize than expected, including due to any required approvals from applicable regulatory authorities. Disruptions associated with the announced global supply chain actions may adversely affect supply and sourcing of materials used in the Company's products.

Investors also should carefully read the Risk Factors described in Item 1A of this Annual Report on Form 10-K for a description of certain risks that could, among other things, cause the Company's actual results to differ materially from those expressed in its forward-looking statements. Investors should understand that it is not possible to predict or identify all such factors and should not consider the risks described above and in Item 1A to be a complete statement of all potential risks and uncertainties. The Company does not undertake to publicly update any forward-looking statement that may be made from time to time, whether as a result of new information or future events or developments.

PART I

Item 1. BUSINESS

General

Johnson & Johnson and its subsidiaries (the Company) have approximately 135,100 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. Johnson & Johnson is a holding company, which has more than 260 operating companies conducting business in virtually all countries of the world. The Company's primary focus is products related to human health and well-being. Johnson & Johnson was incorporated in the State of New Jersey in 1887.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Company's three business segments: Consumer, Pharmaceutical and Medical Devices. Within the strategic parameters provided by the Committee, senior management groups at U.S. and international operating companies are each responsible for their own strategic plans and the day-to-day operations of those companies. Each subsidiary within the business segments is, with limited exceptions, managed by residents of the country where located.

Segments of Business

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. Additional information required by this item is incorporated herein by reference to the narrative and tabular descriptions of segments and operating results under: "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition" of this Report; and Note 18 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Consumer

The Consumer segment includes a broad range of products used in the baby care, oral care, beauty, over-the-counter pharmaceutical, women's health and wound care markets. Baby Care includes the JOHNSON'S® line of products. Oral Care includes the LISTERINE® product line. Major brands in Beauty include the AVEENO®; CLEAN & CLEAR®; DABAO™; JOHNSON'S® Adult; LE PETITE MARSEILLAIS®; NEUTROGENA® and OGX® product lines. Over-the-counter medicines include the broad family of TYLENOL® acetaminophen products; SUDAFED® cold, flu and allergy products; BENADRYL® and ZYRTEC® allergy products; MOTRIN® IB ibuprofen products; and the PEPCID® line of acid reflux products. Major brands in Women's Health outside of North America are STAYFREE® and CAREFREE® sanitary pads and o.b.® tampon brands. Wound Care brands include the BAND-AID® Brand Adhesive Bandages and NEOSPORIN® First Aid product lines. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world.

Pharmaceutical

The Pharmaceutical segment is focused on six therapeutic areas: Immunology (e.g., rheumatoid arthritis, inflammatory bowel disease and psoriasis), Infectious Diseases and Vaccines (e.g., HIV/AIDS), Neuroscience (e.g., mood disorders, neurodegenerative disorders and schizophrenia), Oncology (e.g., prostate cancer and hematologic malignancies), Cardiovascular and Metabolism (e.g., thrombosis and diabetes) and Pulmonary Hypertension (e.g., Pulmonary Arterial Hypertension). Medicines in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. Key products in the Pharmaceutical segment include: REMICADE® (infliximab), a treatment for a number of immune-mediated inflammatory diseases; SIMPONI® (golimumab), a subcutaneous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis and moderately active to severely active ulcerative colitis; SIMPONI ARIA® (golimumab), an intravenous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis and active ankylosing spondylitis; STELARA® (ustekinumab), a treatment for adults and children with moderate to severe plaque psoriasis, for adults with active psoriatic arthritis, and for adults with moderately to severely active Crohn's disease; TREMFYA® (guselkumab), a treatment for adults with moderate to severe plaque psoriasis; EDURANT® (rilpivirine), INTELENCE® (etravirine), PREZISTA® (darunavir) and PREZCOBIX®/REZOLSTA® (darunavir/cobicistat), antiretroviral medicines for the treatment of human immunodeficiency virus (HIV-1) in combination with other antiretroviral products and SYMTUZA® (darunavir/cobicistat/emtricitabine/tenofovir alafenamide), a once-daily single tablet regimen for the treatment of HIV ; CONCERTA® (methylphenidate HCl) extended-release tablets CII, a treatment for attention deficit hyperactivity disorder; INVEGA SUSTENNA®/XEPLION® (paliperidone palmitate), for the treatment of schizophrenia and schizoaffective disorder in adults; INVEGA TRINZA®/TREVICTA® (paliperidone palmitate), for the treatment of schizophrenia in patients after they have been adequately treated with INVEGA SUSTENNA® for at least four months; RISPERDAL CONSTA® (risperidone long-acting injection), for the treatment of schizophrenia and the maintenance treatment of Bipolar 1 Disorder in adults; ZYTIGA® (abiraterone acetate), a treatment for metastatic castration-

resistant prostate cancer (CRPC) and metastatic high-risk castration-sensitive prostate cancer; IMBRUVICA® (ibrutinib), a treatment for certain B-cell malignancies, or blood cancers, chronic graft versus host disease and Waldenström's Macroglobulinemia; DARZALEX® (daratumumab), a treatment for relapsed/refractory multiple myeloma; VELCADE® (bortezomib), a treatment for multiple myeloma mantle cell lymphoma; PROCRIT®/EPREX® (epoetin alfa), a treatment for chemotherapy-induced anemia and patients with chronic kidney disease; XARELTO® (rivaroxaban), an oral anticoagulant for the prevention of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery, to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, and for the treatment and reduction of risk of recurrence of DVT and PE; INVOKANA® (canagliflozin), for the treatment of adults with type 2 diabetes; INVOKAMET®/VOKANAMET® (canagliflozin/metformin HCl), a combination therapy of fixed doses of canagliflozin and metformin hydrochloride for the treatment of adults with type 2 diabetes; and INVOKAMET® XR (canagliflozin/metformin hydrochloride extended-release), a once-daily, fixed-dose combination therapy of canagliflozin and metformin hydrochloride extended-release, for the treatment of adults with type 2 diabetes; OPSUMIT® (macitentan) as monotherapy or in combination, indicated for the long-term treatment of pulmonary arterial hypertension (PAH); UPTRAVI® (selexipag), the only approved oral, selective IP receptor agonist targeting a prostacyclin pathway in PAH. Many of these medicines were developed in collaboration with strategic partners or are licensed from other companies and maintain active lifecycle development programs.

Medical Devices

The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, interventional solutions (cardiovascular and neurovascular), diabetes care (divested in the fiscal fourth quarter of 2018) and eye health fields. These products are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics. They include orthopaedic products; general surgery, biosurgical, endomechanical and energy products; electrophysiology products to treat cardiovascular disease; sterilization and disinfection products to reduce surgical infection; and vision products such as disposable contact lenses and ophthalmic products related to cataract and laser refractive surgery.

Geographic Areas

The business of Johnson & Johnson is conducted by more than 260 operating companies located in more than 60 countries, including the U.S., which sell products in virtually all countries throughout the world. The products made and sold in the international business include many of those described above under "– Segments of Business – Consumer," "– Pharmaceutical" and "– Medical Devices." However, the principal markets, products and methods of distribution in the international business vary with the country and the culture. The products sold in international business include those developed in the U.S. and by subsidiaries abroad.

Investments and activities in some countries outside the U.S. are subject to higher risks than comparable U.S. activities because the investment and commercial climate may be influenced by financial instability in international economies, restrictive economic policies and political and legal system uncertainties.

Raw Materials

Raw materials essential to the Company's business are generally readily available from multiple sources. Where there are exceptions, the temporary unavailability of those raw materials would not likely have a material adverse effect on the financial results of the Company.

Patents

The Company's subsidiaries have made a practice of obtaining patent protection on their products and processes where possible. They own, or are licensed under, a significant number of patents in the U.S. and other countries relating to their products, product uses, formulations and manufacturing processes, which in the aggregate are believed to be of material importance to the Company in the operation of its businesses. The Company's subsidiaries face patent challenges from third parties, including challenges seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. Significant legal proceedings and claims involving the Company's patent and other intellectual property are described in Note 21, "Legal Proceedings—Intellectual Property" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Sales of the Company's 2nd largest product, STELARA® (ustekinumab), accounted for approximately 6.3% of the Company's total revenues for fiscal 2018. Accordingly, the patents related to this product are believed to be material to the Company.

There is one set of granted patents related specifically to STELARA®. This set of patents is owned by Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson. These patents are in force in the U.S. and many countries outside the

United States. In the U.S., the latest projected expiration date for patents in this set is 2023 due to a patent term extension. In Europe, the latest projected expiration date for patents in this set is 2024 due to a Supplemental Patent Certificate (patent term extension). In most other countries, the latest projected expiration date is 2021.

In addition to competing in the immunology market with STELARA®, the Company is currently marketing SIMPONI® (golimumab) and SIMPONI ARIA® (golimumab), next generation immunology products with remaining patent lives of up to six years. The Company also markets REMICADE® (infliximab) in the immunology market which is the Company's largest product. Patents on this product have expired and the Food and Drug Administration approved the first infliximab biosimilar for sale in the U.S. in 2016, and a number of such products have been launched since then. For a more extensive description of legal matters regarding the patents related to REMICADE®, see Note 21 "Legal Proceedings - Intellectual Property - Pharmaceutical - REMICADE® Related Cases" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Trademarks

The Company's subsidiaries have made a practice of selling their products under trademarks and of obtaining protection for these trademarks by all available means. These trademarks are protected by registration in the U.S. and other countries where such products are marketed. The Company considers these trademarks in the aggregate to be of material importance in the operation of its businesses.

Seasonality

Worldwide sales do not reflect any significant degree of seasonality; however, spending has been heavier in the fourth quarter of each year than in other quarters. This reflects increased spending decisions, principally for advertising and research and development activity.

Competition

In all of their product lines, the Company's subsidiaries compete with companies both locally and globally. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, both internally and externally sourced, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products, as well as protecting the underlying intellectual property of the Company's product portfolio, is important to the Company's success in all areas of its business. The competitive environment requires substantial investments in continuing research. In addition, the development and maintenance of customer demand for the Company's consumer products involve significant expenditures for advertising and promotion.

Environment

The Company is subject to a variety of U.S. and international environmental protection measures. The Company believes that its operations comply in all material respects with applicable environmental laws and regulations. The Company's compliance with these requirements did not change during the past year, and is not expected to have a material effect upon its capital expenditures, cash flows, earnings or competitive position.

Regulation

The Company's businesses are subject to varying degrees of governmental regulation in the countries in which operations are conducted, and the general trend is toward increasingly stringent regulation. In the U.S., the drug, device and cosmetic industries have long been subject to regulation by various federal and state agencies, primarily as to product safety, efficacy, manufacturing, advertising, labeling and safety reporting. The exercise of broad regulatory powers by the U.S. Food and Drug Administration (the FDA) continues to result in increases in the amounts of testing and documentation required for FDA approval of new drugs and devices and a corresponding increase in the expense of product introduction. Similar trends are also evident in major markets outside of the U.S. The new medical device regulatory framework and the new privacy regulations in Europe are examples of such increased regulation.

The costs of human health care have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. In the U.S., attention has been focused on drug prices and profits and programs that encourage doctors to write prescriptions for particular drugs, or to recommend, use or purchase particular medical devices. Payers have become a more potent force in the market place and increased attention is being paid to drug and medical device pricing, appropriate drug and medical device utilization and the quality and costs of health care generally.

U.S. government agencies continue to implement the extensive requirements of the Patient Protection and Affordable Care Act (the ACA). These have both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of the ACA, and potential modification or repeal of ACA provisions, will ultimately affect the industry.

The regulatory agencies under whose purview the Company operates have administrative powers that may subject it to actions such as product withdrawals, recalls, seizure of products and other civil and criminal sanctions. In some cases, the Company's subsidiaries may deem it advisable to initiate product recalls.

In addition, business practices in the health care industry have come under increased scrutiny, particularly in the U.S., by government agencies and state attorneys general, and resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Further, the Company relies on global supply chains, and production and distribution processes, that are complex, are subject to increasing regulatory requirements, and may be faced with unexpected changes such as those resulting from Brexit, that may affect sourcing, supply and pricing of materials used in the Company's products. These processes also are subject to lengthy regulatory approvals.

Available Information

The Company's main corporate website address is *www.jnj.com.* All of the Company's SEC filings are also available on the Company's website at *www.investor.jnj.com/sec.cfm*, as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*. In addition, the written charters of the Audit Committee, the Compensation & Benefits Committee, the Nominating & Corporate Governance Committee, the Regulatory Compliance Committee and the Science, Technology & Sustainability Committee of the Board of Directors and the Company's Principles of Corporate Governance, Code of Business Conduct (for employees), Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers, and other corporate governance materials, are available at *www.investor.jnj.com/gov.cfm* on the Company's website and will be provided without charge to any shareholder submitting a written request, as provided above. The information on the Company's website is not, and will not be deemed, a part of this Report or incorporated into any other filings the Company makes with the SEC.

Item 1A. RISK FACTORS

The Company faces a number of uncertainties and risks that are difficult to predict and many of which are outside of the Company's control. In addition to the other information in this report and the Company's other filings with the SEC, investors should consider carefully the factors set forth below. Investors should be aware that it is not possible to predict or identify all such factors and that the following is not meant to be a complete discussion of all potential risks or uncertainties. If known or unknown risks or uncertainties materialize, the Company's business, results of operations or financial condition could be adversely affected, potentially in a material way.

Global sales in the Company's pharmaceutical and medical devices segments may be negatively impacted by healthcare reforms and increasing pricing pressures.

Sales of the Company's pharmaceutical and medical device products are significantly affected by reimbursements by third-party payers such as government healthcare programs, private insurance plans and managed care organizations. As part of various efforts to contain healthcare costs, these payers are putting downward pressure on prices at which products will be reimbursed. In the U.S., increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, in part due to continued consolidation among health care providers, could result in further pricing pressures. In addition, increased political scrutiny could result in additional pricing pressures. Outside the U.S., numerous major markets, including the EU and Japan, have pervasive government involvement in funding healthcare and, in that regard, directly or indirectly impose price controls, limit access to, or reimbursement for, the Company's products, or reduce the value of its intellectual property protection.

The Company is subject to significant legal proceedings that can result in significant expenses, fines and reputational damage.

In the ordinary course of business, Johnson & Johnson and its subsidiaries are subject to numerous claims and lawsuits involving various issues such as patent disputes, product liability and claims that their product sales, marketing and pricing practices violate various antitrust, unfair trade practices and/or consumer protection laws. The most significant of these proceedings are described in Note 21, "Legal Proceedings" under Notes to the Consolidated Financial Statements included in Item 8 of this Report. While the Company believes it has substantial defenses in these matters, it is not feasible to predict the ultimate outcome of litigation. The Company could in the future be required to pay significant amounts as a result of settlements or judgments in these matters, potentially in excess of accruals, including matters where the Company could be held jointly and severally liable among other defendants. The resolution of, or increase in accruals for, one or more of these matters in any reporting period could have a material adverse effect on the Company's results of operations and cash flows for that period. Furthermore, as a result of cost and availability factors, effective November 1, 2005, the Company ceased purchasing third-party product liability insurance.

Product reliability, safety and effectiveness concerns can have significant negative impacts on sales and results of operations, lead to litigation and cause reputational damage.

Concerns about product safety, whether raised internally or by litigants, regulators or consumer advocates, and whether or not based on scientific evidence, can result in safety alerts, product recalls, governmental investigations, regulatory action on the part of the FDA (or its counterpart in other countries), private claims and lawsuits, payment of fines and settlements, declining sales and reputational damage. These circumstances can also result in damage to brand image, brand equity and consumer trust in the Company's products. Product recalls have in the past, and could in the future, prompt government investigations and inspections, the shutdown of manufacturing facilities, continued product shortages and related sales declines, significant remediation costs, reputational damage, possible civil penalties and criminal prosecution.

Changes in tax laws or exposures to additional tax liabilities could negatively impact the Company's operating results.

Changes in tax laws or regulations around the world could negatively impact the Company's effective tax rate and results of operations. A change in statutory tax rate in any country would result in the revaluation of the Company's deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is enacted. This change would result in an expense or benefit recorded to the Company's Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries where it operates. Changes to the statutory tax rate may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted.

On December 22, 2017, the U.S. enacted The Tax Cuts and Jobs Act (the TCJA), which introduced significant changes to U.S. corporate income tax law that will have a meaningful impact on the Company's provision for income taxes. Accounting for the income tax effects of the TCJA requires significant judgments to be made in interpreting its provisions. Anticipated guidance from the U.S. Treasury about implementing the TCJA, which should be final by June 22, 2019 (18 months after enactment),

may result in adjustments that could materially affect the Company's financial position and results of operations as well as the effective tax rate in the period in which the adjustments are made.

On September 28, 2018, the Swiss Parliament approved the Federal Act on Tax Reform and AHV Financing (Swiss Tax Reform). However, a referendum has been called and, as a result, a public vote on the Swiss Tax Reform will take place on May 19th, 2019. If the Swiss Tax Reform passes, then the measures are expected to come into force in either January 2020 or January 2021. Prior to approval in the referendum and its subsequent cantonal implementation, the proposed Swiss Tax Reform is not enacted and therefore the Company has not reflected any of the potential impacts in its fiscal results. The Company is currently assessing the impact of the proposed Swiss Tax Reform, and when enacted, the law may have a material impact on the Company's operating results.

The Company conducts business and files tax returns in numerous countries and is addressing tax audits and disputes with many tax authorities. In connection with the Organization for Economic Cooperation and Development Base Erosion and Profit Shifting (BEPS) project, companies are required to disclose more information to tax authorities on operations around the world, which may lead to greater audit scrutiny of profits earned in other countries. The Company regularly assesses the likely outcomes of its tax audits and disputes to determine the appropriateness of its tax reserves. However, any tax authority could take a position on tax treatment that is contrary to the Company's expectations, which could result in tax liabilities in excess of reserves.

The Company may not be able to successfully secure and defend intellectual property rights essential to the Company's businesses.

The Company owns or licenses a significant number of patents and other proprietary rights, determined by patent offices, courts and lawmakers in various countries, relating to its products and manufacturing processes. These rights are essential to the Company's businesses and materially important to the Company's results of operations. Public policy, both within and outside the U.S., has become increasingly unfavorable toward intellectual property rights. The Company cannot be certain that it will obtain adequate patent protection for new products and technologies in the U.S. and other important markets or that such protections, once granted, will last as long as originally anticipated.

Competitors routinely challenge the validity or extent of the Company's owned or licensed patents and proprietary rights through litigation, interferences, oppositions and other proceedings. These proceedings absorb resources and can be protracted as well as unpredictable. In addition, challenges that the Company's products infringe the patents of third parties could result in the need to pay past damages and future royalties and adversely affect the competitive position and sales of the products in question.

The Company has faced increasing patent challenges from third parties seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the U.S., manufacturers of generic versions of innovative human pharmaceutical products may challenge the validity, or claim non-infringement, of innovator products through the Abbreviated New Drug Application, or ANDA, process with the FDA. The Biologics Price Competition and Innovation Act (BPCIA), enacted in 2010, which created a new regulatory pathway for the approval by the FDA of biosimilar alternatives to innovator-developed biological products, also created mechanisms for biosimilar applicants to challenge the patents on the innovator biologics. The inter partes review (IPR) process with the USPTO, created under the 2011 America Invents Act, is also being used by competitors to challenge patents held by the Company's subsidiaries.

In the event the Company is not successful in defending its patents against such challenges, or upon the "at-risk" launch (despite pending patent infringement litigation) by the generic or biosimilar firm of its product, the Company can lose a major portion of revenues for the referenced product in a very short period of time. Current legal proceedings involving the Company's patents and other intellectual property rights are described in Note 21, "Legal Proceedings—Intellectual Property" of the Notes to the Consolidated Financial Statements included in Item 8 of this Report.

The Company's businesses operate in highly competitive product markets and competitive pressures could adversely affect the Company's earnings.

The Company faces substantial competition in all three operating segments and in all geographic markets. The Company's businesses compete with companies of all sizes on the basis of cost-effectiveness, technological innovations, intellectual property rights, product performance, real or perceived product advantages, pricing and availability and rate of reimbursement. The Company also competes with other market participants in securing rights to acquisitions, collaborations and licensing agreements with third parties. Competition for rights to product candidates and technologies may result in significant investment and acquisition costs and onerous agreement terms for the Company. Competitors' development of more effective or

less costly products, and/or their ability to secure patent and other intellectual property rights and successfully market products ahead of the Company, could negatively impact sales of the Company's existing products as well as its ability to bring new products to market despite significant prior investment in the related product development.

For the Company's pharmaceutical businesses, loss of patent exclusivity for a product often is followed by a substantial reduction in sales as competitors gain regulatory approval for generic and other competing products and enter the market. Similar competition can be triggered by the loss of exclusivity for a biological product. For the Company's medical device businesses, technological innovation, product quality, reputation and customer service are especially important to competitiveness. Development by other companies of new or improved products, processes and technologies could threaten to make the Company's products or technologies less desirable, less economical or obsolete. The Company's consumer businesses face intense competition from other branded products and retailers' private-label brands. If the Company fails to sufficiently differentiate and market its brand name consumer products, this could adversely affect revenues and profitability of those products.

Significant challenges or delays in the Company's innovation and development of new products, technologies and indications could have an adverse impact on the Company's long-term success.

The Company's continued growth and success depends on its ability to innovate and develop new and differentiated products and services that address the evolving health care needs of patients, providers and consumers. Development of successful products and technologies is also necessary to offset revenue losses when the Company's existing products lose market share due to various factors such as competition and loss of patent exclusivity. New products introduced within the past five years accounted for approximately 25% of 2018 sales. The Company cannot be certain when or whether it will be able to develop, license or otherwise acquire companies, products and technologies, whether particular product candidates will be granted regulatory approval, and, if approved, whether the products will be commercially successful.

The Company pursues product development through internal research and development as well as through collaborations, acquisitions, joint ventures and licensing or other arrangements with third parties. In all of these contexts, developing new products, particularly pharmaceutical and biotechnology products and medical devices, requires significant investment of resources over many years. Only a very few biopharmaceutical research and development programs result in commercially viable products. The process depends on many factors including the ability to discern patients' and health care providers' future needs; develop promising new compounds, strategies and technologies; achieve successful clinical trial results; secure effective intellectual property protection; obtain regulatory approvals on a timely basis; and, if and when they reach the market, successfully differentiate the Company's products from competing products and approaches to treatment. New products or enhancements to existing products may not be accepted quickly or significantly in the marketplace due to product and price competition, changes in customer preferences or healthcare purchasing patterns, resistance by healthcare providers or uncertainty over third-party reimbursement. Even following initial regulatory approval, the success of a product can be adversely impacted by safety and efficacy findings in larger real world patient populations, as well as market entry of competitive products.

The Company faces increasing regulatory scrutiny which imposes significant compliance costs and exposes the Company to government investigations, legal actions and penalties.

Like other companies in the healthcare industry, the Company is subject to extensive regulation, investigations and legal action, by national, state and local government agencies in the U.S. and other countries in which they operate. Regulatory issues regarding compliance with Good Manufacturing Practices (cGMP) (and comparable quality regulations in foreign countries) by manufacturers of drugs, devices and consumer products can lead to fines and penalties, product recalls, product shortages, interruptions in production, delays in new product approvals and litigation. In addition, the marketing, pricing and sale of the Company's products are subject to regulation, investigations and legal actions including under the Federal Food, Drug, and Cosmetic Act, the Medicaid Rebate Program, federal and state false claims acts, state unfair trade practices acts and consumer protection laws. Increased scrutiny of health care industry business practices in recent years by government agencies and state attorneys general in the U.S., and any resulting investigations and prosecutions, carry risk of significant civil and criminal penalties including, but not limited to, debarment from participation in government healthcare programs. Any such debarment could have a material adverse effect on the Company's business and results of operations. The most significant current investigations and litigation brought by government agencies are described in Note 21, "Legal Proceedings-Government Proceedings" under Notes to the Consolidated Financial Statements included in Item 8 of this Report.

The Company faces a variety of risks associated with conducting business internationally.

The Company's extensive operations and business activity outside the U.S. are accompanied by certain financial, economic and political risks, including those listed below.

Foreign Currency Exchange: In fiscal 2018, approximately 49% of the Company's sales occurred outside of the U.S., with approximately 23% in Europe, 8% in the Western Hemisphere, excluding the U.S., and 18% in the Asia-Pacific and Africa region. Changes in non-U.S. currencies relative to the U.S. dollar impact the Company's revenues and expenses. While the Company uses financial instruments to mitigate the impact of fluctuations in currency exchange rates on its cash flows, unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the U.S. dollar may result in significant favorable or unfavorable translation effects when the operating results of the Company's non-U.S. business activity are translated into U.S. dollars.

Inflation and Currency Devaluation Risks: The Company faces challenges in maintaining profitability of operations in economies experiencing high inflation rates. The Company has accounted for operations in Argentina (beginning in the fiscal third quarter of 2018) and Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. While the Company strives to maintain profit margins in these areas through cost reduction programs, productivity improvements and periodic price increases, it might experience operating losses as a result of continued inflation. In addition, the impact of currency devaluations in countries experiencing high inflation rates or significant currency exchange fluctuations could negatively impact the Company's operating results.

Illegal Importation of Pharmaceutical Products: The illegal importation of pharmaceutical products from countries where government price controls or other market dynamics result in lower prices may adversely affect the Company's sales and profitability in the U.S. and other countries in which the Company operates. With the exception of limited quantities of prescription drugs for personal use, foreign imports of pharmaceutical products are illegal under current U.S. law. However, the volume of illegal imports continues to rise as the ability of patients and other customers to obtain the lower-priced imports has grown significantly.

Anti-Bribery and Other Regulations: The Company is subject to various federal and foreign laws that govern its international business practices with respect to payments to government officials. Those laws include the U.S. Foreign Corrupt Practices Act (FCPA), which prohibits U.S. publicly traded companies from promising, offering, or giving anything of value to foreign officials with the corrupt intent of influencing the foreign official for the purpose of helping the Company obtain or retain business or gain any improper advantage. The Company's business is heavily regulated and therefore involves significant interaction with foreign officials. Also, in many countries outside the U.S., the health care providers who prescribe human pharmaceuticals are employed by the government and the purchasers of human pharmaceuticals are government entities; therefore, the Company's interactions with these prescribers and purchasers are subject to regulation under the FCPA. In addition to the U.S. application and enforcement of the FCPA, various jurisdictions in which the Company operates have laws and regulations, including the U.K Bribery Act 2010, aimed at preventing and penalizing corrupt and anticompetitive behavior. Enforcement activities under these laws could subject the Company to additional administrative and legal proceedings and actions, which could include claims for civil penalties, criminal sanctions, and administrative remedies, including exclusion from health care programs.

Other Legal, Social and Political Risks. Other risks inherent in conducting business globally include:

- protective economic policies taken by governments such as trade protection measures and import/export licensing requirements;
- compliance with local regulations and laws including, in some countries, regulatory requirements restricting the Company's ability to manufacture or sell its products in the relevant market;
- diminished protection of intellectual property and contractual rights in certain jurisdictions;
- potential nationalization or expropriation of the Company's foreign assets; and
- disruptions to markets due to war, armed conflict, terrorism, social upheavals or pandemics.

Interruptions and delays in manufacturing operations could adversely affect the Company's business, sales and reputation.

The Company's manufacture of products requires the timely delivery of sufficient amounts of complex, high-quality components and materials. The Company's subsidiaries operate 111 manufacturing facilities as well as sourcing from hundreds of suppliers around the world. The Company has in the past, and may in the future, face unanticipated interruptions and delays in manufacturing through its internal or external supply chain. Manufacturing disruptions can occur for many reasons including regulatory action, production quality deviations or safety issues, labor disputes, site-specific incidents (such as fires), natural disasters such as hurricanes and other severe weather events, raw material shortages, political unrest and terrorist attacks. Such delays and difficulties in manufacturing can result in product shortages, declines in sales and reputational impact as well as significant remediation and related costs associated with addressing the shortage.

The Company relies on third parties to manufacture certain of our products. Any failure by or loss of a third party manufacturer could result in delays and increased costs, which may adversely affect our business.

The Company relies on third parties to manufacture certain of our products. We depend on these third party manufacturers to allocate to us a portion of their manufacturing capacity sufficient to meet our needs, to produce products of acceptable quality and at acceptable manufacturing yields and to deliver those products to us on a timely basis and at acceptable prices. However, we cannot guarantee that these third party manufacturers will be able to meet our near-term or long-term manufacturing requirements, which could result in lost sales and have an adverse effect on our business.

Other risks associated with our reliance on third parties to manufacture these products include, reliance on the third party for regulatory compliance and quality assurance, misappropriation of the Company's intellectual property, limited ability to manage our inventory, possible breach of the manufacturing agreement by the third party and the possible termination or nonrenewal of the manufacturing agreement by the third party at a time that is costly or inconvenient for us. Moreover, if any of our third party manufacturers suffer any damage to facilities, lose benefits under material agreements, experience power outages, encounter financial difficulties, are unable to secure necessary raw materials from their suppliers or suffer any other reduction in efficiency, the Company may experience significant business disruption. In the event of any such disruption, the Company would need to seek and source other qualified third party manufacturers, likely resulting in further delays and increased costs which could affect our business adversely.

An information security incident, including a cybersecurity breach, could have a negative impact to the Company's business or reputation

To meet business objectives, the Company relies on both internal information technology (IT) systems and networks, and those of third parties and their vendors, to process and store sensitive data, including confidential research, business plans, financial information, intellectual property, and personal data that may be subject to legal protection. The extensive information security and cybersecurity threats, which affect companies globally, pose a risk to the security and availability of these IT systems and networks, and the confidentiality, integrity, and availability of the Company's sensitive data. The Company continually assesses these threats and makes investments to increase internal protection, detection, and response capabilities, as well as ensure the Company's third party providers have required capabilities and controls, to address this risk. To date, the Company has not experienced any material impact to the business or operations resulting from information or cybersecurity attacks; however, because of the frequently changing attack techniques, along with the increased volume and sophistication of the attacks, there is the potential for the Company to be adversely impacted. This impact could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action. The Company maintains cybersecurity insurance in the event of an information security or cyber incident, however, the coverage may not be sufficient to cover all financial losses.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

The Company's subsidiaries operate 111 manufacturing facilities occupying approximately 20.5 million square feet of floor space. The manufacturing facilities are used by the industry segments of the Company's business approximately as follows:

Segment	Square Feet (in thousands)
Consumer	6,503
Pharmaceutical	6,819
Medical Devices	7,183
Worldwide Total	20,505

Within the U.S., five facilities are used by the Consumer segment, five by the Pharmaceutical segment and 27 by the Medical Devices segment. Outside of the U.S., 25 facilities are used by the Consumer segment, 14 by the Pharmaceutical segment and 35 by the Medical Devices segment.

The locations of the manufacturing facilities by major geographic areas of the world are as follows:

Geographic Area	Number of Facilities	Square Feet (in thousands)
United States	37	5,855
Europe	34	7,587
Western Hemisphere, excluding U.S.	12	2,800
Africa, Asia and Pacific	28	4,263
Worldwide Total	111	20,505

In addition to the manufacturing facilities discussed above, the Company maintains numerous office and warehouse facilities throughout the world. Research facilities are also discussed in Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition" of this Report.

The Company's subsidiaries generally seek to own, rather than lease, their manufacturing facilities, although some, principally in non-U.S. locations, are leased. Office and warehouse facilities are often leased. The Company also engages contract manufacturers.

The Company is committed to maintaining all of its properties in good operating condition.

McNEIL-PPC, Inc. (now Johnson & Johnson Consumer Inc.) (McNEIL-PPC) continues to operate under a consent decree, signed in 2011 with the FDA, which governs certain McNeil Consumer Healthcare manufacturing operations, and requires McNEIL-PPC to remediate the facilities it operates in Lancaster, Pennsylvania, Fort Washington, Pennsylvania, and Las Piedras, Puerto Rico (the "Consent Decree"). Following FDA inspections in 2015, McNEIL-PPC received notifications from the FDA that all three manufacturing facilities are in conformity with applicable laws and regulations, and commercial production has restarted.

Under the Consent Decree, after receiving notice from the FDA of being in compliance with applicable laws and regulations, each of the three facilities is subject to a five-year audit period by a third-party cGMP expert. Thus, a third-party expert will continue to reassess the sites at various times until at least 2020.

For information regarding lease obligations, see Note 16 "Rental Expense and Lease Commitments" of the Notes to Consolidated Financial Statements included in Item 8 of this Report. Segment information on additions to property, plant and equipment is contained in Note 18 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 3. LEGAL PROCEEDINGS

The information called for by this item is incorporated herein by reference to the information set forth in Note 21 "Legal Proceedings" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

In addition, Johnson & Johnson and its subsidiaries are also parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the cost of past and/or future remediation.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

EXECUTIVE OFFICERS OF THE REGISTRANT

Listed below are the executive officers of the Company. There are no family relationships between any of the executive officers, and there is no arrangement or understanding between any executive officer and any other person pursuant to which the executive officer was selected. At the annual meeting of the Board of Directors, the executive officers are elected by the Board to hold office for one year and until their respective successors are elected and qualified, or until earlier resignation or removal.

Information with regard to the directors of the Company, including information for Alex Gorsky, who is also an executive officer, is incorporated herein by reference to the material captioned "Item 1. Election of Directors" in the Proxy Statement.

Name	Age	Position
Joaquin Duato	56	Vice Chairman, Executive Committee[a]
Peter M. Fasolo	56	Member, Executive Committee; Executive Vice President, Chief Human Resources Officer[b]
Alex Gorsky	58	Chairman, Board of Directors; Chairman, Executive Committee; Chief Executive Officer
Ashley McEvoy	48	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Medical Devices[c]
Jorge Mesquita	57	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Consumer[d]
Thibaut Mongon	49	Appointee, Member, Executive Committee, Executive Vice President, Worldwide Chairman, Consumer[e]
Michael E. Sneed	59	Member, Executive Committee; Executive Vice President, Global Corporate Affairs and Chief Communication Officer[f]
Paulus Stoffels	56	Vice Chairman, Executive Committee; Chief Scientific Officer[g]
Jennifer L. Taubert	55	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Pharmaceuticals[h]
Michael H. Ullmann	60	Member, Executive Committee; Executive Vice President, General Counsel[i]
Kathryn E. Wengel	53	Member, Executive Committee; Executive Vice President, Chief Global Supply Chain Officer[j]
Joseph J. Wolk	52	Member, Executive Committee; Executive Vice President, Chief Financial Officer[k]

(a) Mr. J. Duato joined the Company in 1989 with Janssen-Farmaceutica S.A. (Spain), a subsidiary of the Company, and held executive positions of increasing responsibility in the Pharmaceutical sector. In 2009, he was named Company Group Chairman, Pharmaceuticals, and in 2011, he was named Worldwide Chairman, Pharmaceuticals. In 2016, Mr. Duato became a member of the Executive Committee and was named Executive Vice President, Worldwide Chairman,

Pharmaceuticals. In July 2018, Mr. Duato was promoted to Vice Chairman of the Executive Committee, with responsibility for the company's Pharmaceutical and Consumer sectors, supply chain, information technology, global services and the Health & Wellness groups.

(b) Dr. P. M. Fasolo joined the Company in 2004 as Vice President, Worldwide Human Resources for Cordis Corporation, a subsidiary of the Company, and was subsequently named Vice President, Global Talent Management for the Company. He left Johnson & Johnson in 2007 to join Kohlberg Kravis Roberts & Co. as Chief Talent Officer. Dr. Fasolo returned to the Company in 2010 as the Vice President, Global Human Resources, and in 2011, he became a member of the Executive Committee. In April 2016, he was named Executive Vice President, Chief Human Resources Officer. Mr. Fasolo has responsibility for global talent, recruiting, diversity, compensation, benefits, employee relations and all aspects of the human resources agenda for the Company.

(c) Ms. A. McEvoy joined the Company in 1997 as Assistant Brand Manager of McNeil Consumer Health, a subsidiary of the Company, advancing through positions of increasing responsibilities until she was appointed Company Group Chairman, Vision Care in 2012, followed by Company Group Chairman, Consumer Medical Devices in 2014. In July 2018, Ms. McEvoy was promoted to Executive Vice President, Worldwide Chairman, Medical Devices, and became a member of the Executive Committee. She has responsibility for the surgery, orthopaedics, interventional solutions and eye health businesses across Ethicon, DePuy Synthes, Biosense Webster and Johnson & Johnson Vision.

(d) Mr. J. Mesquita joined the Company in 2014 as Worldwide Chairman, Consumer. Prior to joining the Company, he served in various marketing and leadership capacities across Latin America, including roles in Oral Care and Beauty at The Procter & Gamble Company from 1984 to 2013. In April 2016, Mr. Mesquita became a member of the Executive Committee and was promoted to Executive Vice President, Worldwide Chairman, Consumer. Mr. Mesquita plans to retire from the Company in March 2019.

(e) Mr. T. Mongon joined the Company in 2000 as Director of Marketing for the Vision Care group in France and subsequently held general management positions as Country Manager France, Belgium and North Africa, Managing Director Latin America, and President Asia-Pacific. Mr. Mongon transitioned to the Pharmaceutical sector in 2012 as the Global Commercial Strategy Leader for the Neuroscience therapeutic area, before joining the consumer sector as Company Group Chairman Asia-Pacific. The Company has announced that Mr. Mongon will be named Executive Vice President and Worldwide Chairman, Consumer, and a member of the Executive Committee, upon the retirement of his predecessor, Mr. Mesquita, effective March 1, 2019. In addition to leading the Consumer business, Mr. Mongon will have responsibility for Johnson & Johnson Southeast Asia.

(f) Mr. M. E. Sneed joined the Company in 1986 as Product Director for Personal Products, a subsidiary of the Company, and gained increased responsibilities in executive positions across the global enterprise. In 2004, Mr. Sneed was appointed Company Group Chairman, Consumer North America, followed by Company Group Chairman, Vision Care Franchise in 2007. In 2012, he became the Vice President, Global Corporate Affairs and Chief Communications Officer. Mr. Sneed was appointed Executive Vice President, Global Corporate Affairs and Chief Communications Officer in January 2018, and became a member of the Executive Committee in July 2018, leading the corporation's global marketing, communication, design and philanthropy functions.

(g) Dr. P. Stoffels joined the Company in 2002 with the acquisition of Tibotec Virco NV, where he was Chief Executive Officer of Virco NV and Chairman of Tibotec NV. In 2005, he was appointed Company Group Chairman, Global Virology. In 2006, he assumed the role of Company Group Chairman, Pharmaceuticals. Dr. Stoffels was appointed Global Head, Research & Development, Pharmaceuticals in 2009, and in 2011, became Worldwide Chairman, Pharmaceuticals. In 2012, Dr. Stoffels was appointed Chief Scientific Officer, and became a member of the Executive Committee. In 2016, Dr. Stoffels was named Executive Vice President, Chief Scientific Officer. In 2018, Dr. Stoffels was promoted to Vice Chairman of the Executive Committee, Chief Scientific Officer. He is responsible for the Company's innovation agenda across the Pharmaceutical, Medical Devices and Consumer sectors, product safety strategy, and the Company's global public health strategy.

(h) Ms. J. L. Taubert joined the Company in 2005 as Worldwide Vice President at Johnson & Johnson Pharmaceutical Services, a subsidiary of the Company. She held several executive positions in the Pharmaceutical sector until 2012 when she was appointed Company Group Chairman, North America Pharmaceuticals, and in 2015 became Company Group Chairman, The Americas, Pharmaceuticals. In July 2018, Ms. Taubert was promoted to Executive Vice President, Worldwide Chairman, Pharmaceuticals, and became a member of the Executive Committee.

(i) Mr. M. H. Ullmann joined the Company in 1989 as a corporate attorney in the Law Department. He was appointed Corporate Secretary in 1999 and served in that role until 2006. During that time, he also held various management positions in the Law Department. In 2006, he was named General Counsel, Medical Devices and Diagnostics and was appointed Vice President, General Counsel and became a member of the Executive Committee in 2012. In April 2016, Mr. Ullmann was named Executive Vice President, General Counsel. Mr. Ullmann has worldwide responsibility for legal, government affairs & policy, global security, aviation and health care compliance & privacy.

(j) Ms. K. E. Wengel joined the Company in 1988 as Project Engineer and Engineering Supervisor at Janssen, a subsidiary of the Company. During her tenure with the Company, she has held a variety of strategic leadership and executive positions across the global enterprise, in roles within operations, quality, engineering, new products, information technology, and other technical and business functions. In 2010, Ms. Wengel became the first Chief Quality Officer of the Company. In 2014, she was promoted to Vice President, Johnson & Johnson Supply Chain. In July 2018, she was promoted to Executive Vice President, Chief Global Supply Chain Officer, and became a member of the Executive Committee.

(k) Mr. J. J. Wolk joined the Company in 1998 as Finance Manager, Business Development for Ortho-McNeil, a subsidiary of the Company, and through the years held a variety of senior leadership roles in several segments and functions across the Company's subsidiaries, in Pharmaceuticals, Medical Devices and Supply Chain. From 2014 to 2016, he served as Vice President, Finance and Chief Financial Officer of the Janssen Pharmaceutical Companies of Johnson & Johnson. In 2016, Mr. Wolk became the Vice President, Investor Relations. In July 2018, he was appointed Executive Vice President, Chief Financial Officer and became a member of the Executive Committee. Mr. Wolk is responsible for leading the development and execution of the Company's global long-term financial strategy.

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

As of February 15, 2019, there were 142,029 record holders of common stock of the Company. Additional information called for by this item is incorporated herein by reference to the following sections of this Report: Note 17 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements included in Item 8; and Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters – Equity Compensation Plan Information".

Issuer Purchases of Equity Securities

On December 17, 2018, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's Common Stock. Share repurchases take place from time to time on the open market or through privately negotiated transactions. The repurchase program has no time limit and may be suspended for periods or discontinued at any time.

The following table provides information with respect to common stock purchases by the Company during the fiscal fourth quarter of 2018. Common stock purchases on the open market are made as part of a systematic plan to meet the needs of the Company's compensation programs. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal fourth quarter.

Period	Total Number of Shares Purchased[1]	Avg. Price Paid Per Share	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs[2]	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs[3]
October 1, 2018 through October 28, 2018	2,192,500	$ 138.74	-	-
October 29, 2018 through November 25, 2018	6,849,298	143.27	-	-
November 26, 2018 through December 30, 2018	18,130,189	139.10	7,073,136	32,131,870
Total	27,171,987			

(1) During the fiscal fourth quarter of 2018, the Company repurchased an aggregate of 27,171,987 shares of Johnson & Johnson Common Stock in open-market transactions, of which 7,073,136 shares were purchased pursuant to the repurchase program that was publicly announced on December 17, 2018, and of which 20,098,851 shares were purchased in open-market transactions as part of a systematic plan to meet the needs of the Company's compensation programs.

(2) As of December 30, 2018, an aggregate of 7,073,136 shares were purchased for a total of $0.9 billion since the inception of the repurchase program announced on December 17, 2018.

(3) As of December 30, 2018, the maximum number of shares that may yet be purchased under the plan is 32,131,870 based on the closing price of Johnson & Johnson Common Stock on the New York Stock Exchange on December 28, 2018 of $127.27 per share.

Item 6. SELECTED FINANCIAL DATA

Summary of Operations and Statistical Data 2008-2018*

(Dollars in Millions Except Per Share Amounts)	2018	2017	2016	2015	2014	2013	2012	2011	2010	2009	2008
Sales to customers — U.S.	$41,884	39,863	37,811	35,687	34,782	31,910	29,830	28,908	29,450	30,889	32,309
Sales to customers — International	39,697	36,587	34,079	34,387	39,549	39,402	37,394	36,122	32,137	31,008	31,438
Total sales	81,581	76,450	71,890	70,074	74,331	71,312	67,224	65,030	61,587	61,897	63,747
Cost of products sold	27,091	25,439	21,789	21,426	22,684	22,181	21,515	20,219	18,688	18,380	18,463
Selling, marketing and administrative expenses	22,540	21,520	20,067	21,079	21,887	21,650	20,697	20,800	19,296	19,712	21,431
Research and development expense	10,775	10,594	9,143	8,999	8,471	8,119	7,602	7,486	6,796	6,949	7,554
In-process research and development	1,126	408	29	224	178	580	1,163	—	—	—	181
Interest income	(611)	(385)	(368)	(128)	(67)	(74)	(64)	(91)	(107)	(90)	(361)
Interest expense, net of portion capitalized	1,005	934	726	552	533	482	532	571	455	451	435
Other (income) expense, net	1,405	(42)	210	(1,783)	82	2,903	2,004	3,115	(488)	(333)	(885)
Restructuring	251	309	491	509	—	—	—	569	—	1,073	—
	63,582	58,777	52,087	50,878	53,768	55,841	53,449	52,669	44,640	46,142	46,818
Earnings before provision for taxes on income	$17,999	17,673	19,803	19,196	20,563	15,471	13,775	12,361	16,947	15,755	16,929
Provision for taxes on income	2,702	16,373	3,263	3,787	4,240	1,640	3,261	2,689	3,613	3,489	3,980
Net earnings	15,297	1,300	16,540	15,409	16,323	13,831	10,514	9,672	13,334	12,266	12,949
Add: Net loss attributable to noncontrolling interest	—	—	—	—	—	—	339	—	—	—	—
Net earnings attributable to Johnson & Johnson	15,297	1,300	16,540	15,409	16,323	13,831	10,853	9,672	13,334	12,266	12,949
Percent of sales to customers	18.8%	1.7	23.0	22.0	22.0	19.4	16.1	14.9	21.7	19.8	20.3
Diluted net earnings per share of common stock [1]	$5.61	0.47	5.93	5.48	5.70	4.81	3.86	3.49	4.78	4.40	4.57
Percent return on average shareholders' equity	25.5%	2.0	23.4	21.9	22.7	19.9	17.8	17.0	24.9	26.4	30.2
Percent increase (decrease) over previous year:											
Sales to customers	6.7%	6.3	2.6	(5.7)	4.2	6.1	3.4	5.6	(0.5)	(2.9)	4.3
Diluted net earnings per share	N/M	(92.1)%	8.2	(3.9)	18.5	24.6	10.6	(27.0)	8.6	(3.7)	25.9
Supplementary balance sheet data:											
Property, plant and equipment, net	17,035	17,005	15,912	15,905	16,126	16,710	16,097	14,739	14,553	14,759	14,365
Additions to property, plant and equipment	3,670	3,279	3,226	3,463	3,714	3,595	2,934	2,893	2,384	2,365	3,066
Total assets	152,954	157,303	141,208	133,411	130,358	131,754	121,347	113,644	102,908	94,682	84,912
Long-term debt	27,684	30,675	22,442	12,857	15,122	13,328	11,489	12,969	9,156	8,223	8,120
Operating cash flow	22,201	21,056	18,767	19,569	18,710	17,414	15,396	14,298	16,385	16,571	14,972
Common stock information											
Dividends paid per share	$3.54	3.32	3.15	2.95	2.76	2.59	2.40	2.25	2.11	1.93	1.795
Shareholders' equity per share	22.44	22.43	26.02	25.82	25.06	26.25	23.33	20.95	20.66	18.37	15.35
Market price per share (year-end close)	$127.27	139.72	115.21	102.72	105.06	92.35	69.48	65.58	61.85	64.41	58.56
Average shares outstanding (millions)											
— basic	2,681.5	2,692.0	2,737.3	2,771.8	2,815.2	2,809.2	2,753.3	2,736.0	2,751.4	2,759.5	2,802.5
— diluted	2,728.7	2,745.3	2,788.9	2,812.9	2,863.9	2,877.0	2,812.6	2,775.3	2,788.8	2,789.1	2,835.6
Employees (thousands)	135.1	134.0	126.4	127.1	126.5	128.1	127.6	117.9	114.0	115.5	118.7

[1] Attributable to Johnson & Johnson

* Per the adoption of ASU 2017-07 prior year amounts on the Consolidated Statement of Earnings have been reclassified to retroactively apply classification of the service cost component and the other components of net periodic benefit cost

N/M = Not Meaningful

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF RESULTS OF OPERATIONS AND FINANCIAL CONDITION

Organization and Business Segments

Description of the Company and Business Segments

Johnson & Johnson and its subsidiaries (the Company) have approximately 135,100 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. The Consumer segment includes a broad range of products used in the baby care, oral care, beauty, over-the-counter pharmaceutical, women's health and wound care markets. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on six therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, pulmonary hypertension, and cardiovascular and metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, interventional solutions (cardiovascular and neurovascular), diabetes care (divested in the fiscal fourth quarter of 2018) and vision fields which are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Consumer, Pharmaceutical and Medical Devices business segments.

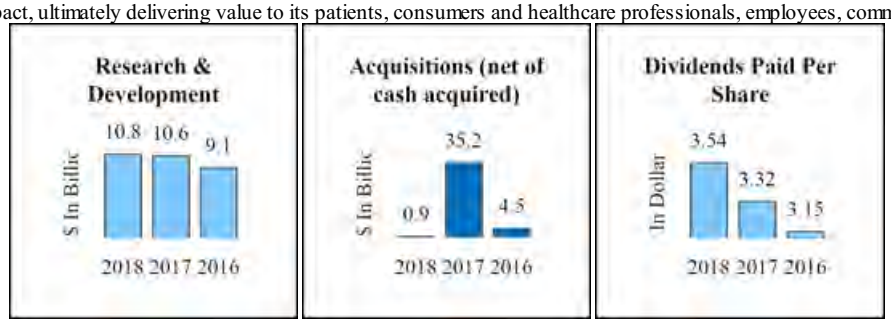
In all of its product lines, the Company competes with companies both locally and globally, throughout the world. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products, as well as protecting the underlying intellectual property of the Company's product portfolio, is important to the Company's success in all areas of its business. The competitive environment requires substantial investments in continuing research. In addition, the development and maintenance of customer demand for the Company's consumer products involves significant expenditures for advertising and promotion.

Management's Objectives

With "Our Credo" as the foundation, the Company's purpose is to blend heart, science and ingenuity to profoundly change the trajectory of health for humanity. The Company is committed to bringing its full breadth and depth to ensure health for people today and for future generations. United around this common ambition, the Company is poised to fulfill its purpose and successfully meet the demands of the rapidly evolving markets in which it competes.

The Company is broadly based in human healthcare, and is committed to creating value by developing accessible, high quality, innovative products and services. New products introduced within the past five years accounted for approximately 25% of 2018 sales. In 2018, $10.8 billion was invested in research and development and $0.9 billion spent on acquisitions, reflecting management's commitment to create life-enhancing innovations and to create value through partnerships that will profoundly change the trajectory of health for humanity.

A critical driver of the Company's success, is the 135,100 diverse employees that work across more than 260 operating companies, which are located in more than 60 countries. Employees are empowered and inspired to lead with the Company's Our Credo and purpose as guides. This allows every employee to use the Company's reach and size to advance the Company's purpose, and to also lead with agility and urgency. Leveraging the extensive resources across the enterprise, enables the Company to innovate and execute with excellence. This ensures the Company can remain focused on addressing the unmet needs of society every day and invest for an enduring impact, ultimately delivering value to its patients, consumers and healthcare professionals, employees, communities and shareholders.



Results of Operations

Analysis of Consolidated Sales

In 2018, worldwide sales increased 6.7% to $81.6 billion, compared to an increases of 6.3% and 2.6% in 2017 and 2016, respectively. These sales changes consisted of the following:

Sales increase/(decrease) due to:	2018	2017	2016
Volume	8.5 %	8.0%	3.2%
Price	(2.2)	(2.0)	0.7
Currency	0.4	0.3	(1.3)
Total	**6.7 %**	**6.3%**	**2.6%**

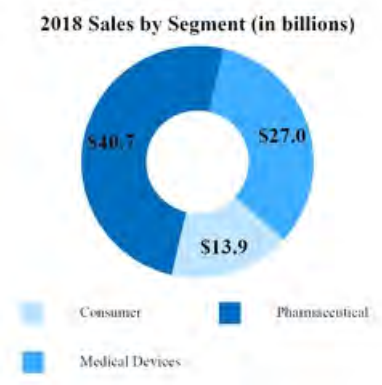
In 2018, the net impact of acquisitions and divestitures on the worldwide sales growth was a positive impact of 0.8%. In 2017, acquisitions and divestitures had a positive impact of 3.6% on the worldwide sales growth. In 2016, acquisitions and divestitures had a negative impact of 1.1% on the worldwide sales growth and competitive products to the Company's Hepatitis C products, OLYSIO®/SOVRIAD® (simeprevir) and INCIVO® (telaprevir), had a negative impact of 0.8% on the worldwide sales growth. Operations in Venezuela negatively impacted the worldwide sales growth 0.3%.

Sales by U.S. companies were $41.9 billion in 2018, $39.9 billion in 2017 and $37.8 billion in 2016. This represents increases of 5.1% in 2018, 5.4% in 2017 and 6.0% in 2016. Sales by international companies were $39.7 billion in 2018, $36.6 billion in 2017 and $34.1 billion in 2016. This represents an increase of 8.5% in 2018, 7.4% in 2017, and a decrease of 0.9% in 2016.

The five-year compound annual growth rates for worldwide, U.S. and international sales were 2.7%, 5.6% and 0.1%, respectively. The ten-year compound annual growth rates for worldwide, U.S. and international sales were 2.5%, 2.6% and 2.4%, respectively.

In 2018, sales by companies in Europe achieved growth of 9.5% as compared to the prior year, including operational growth of 6.2% and a positive currency impact of 3.3%. Sales by companies in the Western Hemisphere (excluding the U.S.) achieved growth of 1.2% as compared to the prior year, including operational growth of 8.2% and a negative currency impact of 7.0%. Sales by companies in the Asia-Pacific, Africa region achieved growth of 10.5% as compared to the prior year, including operational growth of 9.4% and a positive currency impact of 1.1%.

In 2018, the Company had three wholesalers distributing products for all three segments that represented approximately 14.0%, 11.0% and 11.0% of the total consolidated revenues. In 2017, the Company had two wholesalers distributing products for all three segments that represented approximately 14.0% and 10.0% of the total consolidated revenues. In 2016, the Company had two wholesalers distributing products for all three segments that represented approximately 13.5% and 10.7% of the total consolidated revenues.



Analysis of Sales by Business Segments

Consumer Segment

Consumer segment sales in 2018 were $13.9 billion, an increase of 1.8% from 2017, which included 2.2% operational growth and a negative currency impact of 0.4%. U.S. Consumer segment sales were $5.8 billion, an increase of 3.5%. International sales were $8.1 billion, an increase of 0.7%, which included 1.4% operational growth and a negative currency impact of 0.7%. In 2018, acquisitions and divestitures had a net negative impact of 1.0% on the operational sales growth of the worldwide Consumer segment.

Major Consumer Franchise Sales:

				% Change	
(Dollars in Millions)	**2018**	**2017**	**2016**	**'18 vs. '17**	**'17 vs. '16**
Beauty	$ 4,382	4,200	3,897	4.3 %	7.8
OTC	4,334	4,126	3,977	5.0	3.7
Baby Care	1,858	1,916	2,001	(3.0)	(4.2)
Oral Care	1,555	1,531	1,568	1.6	(2.4)
Women's Health	1,049	1,050	1,067	(0.1)	(1.6)
Wound Care/Other	675	779	797	(13.4)	(2.3)
Total Consumer Sales	**$ 13,853**	**13,602**	**13,307**	**1.8 %**	**2.2**

The Beauty franchise sales of $4.4 billion increased 4.3% as compared to the prior year. Growth was primarily driven by NEUTROGENA®, OGX® and AVEENO® products as well as strength of DR. CI: LABO and DABAO® products outside the U.S. Growth was partially offset by the divestiture of NIZORAL®.

The Over-the-Counter (OTC) franchise sales of $4.3 billion increased 5.0% as compared to the prior year. Growth was primarily driven by share, consumption and market growth across multiple brands including ZYRTEC®, TYLENOL® and Children's MOTRIN®, as well as digestive health products and anti-smoking aids. Additionally, sales from the recent U.S. acquisition of Zarbee's Inc. contributed approximately 0.9% to growth.

The Baby Care franchise sales were $1.9 billion in 2018, a decrease of 3.0% compared to the prior year, primarily due to JOHNSON's® share decline and increased trade promotions due to the JOHNSON's® baby relaunch and the negative impact of currency. This was partially offset by strong growth of AVEENO® baby driven by geographic expansion.

The Oral Care franchise sales of $1.6 billion increased 1.6% as compared to the prior year, primarily driven by strong marketing campaigns and new product launches.

The Women's Health franchise sales were $1.0 billion in 2018, a decrease of 0.1% as compared to the prior year. Growth in Latin America was offset by the negative impact of currency.

The Wound Care/Other franchise sales were $0.7 billion in 2018, a decrease of 13.4% as compared to the prior year, primarily due to the divestiture of COMPEED®.

Consumer segment sales in 2017 were $13.6 billion, an increase of 2.2% from 2016, which included 1.3% operational growth and a positive currency impact of 0.9%. U.S. Consumer segment sales were $5.6 billion, an increase of 2.7%. International sales were $8.0 billion, an increase of 1.9%, which included 0.4% operational growth and a positive currency impact of 1.5%. In 2017, acquisitions and divestitures had a net positive impact of 1.8% on the operational sales growth of the worldwide Consumer segment.

Pharmaceutical Segment

Pharmaceutical segment sales in 2018 were $40.7 billion, an increase of 12.4% from 2017, which included operational growth of 11.8% and a positive currency impact of 0.6%. U.S. sales were $23.3 billion, an increase of 8.4%. International sales were $17.4 billion, an increase of 18.0%, which included 16.5% operational growth and a positive currency impact of 1.5%. In 2018, acquisitions and divestitures had a net positive impact of 3.4% on the operational sales growth of the worldwide Pharmaceutical segment.

Major Pharmaceutical Therapeutic Area Sales:*

				% Change	
(Dollars in Millions)	**2018**	**2017**	**2016**	**'18 vs. '17**	**'17 vs. '16**
Total Immunology	**$ 13,120**	**12,244**	**11,968**	**7.2 %**	**2.3**
REMICADE®	5,326	6,315	6,966	(15.7)	(9.3)
SIMPONI®/SIMPONI ARIA®	2,084	1,833	1,745	13.7	5.0
STELARA®	5,156	4,011	3,232	28.5	24.1
TREMFYA®	544	63	—	**	**
Other Immunology	10	22	25	(54.5)	(12.0)
Total Infectious Diseases	**3,304**	**3,154**	**3,208**	**4.8**	**(1.7)**
EDURANT®/rilpivirine	816	714	573	14.3	24.6
PREZISTA®/ PREZCOBIX®/REZOLSTA®/SYMTUZA®	1,955	1,821	1,851	7.4	(1.6)
Other Infectious Diseases	533	619	784	(13.9)	(21.0)
Total Neuroscience	**6,077**	**5,986**	**6,085**	**1.5**	**(1.6)**
CONCERTA®/methylphenidate	663	791	863	(16.2)	(8.3)
INVEGA SUSTENNA®/XEPLION®/INVEGA TRINZA®/TREVICTA®	2,928	2,569	2,214	14.0	16.0
RISPERDAL CONSTA®	737	805	893	(8.4)	(9.9)
Other Neuroscience	1,749	1,821	2,115	(4.0)	(13.9)
Total Oncology	**9,844**	**7,258**	**5,807**	**35.6**	**25.0**
DARZALEX®	2,025	1,242	572	63.0	**
IMBRUVICA®	2,615	1,893	1,251	38.1	51.3
VELCADE®	1,116	1,114	1,224	0.2	(9.0)
ZYTIGA®/abiraterone acetate	3,498	2,505	2,260	39.6	10.8
Other Oncology	590	504	500	17.1	0.8
Pulmonary Hypertension	**2,573**	**1,327**	**—**	**93.9**	***
OPSUMIT®	1,215	573	—	**	***
TRACLEER®	546	403	—	35.5	***
UPTRAVI®	663	263	—	**	***
Other	149	88	—	69.3	***
Cardiovascular / Metabolism / Other	**5,816**	**6,287**	**6,396**	**(7.5)**	**(1.7)**
XARELTO®	2,477	2,500	2,288	(0.9)	9.3
INVOKANA®/ INVOKAMET®	881	1,111	1,407	(20.7)	(21.0)
PROCRIT®/EPREX®	988	972	1,105	1.6	(12.0)
Other	1,470	1,704	1,596	(13.7)	6.8
Total Pharmaceutical Sales	**$ 40,734**	**36,256**	**33,464**	**12.4 %**	**8.3**

* Prior year amounts have been reclassified to conform to current year presentation
** Percentage greater than 100% or not meaningful
***Products acquired from Actelion on June 16, 2017

Immunology products sales were $13.1 billion in 2018, representing an increase of 7.2% as compared to the prior year. Growth was driven by strong uptake of STELARA® (ustekinumab) in Crohn's disease, strong launch uptake of TREMFYA® (guselkumab), expanded indications of SIMPONI®/SIMPONI ARIA® (golimumab), and the U.S. immunology market growth. Immunology was negatively impacted by lower sales of REMICADE® (infliximab) due to increased discounts/rebates and biosimilar competition.

The patents for REMICADE® (infliximab) in certain countries in Europe expired in February 2015. Biosimilar versions of REMICADE® have been introduced in certain markets outside the U.S., resulting in a reduction in sales of REMICADE® in those markets. Additional biosimilar competition will likely result in a further reduction in REMICADE® sales in markets outside the United States. In the U.S., a biosimilar version of REMICADE® was introduced in 2016, and additional competitors continue to enter the market. Continued infliximab biosimilar competition in the U.S. market will result in a further reduction in U.S. sales of REMICADE®. See Note 21 to the Consolidated Financial Statements for a description of legal matters regarding the REMICADE® patents.

Infectious disease products sales were $3.3 billion in 2018, representing an increase of 4.8% as compared to the prior year. Sales growth of PREZCOBIX®/REZOLSTA® (darunavir/cobicistat), EDURANT®/rilpivirine, and the launch of SYMTUZA® and JULUCA® (dolutegravir/rilpivirine) was partially offset by lower sales of PREZISTA® (darunavir).

Neuroscience products sales were $6.1 billion, representing an increase of 1.5% as compared to the prior year. Strong sales of long-acting injectables INVEGA TRINZA®/TREVICTA® (paliperidone palmitate) and INVEGA SUSTENNA®/XEPLION® were partially offset by cannibalization of RISPERDAL CONSTA® (risperidone) and generic competition for CONCERTA®/methylphenidate.

Oncology products achieved sales of $9.8 billion in 2018, representing an increase of 35.6% as compared to the prior year. Contributors to the growth were strong sales of DARZALEX® (daratumumab) with continued market growth and share gain, IMBRUVICA® (ibrutinib) due to increased patient uptake globally and sales of ZYTIGA® (abiraterone acetate) driven by LATITUDE data and market growth. Additionally, sales from the launch of ERLEADA™ (apalutamide) contributed to the growth. A number of companies marketing generic pharmaceuticals have filed Abbreviated New Drug Applications (ANDAs) with the FDA, or undertaken similar regulatory processes outside of the U.S., seeking to market generic forms of ZYTIGA® prior to expiration of its applicable patents. These ANDAs include allegations of non-infringement and invalidity of the applicable patents. In October 2018, the Court issued a ruling invalidating all asserted claims of the applicable patent. Janssen has appealed the Court’s decision. In November 2018, the U.S. Court of Appeals for the Federal Circuit denied Janssen’s request for an injunction pending appeal. As a result, several generic versions of ZYTIGA® have entered the market, resulting in a decline in sales of ZYTIGA® in the United States. In 2018, the Company reported U.S. sales of $1.8 billion for ZYTIGA®. See Note 21 to the Consolidated Financial Statements for a description of legal matters regarding ZYTIGA®.

The Pulmonary Hypertension therapeutic area was established with the acquisition of Actelion Ltd on June 16, 2017. Sales in 2018 represented a full year as compared to half a year in 2017. Sales of OPSUMIT® (macitentan) and UPTRAVI® (selexipag) were positively impacted by market growth and share gains while sales of TRACLEER® (bosetan) were negatively impacted by increased use of OPSUMIT® and generics.

Cardiovascular/Metabolism/Other products sales were $5.8 billion, a decline of 7.5% as compared to the prior year. Lower sales of INVOKANA®/INVOKAMET® (canagliflozin) in the U.S. was primarily due to an increase in price discounts, higher rebates and market share decline driven by competitive pressure. Lower sales of XARELTO® (rivaroxaban) were driven by an increase in discounts and rebates, partially offset by an increase in market share.

During 2018, the Company advanced its pipeline with several regulatory submissions and approvals for new drugs and additional indications for existing drugs as follows:

Product Name (Chemical Name)	Indication	US Approval	EU Approval	US Filing	EU Filing
DARZALEX®(daratumumab)	Frontline multiple myeloma transplant ineligible patients in combination with bortezomib, melphalan, and prednisone	☐	☐		
erdafitinib	Treatment of locally advanced or metastatic urothelial cancer			☐	
ERLEADA™(apalutamide)	Treatment of non-metastatic castration-resistant prostate cancer	☐			☐
esketamine	Antidepressant for treatment-resistant depression in adults			☐	☐
IMBRUVICA® (ibrutinib)	Treatment of Waldenstrom's macroglobulinemia used in combination with rituximab	☐			☐
	Treatment for previously untreated Chronic Lymphocytic Leukemia in combination with obinutuzumab			☐	☐
INVOKANA® (canagliflozin)	Reduce the risk of death in type 2 diabetes with established, or risk for, cardiovascular disease. (CANVAS/CANVAS-R)	☐	☐		
JULUCA®(rilpivirine and dolutegravir)	Single-tablet, once-daily, two-drug regimen for the treatment of HIV-1 infection		☐		
OPSUMIT®(macitentan)	Treatment of adults with inoperable chronic thromboembolic pulmonary hypertension to improve exercise capacity and pulmonary vascular resistance			☐	☐
STELARA® (ustekinumab)	Treatment of adults with moderately to severely active ulcerative colitis			☐	☐
SYMTUZA® (darunavir/cobicistat/ emtricitabine/tenofovir alafenamide)	A complete darunavir-based single-tablet regimen for the treatment of HIV-1 infection	☐			
TREMFYA® (guselkumab)	Patient controlled injector for the treatment of adults living with moderate to severe plaque psoriasis		☐	☐	
XARELTO® (rivaroxaban)	Treatment to reduce the risk of major cardiovascular events in people with chronic coronary or peripheral artery disease	☐			
	For the prevention of venous thromboembolism for medically ill patients			☐	
ZYTIGA® (abiraterone acetate)	Treatment of Hormone Naïve Metastatic Prostate Cancer	☐			

Pharmaceutical segment sales in 2017 were $36.3 billion, an increase of 8.3% from 2016, which included operational growth of 8.0% and a positive currency impact of 0.3%. U.S. sales were $21.5 billion, an increase of 6.7%. International sales were $14.8 billion, an increase of 10.8%, which included 10.1% operational growth and a positive currency impact of 0.7%. In 2017, acquisitions and divestitures had a net positive impact of 3.8% on the operational sales growth of the worldwide Pharmaceutical segment. Adjustments to previous reserve estimates, as compared to the prior year, negatively impacted the reported Pharmaceutical segment operational growth by approximately 1.8%, primarily in the Immunology and Cardiovascular/Metabolism/Other therapeutic areas.

Medical Devices Segment

The Medical Devices segment sales in 2018 were $27.0 billion, an increase of 1.5% from 2017, which included an operational increase of 1.1% and a positive currency impact of 0.4%. U.S. sales were $12.8 billion, an increase of 0.1% as compared to the prior year. International sales were $14.2 billion, an increase of 2.8% as compared to the prior year, with an operational increase of 1.9% and a positive currency impact of 0.9%. In 2018, acquisitions and divestitures had a net negative impact of 1.5% on the worldwide operational sales growth of the Medical Devices segment as compared to 2017.

Major Medical Devices Franchise Sales:*

(Dollars in Millions)	2018	2017	2016	% Change '18 vs. '17	% Change '17 vs. '16
Surgery	**$ 9,901**	**9,559**	**9,296**	**3.6 %**	**2.8**
Advanced	4,002	3,756	3,517	6.5	6.8
General	4,557	4,463	4,362	2.1	2.3
Specialty	1,342	1,340	1,417	0.1	(5.4)
Orthopaedics	**8,885**	**9,058**	**9,128**	**(1.9)**	**(0.8)**
Hips	1,418	1,394	1,361	1.7	2.4
Knees	1,502	1,523	1,524	(1.4)	(0.1)
Trauma	2,699	2,616	2,569	3.2	1.8
Spine & Other	3,266	3,525	3,674	(7.3)	(4.1)
Vision	**4,553**	**4,063**	**2,785**	**12.1**	**45.9**
Contact Lenses/Other	3,302	3,036	2,785	8.8	9.0
Surgical	1,251	1,027	—	21.8	**
Interventional Solutions (1)	**2,646**	**2,296**	**2,055**	**15.2**	**11.7**
Diabetes Care	**1,009**	**1,615**	**1,789**	**(37.5)**	**(9.7)**
Diagnostics (2)	**—**	**1**	**66**	***	***
Total Medical Devices Sales	**$ 26,994**	**26,592**	**25,119**	**1.5 %**	**5.9**

(1)Previously referred to as Cardiovascular

(2)On June 30, 2014, the Company divested the Ortho-Clinical Diagnostics business (the Diagnostics Franchise) and amounts represent transitional service agreement that concluded in 2017.

* Prior year amounts have been reclassified to conform to current year presentation

**Products acquired from Abbott Medical Optics (AMO) on February 27, 2017

*** Percentage greater than 100% or not meaningful

The Surgery franchise sales were $9.9 billion in 2018, an increase of 3.6% from 2017. Growth in Advanced Surgery was primarily driven by endocutter, biosurgery and energy products. Growth in General Surgery was primarily driven by wound care products. Growth in Specialty Surgery was primarily driven by Advanced Sterilization Products.

The Orthopaedics franchise sales were $8.9 billion in 2018, a decrease of 1.9% from 2017. The decline in Spine & Other was primarily due to the Codman Neurosurgery divestiture and share loss in Spine partially offset by new product launches. The decline in knees was primarily due to competitive pressure in the U.S. partially offset by growth in Asia Pacific. Growth in hips and trauma was due to continued uptake of new products.

The Vision franchise achieved sales of $4.6 billion in 2018, an increase of 12.1% from 2017. Growth was primarily driven by strength of the astigmatism and daily disposable lenses in the OASYS® contact lenses category. Surgical growth was driven by cataract performance primarily outside the U.S.

The Interventional Solutions franchise (includes the Cerenovus business previously included in Spine and Other in Orthopaedics) sales were $2.6 billion, an increase of 15.2% from 2017. Strong growth in the electrophysiology business was driven by Atrial Fibrillation procedure growth and continued uptake of the THERMOCOOL SMARTTOUCH® Contact Force Sensing Catheter.

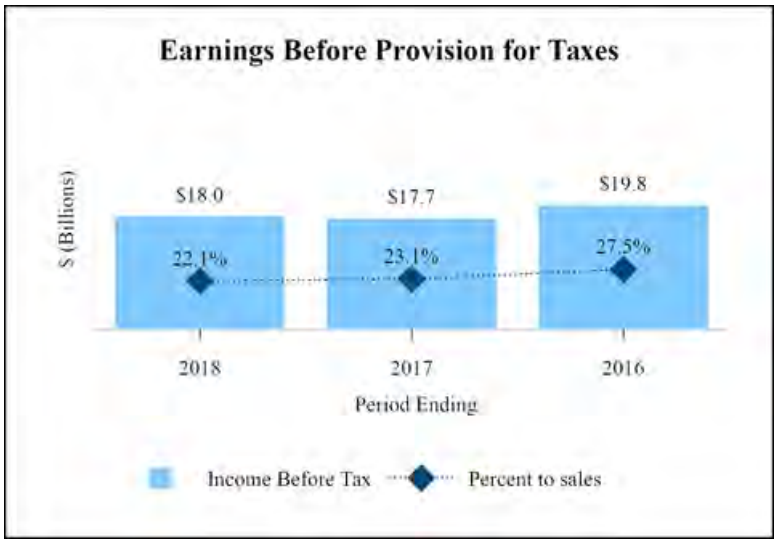
The Diabetes Care franchise sales were $1.0 billion, a decrease of 37.5% from 2017. The decline was primarily due to divestiture of its LifeScan business in the fiscal fourth quarter of 2018 and the Company's decision to exit the Animas insulin pump business in the fiscal fourth quarter of 2017.

The Medical Devices segment sales in 2017 were $26.6 billion, an increase of 5.9% from 2016, which included an operational increase of 5.7% and a positive currency impact of 0.2%. U.S. sales were $12.8 billion, an increase of 4.5% as compared to the prior year. International sales were $13.8 billion, an increase of 7.1% as compared to the prior year, with an

operational increase of 6.7% and a positive currency impact of 0.4%. In 2017, acquisitions and divestitures had a net positive impact of 4.2% on the worldwide operational sales growth of the Medical Devices segment as compared to 2016.

Analysis of Consolidated Earnings Before Provision for Taxes on Income

Consolidated earnings before provision for taxes on income was $18.0 billion, $17.7 billion and $19.8 billion for the fiscal years ended 2018, 2017 and 2016, respectively. As a percent to sales, consolidated earnings before provision for taxes on income was 22.1%, 23.1%, and 27.5% in 2018, 2017 and 2016, respectively.



Cost of Products Sold and Selling, Marketing and Administrative Expenses: Cost of products sold and selling, marketing and administrative expenses as a percent to sales were as follows:*

% of Sales	2018	2017	2016
Cost of products sold*	33.2%	33.3	30.3
Percent point increase/(decrease) over the prior year	(0.1)	3.0	(0.3)
Selling, marketing and administrative expenses*	27.6%	28.1	27.9
Percent point increase/(decrease) over the prior year	(0.5)	0.2	(2.2)

*Prior years amounts were reclassified to conform to current year presentation (adoption of ASU 2017-07)

In 2018, cost of products sold as a percent to sales decreased to 33.2% from 33.3% as compared to the same period a year ago primarily due to lower inventory step-up costs related to the Actelion acquisition and favorable product and segment mix driven by a higher percentage of sales from the Pharmaceutical segment. This was mostly offset by higher amortization expense primarily related to the Actelion acquisition on June 16, 2017. Intangible asset amortization expense of $4.4 billion was included in cost of products sold for 2018 as compared to $3.0 billion in 2017. There was a decrease in the percent to sales of selling, marketing and administrative expenses in 2018 as compared to the prior year, primarily due to lower costs relative to sales growth in the Pharmaceutical business and favorable segment mix.

In 2017, cost of products sold as a percent to sales increased to 33.3% from 30.3% as compared to the same period a year ago. The unfavorable increase was primarily driven by $2.3 billion of higher amortization expense and charges for inventory step-up related to the recent acquisitions, primarily Actelion. Intangible asset amortization expense of $3.0 billion was included in cost of products sold for 2017 as compared to $1.2 billion in 2016. There was an increase in the percent to sales of selling, marketing and administrative expenses in 2017 as compared to the prior year, primarily due to investments in new product launches partially offset by favorable mix.

Research and Development Expense: Research and development expense by segment of business was as follows:*

(Dollars in Millions)	2018 Amount	2018 % of Sales**	2017 Amount	2017 % of Sales**	2016 Amount	2016 % of Sales**
Consumer	$ 565	4.1%	586	4.3	585	4.4
Pharmaceutical	8,446	20.7	8,392	23.1	7,001	20.9
Medical Devices	1,764	6.5	1,616	6.1	1,557	6.2
Total research and development expense	$ 10,775	13.2%	10,594	13.9	9,143	12.7
Percent increase/(decrease) over the prior year	1.7%		15.9		1.6	

*Prior years amounts were reclassified to conform to current year presentation (adoption of ASU 2017-07)
**As a percent to segment sales

Research and development activities represent a significant part of the Company's business. These expenditures relate to the processes of discovering, testing and developing new products, upfront payments and milestones, improving existing products, as well as ensuring product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products. In 2018, worldwide costs of research and development activities increased by 1.7% compared to 2017 but decreased as a percent of sales. The decrease as a percent of sales in the Pharmaceutical segment was attributable to lower costs relative to sales growth. The increased dollar spend in the Medical Devices and Pharmaceutical segments was for investment spending to advance the pipeline. In 2017, worldwide costs of research and development activities increased by 15.9% compared to 2016. The increase as a percent of sales was primarily in the Pharmaceutical segment due to general portfolio progression as well as collaborative agreements entered into with Idorsia Ltd. and Legend Biotech. Research facilities are located in the U.S., Belgium, Brazil, China, France, Germany, India, Israel, the Netherlands, Poland, Singapore, Sweden, Switzerland and the United Kingdom with additional R&D support in over 30 other countries.

In-Process Research and Development (IPR&D): In 2018, the Company recorded an IPR&D charge of $1.1 billion. Of the $1.1 billion, a partial impairment charge of $0.8 billion related to the development program of AL-8176, an investigational drug for the treatment of Respiratory Syncytial Virus (RSV) and human metapneumovirus (hMPV) acquired with the 2014 acquisition of Alios Biopharma Inc. The impairment charge was calculated based on updated cash flow projections discounted for the inherent risk in the asset development and reflects the impact of the phase 2b clinical trial suspension, a decrease in the probability of success factors and the ongoing analysis of asset development activities. The Company continues to evaluate information with respect to the development program and will monitor the remaining $0.9 billion intangible asset for further impairment. In addition, an impairment charge of $0.3 billion was recorded for the discontinuation of the development project for an anti-thrombin antibody associated with the 2015 acquisition of XO1 Limited.

In 2017, the Company recorded an IPR&D charge of $0.4 billion primarily for the discontinuation of certain development projects related to Novira which was acquired in 2015. The product development was canceled due to safety concerns. In 2016, the Company recorded an IPR&D charge of $29 million for the discontinuation of a development program related to Crucell.

Other (Income) Expense, Net: Other (income) expense, net is the account where the Company records gains and losses related to the sale and write-down of certain investments in equity securities held by Johnson & Johnson Innovation - JJDC, Inc. (JJDC), unrealized gains and losses on investments, gains and losses on divestitures, certain transactional currency gains and losses, acquisition-related costs, litigation accruals and settlements, as well as royalty income.

The change in other (income) expense, net for the fiscal year 2018 was an unfavorable change of $1.4 billion primarily due to litigation expense of $2.0 billion in 2018 as compared to $1.3 billion in 2017. Additionally, 2018 included unrealized losses on securities of $0.2 billion and lower realized gains of $0.4 billion related to investments in equity securities as compared to the prior year. This was partially offset by a reversal of a contingent liability of $0.2 billion and lower costs of $0.1 billion related to the Actelion and AMO acquisitions in 2018 as compared to 2017. The fiscal year of 2017 included a gain of $0.2 billion related to monetization of future royalty receivables offset by an asset impairment charge of $0.2 billion primarily related to the insulin pump business. Divestiture gains were approximately $1.2 billion in 2018 and included the LifeScan business, NIZORAL®, RoC® and certain non-strategic Pharmaceutical products. Divestiture gains were approximately $1.3 billion in 2017 and primarily included the Codman Neurosurgery and COMPEED® divestitures. Additionally, restructuring related expense in 2018 was $0.3 billion as compared to $0.4 billion 2017.

The change in other (income) expense, net for the fiscal year 2017 was a favorable change of $0.3 billion due to higher gains of $0.7 billion on the sale of assets/businesses, primarily the Codman Neurosurgery and COMPEED® divestitures, a gain of $0.2 billion related to monetization of future royalty receivables and a higher gain of $0.3 billion related to the sale of certain investments in equity securities as compared to the prior year. This was partially offset by higher litigation expense of $0.4 billion, $0.3 billion of acquisition costs related to Actelion and AMO, an asset impairment charge of $0.2 billion primarily

related to the insulin pump business and a higher restructuring related charge of $0.2 billion as compared to the fiscal year 2016.

Interest (Income) Expense: Interest income was higher in 2018 as compared to 2017 due to a higher average interest rate and a benefit from net investment hedging partially offset by a lower average cash, cash equivalents and marketable securities balance during the period. Cash, cash equivalents and marketable securities totaled $19.7 billion at the end of 2018, and averaged $19.0 billion as compared to the cash, cash equivalents and marketable securities total of $18.3 billion and $30.1 billion average cash balance in 2017. The decrease in the average balance of cash, cash equivalents and marketable securities was due to the use of cash for general corporate purposes, primarily the Actelion acquisition for $29.6 billion, net of cash acquired late in the fiscal second quarter of 2017.

Interest expense in 2018 was higher as compared to 2017 due to a higher average debt balance. The average debt balance was $32.5 billion in 2018 versus $30.9 billion in 2017. The total debt balance at the end of 2018 was $30.5 billion as compared to $34.6 billion at the end of 2017.

Interest income in 2017 increased slightly as compared to 2016 due to higher average interest rates partially offset by lower cash, cash equivalents and marketable securities balances during the period. Cash, cash equivalents and marketable securities totaled $18.3 billion at the end of 2017, and averaged $30.1 billion as compared to the $40.1 billion average cash balance in 2016. The decrease in the balance of cash, cash equivalents and marketable securities was due to the use of cash for general corporate purposes including acquisitions, primarily the Actelion acquisition for $29.6 billion, net of cash acquired.

Interest expense in 2017 was higher as compared to 2016. The average debt balance was $30.9 billion in 2017 versus $23.5 billion in 2016. The total debt balance at the end of 2017 was $34.6 billion as compared to $27.1 billion at the end of 2016. The higher debt balance of approximately $7.5 billion was primarily due to increased borrowings. The Company increased borrowings in February and November of 2017, capitalizing on favorable terms in the capital markets. The proceeds of the borrowings were used for general corporate purposes, including the completion of the stock repurchase program.

Income Before Tax by Segment

Income before tax by segment of business were as follows:

	Income Before Tax		Segment Sales		Percent of Segment Sales	
(Dollars in Millions)	**2018**	**2017**	**2018**	**2017**	**2018**	**2017**
Consumer	$ 2,320	2,524	13,853	13,602	16.7%	18.6
Pharmaceutical	12,568	11,083	40,734	36,256	30.9	30.6
Medical Devices	4,397	5,392	26,994	26,592	16.3	20.3
Total [1]	19,285	18,999	81,581	76,450	23.6	24.9
Less: Expenses not allocated to segments [2]	1,286	1,326				
Earnings before provision for taxes on income	$ 17,999	17,673	81,581	76,450	22.1%	23.1

(1) See Note 18 to the Consolidated Financial Statements for more details.
(2) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.

Consumer Segment: In 2018, the Consumer segment income before tax as a percent to sales was 16.7%, versus 18.6% in 2017. The decrease in the income before tax as a percent of sales in 2018 as compared to 2017 was primarily attributable to higher litigation expense of $0.3 billion in 2018 partially offset by slower increases in expenses relative to the increase in sales. Divestiture gains for the fiscal year of 2018, which included the divestitures of NIZORAL® and RoC® were comparable to fiscal year of 2017. A gain of $0.3 billion was recognized from the divestiture of NIZORAL®.

In 2017, the Consumer segment income before tax as a percent to sales was 18.6%, versus 18.3% in 2016. The increase in the income before tax as a percent of sales in 2017 as compared to 2016 was attributable to higher gains on divestitures, primarily the divestiture of COMPEED® in 2017. This was partially offset by higher selling, marketing and administrative expenses as compared to the prior year due to increased advertising and promotional spending and slightly higher amortization expense in 2017 related to acquisitions. Additionally, the fiscal year 2016 was negatively impacted by operations in Venezuela.

Pharmaceutical Segment: In 2018, the Pharmaceutical segment income before tax as a percent to sales was 30.9% versus 30.6% in 2017. The increase in the income before tax as a percent of sales was primarily due to lower inventory step-up costs related to Actelion of $0.6 billion, favorable product mix and slower increases in expenses relative to the increase in sales, a contingent liability reversal of $0.2 billion and higher divestiture gains of $0.2 billion from divestitures of certain non-strategic Pharmaceutical products. This was partially offset by higher amortization expense of $1.3 billion primarily related to the Actelion acquisition, a higher IPR&D charge of $0.7 billion and an unrealized loss on securities of $0.2 billion as compared to

the prior year. Additionally, 2017 included a gain of $0.2 billion related to monetization of future royalty receivables and a higher gain of $0.3 billion related to the sale of certain investments in equity securities.

In 2017, the Pharmaceutical segment income before tax as a percent to sales was 30.6% versus 38.3% in 2016. The decrease in the income before tax as a percent of sales was primarily due to $2.3 billion of higher amortization expense and other costs related to the Actelion acquisition, higher research and development expense, a higher IPR&D charge of $0.4 billion related to Novira and lower gains on divestitures as compared to the prior year. Additionally, the fiscal year 2016 included a positive adjustment of $0.5 billion to previous reserve estimates. This was partially offset by a gain of $0.2 billion related to monetization of future royalty receivables, a higher gain of $0.2 billion related to the sale of certain investments in equity securities and favorable product mix in 2017.

Medical Devices Segment: In 2018, the Medical Devices segment income before tax as a percent to sales was 16.3% versus 20.3% in 2017. The decrease in the income before tax as a percent to sales was primarily due higher litigation expense of $1.7 billion in 2018 as compared to $1.1 billion in 2017 and higher investments in the business in 2018. Additionally, 2018 had lower divestiture gains of approximately $0.3 billion as compared to divestiture gains in 2017. In 2018 the Company recorded a gain of $0.5 billion related to the LifeScan divestiture. This was partially offset by lower restructuring expense of $0.2 billion in 2018 as compared to 2017. Additionally, 2017 included an asset impairment charge of $0.2 billion primarily related to the insulin pump business.

In 2017, the Medical Devices segment income before tax as a percent to sales was 20.3% versus 22.2% in 2016. The decrease in the income before tax as a percent to sales was primarily due to $0.3 billion of higher amortization expense and other acquisition costs related to AMO, $0.3 billion of higher litigation, an asset impairment charge of $0.2 billion primarily related to the insulin pump business, $0.1 billion of higher restructuring and investments in new product launches as compared to the fiscal year 2016. This was partially offset by $0.8 billion higher gains in 2017 related to divestitures, primarily the divestiture of Codman Neurosurgery.

Restructuring: In the first quarter of 2016, the Company announced restructuring actions in its Medical Devices segment. The Company has achieved approximately $0.7 billion of annualized pre-tax cost saving in 2018 and is on track to achieve the annualized pre-tax cost savings of $0.8 billion to $1.0 billion as outlined in the restructuring actions. The savings will provide the Company with added flexibility and resources to fund investment in new growth opportunities and innovative solutions for customers and patients. In 2018, the Company recorded a pre-tax charge of $462 million, of which $46 million is included in cost of products sold and $227 million is included in other (income) expense. Total project costs of approximately $2.5 billion have been recorded since the restructuring was announced. This restructuring program was completed in the fiscal fourth quarter of 2018.

In the second quarter of 2018, the Company announced plans to implement actions across its global supply chain that are intended to enable the Company to focus resources and increase investments in critical capabilities, technologies and solutions necessary to manufacture and supply its product portfolio of the future, enhance agility and drive growth. The Company expects these supply chain actions will include expanding its use of strategic collaborations, and bolstering its initiatives to reduce complexity, improving cost-competitiveness, enhancing capabilities and optimizing its network. Discussions regarding specific future actions are ongoing and are subject to all relevant consultation requirements before they are finalized. In total, the Company expects these actions to generate approximately $0.6 to $0.8 billion in annual pre-tax cost savings that will be substantially delivered by 2022. The Company expects to record pre-tax restructuring charges of approximately $1.9 to $2.3 billion. The Company estimates that approximately 70% of the cumulative pre-tax costs will result in cash outlays. In 2018, the Company recorded a pre-tax charge of $238 million, of which $59 million is included in cost of products sold and $117 million is included in other (income) expense.

See Note 22 to the Consolidated Financial Statements for additional details related to the restructuring programs.

Provision for Taxes on Income: The worldwide effective income tax rate was 15.0% in 2018, 92.6% in 2017 and 16.5% in 2016. The 2018 effective tax rate decreased by 77.6% as compared to 2017. The 2017 effective tax rate was primarily driven by a provisional tax charge of approximately $13.0 billion as a result of the Tax Cuts and Jobs Act (TCJA) recorded in the fourth quarter of 2017 and the impact of a Belgian statutory tax rate change which increased the 2017 effective rate by 3.4%. The Company also received a benefit in 2018 from a lower U.S. statutory tax rate vs. 2017 as well as favorable adjustments to the 2017 provisional TCJA tax charge partially offset by unfavorable income tax mix and the U.S. tax on global intangible low-taxed income (GILTI).

The 2017 effective tax rate increased by 76.1% as compared to 2016, primarily driven by the enactment of the Tax Cuts and Jobs Act (TCJA) in the United States in December 2017. The enactment of the TCJA resulted in a provisional tax charge in the fourth quarter of 2017, of approximately $13.0 billion or approximately 73.3 percentage point increase to the effective tax rate. See Note 8 to the Consolidated Financial Statements for additional details related to the TCJA.

The remainder of the increase in the tax rate for 2017 was related to the remeasurement of the Company's deferred tax assets in Belgium, as a result of changes in the Belgian statutory corporate tax rate, enacted in December 2017, offset by a tax benefit for the closure of the Company's Animas insulin pump business.

The government in Switzerland is currently considering tax reform legislation, which could have a material impact on the Company's effective tax rate if enacted into law.

See Note 8 to the Consolidated Financial Statements for additional details related to the TCJA and income taxes.

Liquidity and Capital Resources

Liquidity & Cash Flows

Cash and cash equivalents were $18.1 billion at the end of 2018 as compared to $17.8 billion at the end of 2017. The primary sources and uses of cash that contributed to the $0.3 billion increase were approximately $22.2 billion of cash generated from operating activities. This was partially offset by $3.2 billion net cash used by investing activities, $18.5 billion net cash used by financing activities and $0.2 billion due to the effect on exchange rate changes on cash and cash equivalents. In addition, the Company had $1.6 billion in marketable securities at the end of 2018 and $0.5 billion at the end of 2017. See Note 1 to the Consolidated Financial Statements for additional details on cash, cash equivalents and marketable securities.

Cash flow from operations of $22.2 billion was the result of $15.3 billion of net earnings and $9.2 billion of non-cash expenses and other adjustments for depreciation and amortization, stock-based compensation and assets write-downs, offset by $2.3 billion from net gains on sale of assets/businesses, deferred tax provision and accounts receivable allowances, $3.9 billion related to an increase in accounts receivable, inventories and other current and non-current assets and a decrease in other current and non-current liabilities. Additional sources of operating cash flow of $4.0 billion resulted from an increase in accounts payable and accrued liabilities. The decrease in current and non-current liabilities is primarily due to the 2018 tax payment related to TCJA.

Investing activities use of $3.2 billion was for additions to property, plant and equipment of $3.7 billion, the net purchase of investments primarily marketable securities of $1.3 billion, acquisitions, net of cash acquired of $0.9 billion (primarily the acquisitions of Zarbee's) and other uses of $0.5 billion. This was partially offset by $3.2 billion of proceeds from the disposal of assets/businesses (primarily the divestiture of LifeScan).

Financing activities use of $18.5 billion was primarily for dividends to shareholders of $9.5 billion, $5.9 billion for the repurchase of common stock, $3.9 billion for the net retirement of short and long-term debt and $0.2 billion of other financing. Financing activities also included sources of $1.0 billion of proceeds from stock options exercised/employee withholding tax on stock awards, net.

On December 17, 2018, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's shares of common stock. The repurchase program has no time limit and may be suspended for periods or discontinued at any time. Any shares acquired will be available for general corporate purposes. The Company intends to finance the share repurchase program through available cash. As of December 30, 2018, $0.9 billion has been repurchased under the program.

As of December 30, 2018, the Company's notes payable and long-term debt was in excess of cash, cash equivalents and marketable securities. As of December 30, 2018, the net debt position was $10.8 billion as compared to the prior year of $16.3 billion. There was a decrease in the net debt position due to retirement of debt. The debt balance at the end of 2018 was $30.5 billion as compared to $34.6 billion in 2017. Additionally there was a higher cash, cash equivalents and marketable securities balance at the end of 2018. In 2018, the Company continued to have access to liquidity through the commercial paper market. Additionally, as a result of the TCJA, the Company has access to its cash outside the U.S. at a significantly reduced cost. The Company anticipates that operating cash flows, the ability to raise funds from external sources, borrowing capacity from existing committed credit facilities and access to the commercial paper markets will continue to provide sufficient resources to fund operating needs for the next twelve months. The Company monitors the global capital markets on an ongoing basis and from time to time may raise capital when market conditions are favorable. The Company filed a new shelf registration on February 27, 2017 which will enable it to issue debt securities on a timely basis. For additional details on borrowings, see Note 7 to the Consolidated Financial Statements.

Financing and Market Risk

The Company uses financial instruments to manage the impact of foreign exchange rate changes on cash flows. Accordingly, the Company enters into forward foreign exchange contracts to protect the value of certain foreign currency assets and liabilities and to hedge future foreign currency transactions primarily related to product costs. Gains or losses on these contracts are offset by the gains or losses on the underlying transactions. A 10% appreciation of the U.S. Dollar from the December 30, 2018 market rates would increase the unrealized value of the Company's forward contracts by $57 million. Conversely, a 10% depreciation of the U.S. Dollar from the December 30, 2018 market rates would decrease the unrealized value of the Company's forward contracts by $69 million. In either scenario, the gain or loss on the forward contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated earnings and cash flows.

The Company hedges the exposure to fluctuations in currency exchange rates, and the effect on certain assets and liabilities in foreign currency, by entering into currency swap contracts. A 1% change in the spread between U.S. and foreign interest rates on the Company's interest rate sensitive financial instruments would either increase or decrease the unrealized value of the Company's swap contracts by approximately $226 million. In either scenario, at maturity, the gain or loss on the swap contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated cash flows.

The Company does not enter into financial instruments for trading or speculative purposes. Further, the Company has a policy of only entering into contracts with parties that have at least an investment grade credit rating. The counter-parties to these contracts are major financial institutions and there is no significant concentration of exposure with any one counter-party. Management believes the risk of loss is remote. During the fiscal second quarter of 2017, the Company entered into credit support agreements (CSA) with certain derivative counterparties establishing collateral thresholds based on respective credit ratings and netting agreements.

The Company invests in both fixed rate and floating rate interest earning securities which carry a degree of interest rate risk. The fair market value of fixed rate securities may be adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than predicted if interest rates fall. A 1% (100 basis points) change in spread on the Company's interest rate sensitive investments would either increase or decrease the unrealized value of cash equivalents and current marketable securities by approximately $8 million.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2018, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 12, 2019. Interest charged on borrowings under the credit line agreement is based on either bids provided by banks, the prime rate or London Interbank Offered Rates (LIBOR), plus applicable margins. Commitment fees under the agreement are not material.

Total borrowings at the end of 2018 and 2017 were $30.5 billion and $34.6 billion, respectively. The decrease in borrowings was due to the retirement of debt in 2018. In 2018, net debt (cash and current marketable securities, net of debt) was $10.8 billion compared to net debt of $16.3 billion in 2017. Total debt represented 33.8% of total capital (shareholders' equity and total debt) in 2018 and 36.5% of total capital in 2017. Shareholders' equity per share at the end of 2018 was $22.44 compared to $22.43 at year-end 2017.

A summary of borrowings can be found in Note 7 to the Consolidated Financial Statements.

Contractual Obligations and Commitments

The Company's contractual obligations are primarily for the recently enacted tax legislation, leases, debt and unfunded retirement plans. There are no other significant obligations. To satisfy these obligations, the Company will use cash from operations. The following table summarizes the Company's contractual obligations and their aggregate maturities as of December 30, 2018 (see Notes 7, 8, 10 and 16 to the Consolidated Financial Statements for further details):

(Dollars in Millions)	Tax Legislation (TCJA)	Debt Obligations	Interest on Debt Obligations	Unfunded Retirement Plans	Operating Leases	Total
2019	$ —	2,636	949	92	223	3,900
2020	531	1,098	886	95	188	2,798
2021	812	1,796	841	101	154	3,704
2022	812	2,134	796	108	116	3,966
2023	1,522	1,553	764	115	76	4,030
After 2023	4,565	21,103	8,850	697	139	35,354
Total	**$ 8,242**	**30,320**	**13,086**	**1,208**	**896**	**53,752**

For tax matters, see Note 8 to the Consolidated Financial Statements. For other retirement plan and post-employment medical benefit information, see Note 10 to the Consolidated Financial Statements. The table does not include activity related to business combinations.

Dividends

The Company increased its dividend in 2018 for the 56th consecutive year. Cash dividends paid were $3.54 per share in 2018 compared with dividends of $3.32 per share in 2017, and $3.15 per share in 2016.

Other Information

Critical Accounting Policies and Estimates

Management's discussion and analysis of results of operations and financial condition are based on the Company's consolidated financial statements that have been prepared in accordance with accounting principles generally accepted in the U.S. (GAAP). The preparation of these financial statements requires that management make estimates and assumptions that affect the amounts reported for revenues, expenses, assets, liabilities and other related disclosures. Actual results may or may not differ from these estimates. The Company believes that the understanding of certain key accounting policies and estimates are essential in achieving more insight into the Company's operating results and financial condition. These key accounting policies include revenue recognition, income taxes, legal and self-insurance contingencies, valuation of long-lived assets, assumptions used to determine the amounts recorded for pensions and other employee benefit plans and accounting for stock based awards.

Revenue Recognition: The Company recognizes revenue from product sales when obligations under the terms of a contract with the customer are satisfied; generally, this occurs with the transfer of control of the goods to customers. The Company's global payment terms are typically between 30 to 90 days. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns and discounts to customers are accounted for as variable consideration and recorded as a reduction in sales. See Note 1 to the Consolidated Financial Statements for the Accounting Standards Update related to revenue which was adopted in 2018.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including consideration of competitor pricing. Rebates are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns are estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales return accruals.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The sales returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual net trade sales during the fiscal reporting years 2018, 2017 and 2016.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the same period as related sales. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue. The Company also earns profit-share payments through collaborative arrangements of certain products, which are included in sales to customers. For all years presented, profit-share payments were less than 2.0% of the total revenues and are included in sales to customers.

In addition, the Company enters into collaboration arrangements that contain multiple revenue generating activities. Amounts due from collaborative partners for these arrangements are recognized as each activity is performed or delivered, based on the relative selling price. Upfront fees received as part of these arrangements are deferred and recognized over the performance period. See Note 1 to the Consolidated Financial Statements for additional disclosures on collaborations.

Reasonably likely changes to assumptions used to calculate the accruals for rebates, returns and promotions are not anticipated to have a material effect on the financial statements. The Company currently discloses the impact of changes to assumptions in the quarterly or annual filing in which there is a material financial statement impact.

Below are tables that show the progression of accrued rebates, returns, promotions, reserve for doubtful accounts and reserve for cash discounts by segment of business for the fiscal years ended December 30, 2018 and December 31, 2017.

Consumer Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits	Balance at End of Period
2018				
Accrued rebates [1]	$ 186	836	(751)	271
Accrued returns	68	98	(109)	57
Accrued promotions	481	2,233	(2,217)	497
Subtotal	$ 735	3,167	(3,077)	825
Reserve for doubtful accounts	31	10	(9)	32
Reserve for cash discounts	23	204	(204)	23
Total	$ 789	3,381	(3,290)	880
2017				
Accrued rebates[1]	$ 136	638	(588)	186
Accrued returns	65	128	(125)	68
Accrued promotions	358	2,148	(2,025)	481
Subtotal	$ 559	2,914	(2,738)	735
Reserve for doubtful accounts	24	10	(3)	31
Reserve for cash discounts	25	205	(207)	23
Total	$ 608	3,129	(2,948)	789

(1) Includes reserve for customer rebates of $57 million at December 30, 2018 and $48 million at December 31, 2017, recorded as a contra asset.

Pharmaceutical Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits[2]	Balance at End of Period
2018				
Accrued rebates [1]	$ 4,862	22,644	(19,996)	7,510
Accrued returns	362	385	(311)	436
Accrued promotions	35	46	(68)	13
Subtotal	$ 5,259	23,075	(20,375)	7,959
Reserve for doubtful accounts	77	37	(67)	47
Reserve for cash discounts	55	860	(862)	53
Total	$ 5,391	23,972	(21,304)	8,059
2017				
Accrued rebates [1]	$ 3,420	16,447	(15,005)	4,862
Accrued returns	334	256	(228)	362
Accrued promotions	—	69	(34)	35
Subtotal	$ 3,754	16,772	(15,267)	5,259
Reserve for doubtful accounts	38	40	(1)	77
Reserve for cash discounts	58	714	(717)	55
Total	$ 3,850	17,526	(15,985)	5,391

(1) Includes reserve for customer rebates of $89 million at December 30, 2018 and $90 million at December 31, 2017, recorded as a contra asset.

(2) Includes adjustments

Medical Devices Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits	Balance at End of Period
2018				
Accrued rebates[1]	$ 1,620	6,344	(6,746)	1,218
Accrued returns	152	362	(400)	114
Accrued promotions	83	116	(157)	42
Subtotal	$ 1,855	6,822	(7,303)	1,374
Reserve for doubtful accounts	183	29	(43)	169
Reserve for cash discounts	15	372	(387)	—
Total	$ 2,053	7,223	(7,733)	1,543
2017				
Accrued rebates[1]	$ 1,500	6,407	(6,287)	1,620
Accrued returns	127	729	(704)	152
Accrued promotions	32	135	(84)	83
Subtotal	$ 1,659	7,271	(7,075)	1,855
Reserve for doubtful accounts	190	27	(34)	183
Reserve for cash discounts	16	389	(390)	15
Total	$ 1,865	7,687	(7,499)	2,053

(1) Includes reserve for customer rebates of $632 million at December 30, 2018 and $501 million at December 31, 2017, recorded as a contra asset.

Income Taxes: Income taxes are recorded based on amounts refundable or payable for the current year and include the results of any difference between U.S. GAAP accounting and tax reporting, recorded as deferred tax assets or liabilities. The Company estimates deferred tax assets and liabilities based on enacted tax regulations and rates. Future changes in tax laws and rates may affect recorded deferred tax assets and liabilities.

The Company has unrecognized tax benefits for uncertain tax positions. The Company follows U.S. GAAP, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Management believes that changes in these estimates would not have a material effect on the Company's results of operations, cash flows or financial position.

The Company has recorded deferred tax liabilities on all undistributed earnings prior to December 31, 2017 from its international subsidiaries. The Company has not provided deferred taxes on the undistributed earnings subsequent to January 1, 2018 from certain international subsidiaries where the earnings are considered to be indefinitely reinvested. The Company intends to continue to reinvest these earnings in those international operations. If the Company decides at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company estimates that the total tax effect of this repatriation would be approximately $0.7 billion under current enacted tax laws and regulations and at current currency exchange rates.

See Note 8 to the Consolidated Financial Statements for further information regarding income taxes.

Legal and Self Insurance Contingencies: The Company records accruals for various contingencies, including legal proceedings and product liability claims as these arise in the normal course of business. The accruals are based on management's judgment as to the probability of losses and, where applicable, actuarially determined estimates. The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated.

The Company follows the provisions of U.S. GAAP when recording litigation related contingencies. A liability is recorded when a loss is probable and can be reasonably estimated. The best estimate of a loss within a range is accrued; however, if no estimate in the range is better than any other, the minimum amount is accrued.

See Notes 1 and 21 to the Consolidated Financial Statements for further information regarding product liability and legal proceedings.

Long-Lived and Intangible Assets: The Company assesses changes in economic conditions and makes assumptions regarding estimated future cash flows in evaluating the value of the Company's property, plant and equipment, goodwill and intangible assets. As these assumptions and estimates may change over time, it may or may not be necessary for the Company to record impairment charges.

Employee Benefit Plans: The Company sponsors various retirement and pension plans, including defined benefit, defined contribution and termination indemnity plans, which cover most employees worldwide. These plans are based on assumptions for the discount rate, expected return on plan assets, mortality rates, expected salary increases, health care cost trend rates and attrition rates. See Note 10 to the Consolidated Financial Statements for further details on these rates and the effect a rate change to the health care cost trend would have on the Company's results of operations.

Stock Based Compensation: The Company recognizes compensation expense associated with the issuance of equity instruments to employees for their services. Based on the type of equity instrument, the fair value is estimated on the date of grant using either the Black-Scholes option valuation model or a combination of both the Black-Scholes option valuation model and Monte Carlo valuation model, and is expensed in the financial statements over the service period. The input assumptions used in determining fair value are the expected life, expected volatility, risk-free rate and expected dividend yield. For performance share units the fair market value is calculated for each of the three component goals at the date of grant. The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award, discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. See Note 17 to the Consolidated Financial Statements for additional information.

New Accounting Pronouncements

Refer to Note 1 to the Consolidated Financial Statements for recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of December 30, 2018.

Economic and Market Factors

The Company is aware that its products are used in an environment where, for more than a decade, policymakers, consumers and businesses have expressed concerns about the rising cost of health care. In response to these concerns, the Company has a long-standing policy of pricing products responsibly. For the period 2008 - 2018, in the U.S., the weighted average compound annual growth rate of the Company's net price increases for health care products (prescription and over-the-counter drugs, hospital and professional products) was below the U.S. Consumer Price Index (CPI).

The Company operates in certain countries where the economic conditions continue to present significant challenges. The Company continues to monitor these situations and take appropriate actions. Inflation rates continue to have an effect on worldwide economies and, consequently, on the way companies operate. The Company has accounted for operations in Argentina (beginning in the fiscal third quarter of 2018) and Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. This did not have a material impact to the Company's results in the period. In the face of increasing costs, the Company strives to maintain its profit margins through cost reduction programs, productivity improvements and periodic price increases.

In June 2016, the United Kingdom (U.K.) held a referendum in which voters approved an exit from the European Union (E.U.), commonly referred to as "Brexit" and in March 2017 the U.K. formally started the process for the U.K. to leave the E.U. Given the lack of comparable precedent, it is unclear what financial, trade, regulatory and legal implications the withdrawal of the U.K. from the E.U. will have. Brexit creates global political and economic uncertainty, which may cause, among other consequences, volatility in exchange rates and interest rates, additional cost containment by third-party payors and changes in regulations. However, the Company currently does not believe that these and other related effects will have a material impact on the Company's consolidated financial position or operating results. As of December 30, 2018, the business of the Company's U.K. subsidiaries represented less than 3% of both the Company's consolidated assets and fiscal twelve months revenues, respectively.

The Company is exposed to fluctuations in currency exchange rates. A 1% change in the value of the U.S. Dollar as compared to all foreign currencies in which the Company had sales, income or expense in 2018 would have increased or decreased the translation of foreign sales by approximately $390 million and net income by approximately $100 million.

Governments around the world consider various proposals to make changes to tax laws, which may include increasing or decreasing existing statutory tax rates. A change in statutory tax rate in any country would result in the revaluation of the Company's deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is enacted. This change would result in an expense or benefit recorded to the Company's Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries where it operates. Changes to the statutory tax rate may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted. On September 28, 2018 the Swiss Parliament approved the Federal Act on Tax Reform and AHV Financing (Swiss Tax Reform). However, a referendum has been called and, as a result, a public vote on the Swiss Tax Reform

will take place on May 19th, 2019. If the Swiss Tax Reform passes, then the measures are expected to come into force in either January 2020 or January 2021. Prior to approval in the referendum and its subsequent cantonal implementation, the proposed Swiss Tax Reform is not enacted and therefore the Company has not reflected any of the potential impacts in its fiscal results. The Company is currently assessing the impact of the proposed Swiss Tax Reform, and when enacted, the law may have a material impact on the Company's operating results.

The Company faces various worldwide health care changes that may continue to result in pricing pressures that include health care cost containment and government legislation relating to sales, promotions and reimbursement of health care products.

Changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing health care insurance coverage, as a result of the current global economic downturn, may continue to impact the Company's businesses.

The Company also operates in an environment increasingly hostile to intellectual property rights. Firms have filed Abbreviated New Drug Applications or Biosimilar Biological Product Applications with the FDA or otherwise challenged the coverage and/or validity of the Company's patents, seeking to market generic or biosimilar forms of many of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the event the Company is not successful in defending the patent claims challenged in the resulting lawsuits, generic or biosimilar versions of the products at issue will be introduced to the market, resulting in the potential for substantial market share and revenue losses for those products, and which may result in a non-cash impairment charge in any associated intangible asset. There is also a risk that one or more competitors could launch a generic or biosimilar version of the product at issue following regulatory approval even though one or more valid patents are in place. For further information, see the discussion on "REMICADE® Related Cases" and "Litigation Against Filers of Abbreviated New Drug Applications" in Note 21 to the Consolidated Financial Statements.

Legal Proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability, intellectual property, commercial and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of business.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. The Company has accrued for certain litigation matters and continues to monitor each related legal issue and adjust accruals for new information and further developments in accordance with Accounting Standards Codification (ASC) 450-20-25. For these and other litigation and regulatory matters currently disclosed for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions. The ability to make such estimates and judgments can be affected by various factors, including whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; or there are numerous parties involved.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution of, or increase in accruals for, one or more of these matters in any reporting period may have a material adverse effect on the Company's results of operations and cash flows for that period.

See Note 21 to the Consolidated Financial Statements for further information regarding legal proceedings.

Common Stock

The Company's Common Stock is listed on the New York Stock Exchange under the symbol JNJ. As of February 15, 2019, there were 142,029 record holders of Common Stock of the Company.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The information called for by this item is incorporated herein by reference to "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition - Liquidity and Capital Resources - Financing and Market Risk" of this Report; and Note 1 "Summary of Significant Accounting Policies - Financial Instruments" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Audited Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
At December 30, 2018 and December 31, 2017
(Dollars in Millions Except Share and Per Share Amounts) (Note 1)

		2018	2017
Assets			
Current assets			
Cash and cash equivalents (Notes 1 and 2)	$	18,107	17,824
Marketable securities (Notes 1 and 2)		1,580	472
Accounts receivable trade, less allowances for doubtful accounts $248 (2017, $291)		14,098	13,490
Inventories (Notes 1 and 3)		8,599	8,765
Prepaid expenses and other receivables		2,699	2,537
Assets held for sale (Note 20)		950	—
Total current assets		**46,033**	**43,088**
Property, plant and equipment, net (Notes 1 and 4)		17,035	17,005
Intangible assets, net (Notes 1 and 5)		47,611	53,228
Goodwill (Notes 1 and 5)		30,453	31,906
Deferred taxes on income (Note 8)		7,640	7,105
Other assets		4,182	4,971
Total assets	**$**	**152,954**	**157,303**
Liabilities and Shareholders' Equity			
Current liabilities			
Loans and notes payable (Note 7)	$	2,796	3,906
Accounts payable		7,537	7,310
Accrued liabilities		7,601	7,304
Accrued rebates, returns and promotions		9,380	7,210
Accrued compensation and employee related obligations		3,098	2,953
Accrued taxes on income (Note 8)		818	1,854
Total current liabilities		**31,230**	**30,537**
Long-term debt (Note 7)		27,684	30,675
Deferred taxes on income (Note 8)		7,506	8,368
Employee related obligations (Notes 9 and 10)		9,951	10,074
Long-term taxes payable (Note 8)		8,242	8,472
Other liabilities		8,589	9,017
Total liabilities		**93,202**	**97,143**
Shareholders' equity			
Preferred stock — without par value (authorized and unissued 2,000,000 shares)		—	—
Common stock — par value $1.00 per share (Note 12) (authorized 4,320,000,000 shares; issued 3,119,843,000 shares)		3,120	3,120
Accumulated other comprehensive income (loss) (Note 13)		(15,222)	(13,199)
Retained earnings		106,216	101,793
		94,114	91,714
Less: common stock held in treasury, at cost (Note 12) (457,519,000 shares and 437,318,000 shares)		34,362	31,554
Total shareholders' equity		**59,752**	**60,160**
Total liabilities and shareholders' equity	**$**	**152,954**	**157,303**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EARNINGS
(Dollars and Shares in Millions Except Per Share Amounts) (Note 1)*

		2018	2017	2016
Sales to customers	$	81,581	76,450	71,890
Cost of products sold		27,091	25,439	21,789
Gross profit		54,490	51,011	50,101
Selling, marketing and administrative expenses		22,540	21,520	20,067
Research and development expense		10,775	10,594	9,143
In-process research and development		1,126	408	29
Interest income		(611)	(385)	(368)
Interest expense, net of portion capitalized (Note 4)		1,005	934	726
Other (income) expense, net		1,405	(42)	210
Restructuring (Note 22)		251	309	491
Earnings before provision for taxes on income		17,999	17,673	19,803
Provision for taxes on income (Note 8)		2,702	16,373	3,263
Net earnings	**$**	**15,297**	**1,300**	**16,540**
Net earnings per share (Notes 1 and 15)				
Basic	**$**	**5.70**	**0.48**	**6.04**
Diluted	**$**	**5.61**	**0.47**	**5.93**
Average shares outstanding (Notes 1 and 15)				
Basic		**2,681.5**	**2,692.0**	**2,737.3**
Diluted		**2,728.7**	**2,745.3**	**2,788.9**

*Prior years amounts were reclassified to conform to current year presentation (adoption of ASU 2017-07)

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Dollars in Millions) (Note 1)

	2018	2017	2016
Net earnings	$ 15,297	1,300	16,540
Other comprehensive income (loss), net of tax			
Foreign currency translation	(1,518)	1,696	(612)
Securities: [1]			
Unrealized holding gain (loss) arising during period	(1)	159	(52)
Reclassifications to earnings	1	(338)	(141)
Net change	—	(179)	(193)
Employee benefit plans:			
Prior service credit (cost), net of amortization	(44)	2	21
Gain (loss), net of amortization	(56)	29	(862)
Effect of exchange rates	92	(201)	159
Net change	(8)	(170)	(682)
Derivatives & hedges:			
Unrealized gain (loss) arising during period	(73)	(4)	(359)
Reclassifications to earnings	(192)	359	110
Net change	(265)	355	(249)
Other comprehensive income (loss)	(1,791)	1,702	(1,736)
Comprehensive income	$ 13,506	3,002	14,804

[1] 2018 includes the impact from adoption of ASU 2016-01. For further details see Note 1 to the Consolidated Financial Statements

The tax effects in other comprehensive income for the fiscal years ended 2018, 2017 and 2016 respectively: Foreign Currency Translation $236 million in 2018 due to the enactment of the U.S. Tax Cuts and Jobs Act; Securities: $0 million, $96 million and $104 million, Employee Benefit Plans: $4 million, $83 million and $346 million, Derivatives & Hedges: $70 million, $191 million and $134 million.

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY
(Dollars in Millions) (Note 1)

	Total	Retained Earnings	Accumulated Other Comprehensive Income	Common Stock Issued Amount	Treasury Stock Amount
Balance, January 3, 2016	**$ 71,150**	**103,879**	**(13,165)**	**3,120**	**(22,684)**
Net earnings	16,540	16,540			
Cash dividends paid ($3.15 per share)	(8,621)	(8,621)			
Employee compensation and stock option plans	2,130	(1,181)			3,311
Repurchase of common stock	(8,979)				(8,979)
Other	(66)	(66)			
Other comprehensive income (loss), net of tax	(1,736)		(1,736)		
Balance, January 1, 2017	**70,418**	**110,551**	**(14,901)**	**3,120**	**(28,352)**
Net earnings	1,300	1,300			
Cash dividends paid ($3.32 per share)	(8,943)	(8,943)			
Employee compensation and stock option plans	2,077	(1,079)			3,156
Repurchase of common stock	(6,358)				(6,358)
Other	(36)	(36)			
Other comprehensive income (loss), net of tax	1,702		1,702		
Balance, December 31, 2017	**60,160**	**101,793**	**(13,199)**	**3,120**	**(31,554)**
Cumulative adjustment	(486)	(254) [1]	(232)		
Net earnings	15,297	15,297			
Cash dividends paid ($3.54 per share)	(9,494)	(9,494)			
Employee compensation and stock option plans	1,949	(1,111)			3,060
Repurchase of common stock	(5,868)				(5,868)
Other	(15)	(15)			
Other comprehensive income (loss), net of tax	(1,791)		(1,791)		
Balance, December 30, 2018	**$ 59,752**	**106,216**	**(15,222)**	**3,120**	**(34,362)**

(1) See Note 1 to Consolidated Financial Statements for additional details on the effect of cumulative adjustments to retained earnings.

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Dollars in Millions) (Note 1)

		2018	2017	2016
Cash flows from operating activities				
Net earnings	$	15,297	1,300	16,540
Adjustments to reconcile net earnings to cash flows from operating activities:				
Depreciation and amortization of property and intangibles		6,929	5,642	3,754
Stock based compensation		978	962	878
Asset write-downs		1,258	795	283
Gain on sale of assets/businesses		(1,217)	(1,307)	(563)
Deferred tax provision		(1,016)	2,406	(341)
Accounts receivable allowances		(31)	17	(11)
Changes in assets and liabilities, net of effects from acquisitions and divestitures:				
Increase in accounts receivable		(1,185)	(633)	(1,065)
(Increase)/Decrease in inventories		(644)	581	(249)
Increase in accounts payable and accrued liabilities		3,951	2,725	656
Increase in other current and non-current assets		(275)	(411)	(529)
(Decrease)/Increase in other current and non-current liabilities		(1,844)	8,979	(586)
Net cash flows from operating activities		**22,201**	**21,056**	**18,767**
Cash flows from investing activities				
Additions to property, plant and equipment		(3,670)	(3,279)	(3,226)
Proceeds from the disposal of assets/businesses, net		3,203	1,832	1,267
Acquisitions, net of cash acquired (Note 20)		(899)	(35,151)	(4,509)
Purchases of investments		(5,626)	(6,153)	(33,950)
Sales of investments		4,289	28,117	35,780
Other (primarily intangibles)		(464)	(234)	(123)
Net cash used by investing activities		**(3,167)**	**(14,868)**	**(4,761)**
Cash flows from financing activities				
Dividends to shareholders		(9,494)	(8,943)	(8,621)
Repurchase of common stock		(5,868)	(6,358)	(8,979)
Proceeds from short-term debt		80	869	111
Retirement of short-term debt		(2,479)	(1,330)	(2,017)
Proceeds from long-term debt, net of issuance costs		5	8,992	12,004
Retirement of long-term debt		(1,555)	(1,777)	(2,223)
Proceeds from the exercise of stock options/employee withholding tax on stock awards, net		949	1,062	1,189
Other		(148)	(188)	(15)
Net cash used by financing activities		**(18,510)**	**(7,673)**	**(8,551)**
Effect of exchange rate changes on cash and cash equivalents		(241)	337	(215)
Increase/(Decrease) in cash and cash equivalents		283	(1,148)	5,240
Cash and cash equivalents, beginning of year (Note 1)		17,824	18,972	13,732
Cash and cash equivalents, end of year (Note 1)	**$**	**18,107**	**17,824**	**18,972**
Supplemental cash flow data				
Cash paid during the year for:				
Interest	$	1,049	960	730
Interest, net of amount capitalized		963	866	628
Income taxes		4,570	3,312	2,843

Supplemental schedule of non-cash investing and financing activities				
Treasury stock issued for employee compensation and stock option plans, net of cash proceeds/ employee withholding tax on stock awards	$	2,095	2,062	2,043
Conversion of debt		6	16	35
Acquisitions				
Fair value of assets acquired	$	1,047	36,937	4,586
Fair value of liabilities assumed and noncontrolling interests		(148)	(1,786)	(77)
Net cash paid for acquisitions	**$**	**899**	**35,151**	**4,509**

See Notes to Consolidated Financial Statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Johnson & Johnson and its subsidiaries (the Company). Intercompany accounts and transactions are eliminated.

Description of the Company and Business Segments

The Company has approximately 135,100 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world and its primary focus is on products related to human health and well-being.

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. The Consumer segment includes a broad range of products used in the baby care, oral care, beauty, over-the-counter pharmaceutical, women's health and wound care markets. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on six therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, pulmonary hypertension, and cardiovascular and metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, interventional solutions (cardiovascular and neurovascular), diabetes care (divested in the fiscal fourth quarter of 2018) and vision fields, which are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

New Accounting Standards

Recently Adopted Accounting Standards

ASU 2014-09: Revenue from Contracts with Customers

On January 1, 2018, the Company adopted the new accounting standard, ASC 606, Revenue from Contracts with Customers and all the related amendments (new revenue standard) to all contracts using the modified retrospective method. The cumulative effect of initially applying the new revenue standard was recognized as an adjustment to the opening balance of retained earnings. The comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods. The adoption of the new revenue standard has not had a material impact to either reported Sales to customers or Net earnings. Additionally, the Company will continue to recognize revenue from product sales as goods are shipped or delivered to the customer, as control of goods transfers at the same time.

In accordance with the new revenue standard requirements, the disclosure of the impact of adoption on the Company's Consolidated Statement of Earnings and Balance Sheet was as follows:

Statement of Earnings - For the fiscal year ended December 30, 2018

(Dollars in millions)	As Reported	Effect of change	Balance without adoption of ASC 606
Sales to customers	$ 81,581	(35)	81,546
Net earnings	15,297	(28)	15,269

Balance Sheet - As of December 30, 2018

	As Reported	Effect of change	Balance without adoption of ASC 606
Assets	152,954	23	152,977
Liabilities	93,202	4	93,206
Equity	$ 59,752	19	59,771

The Company made a cumulative effect adjustment to the 2018 opening balance of retained earnings upon adoption of ASU 2014-09, which decreased beginning retained earnings by $47 million.

As part of the adoption of ASC 606 see Note 18 to the Consolidated Financial Statements for further disaggregation of revenue.

ASU 2016-01: Financial Instruments: Recognition and Measurement of Financial Assets and Financial Liabilities
The Company adopted this standard as of the beginning of the fiscal year 2018 on a modified retrospective basis. The amendments in this update supersede the guidance to classify equity securities with readily determinable fair values into different categories (that is, trading or available-for-sale) and require equity securities to be measured at fair value with changes in the fair value recognized through net earnings. The standard amends financial reporting by providing relevant information about an entity's equity investments and reducing the number of items that are recognized in other comprehensive income.

The Company made a cumulative effect adjustment to the opening balance of retained earnings upon adoption of ASU 2016-01 that increased retained earnings by $232 million net of tax and decreased accumulated other comprehensive income for previously unrealized gains from equity investments. For additional details see Note 6 to the Consolidated Financial Statements.

ASU 2016-16: Income Taxes: Intra-Entity Transfers of Assets Other Than Inventory
The Company adopted this standard as of the beginning of the fiscal year 2018. This update removes the current exception in U.S. GAAP prohibiting entities from recognizing current and deferred income tax expenses or benefits related to transfer of assets, other than inventory, within the consolidated entity. The current exception to defer the recognition of any tax impact on the transfer of inventory within the consolidated entity until it is sold to a third party remains unaffected. As discussed further in Note 8 to the Consolidated Financial Statements, in the fourth fiscal quarter of 2018 the Company elected an accounting policy to treat the tax on global intangible low-taxed income (GILTI) under the deferred tax accounting model. As a result, the Company is required to record an additional deferred tax liability related to the basis difference of these intra-entity asset transfers. The Company recorded net adjustments including an increase to deferred tax assets of approximately $2.0 billion, an increase to deferred tax liabilities of approximately $1.7 billion, related to the GILTI accounting policy election in the fourth fiscal quarter of 2018, a decrease to Other Assets of approximately $0.7 billion and a decrease to retained earnings of approximately $0.4 billion. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

ASU 2017-01: Clarifying the Definition of a Business
The Company adopted this standard as of the beginning of the fiscal year 2018. This update narrows the definition of a business by providing a screen to determine when an integrated set of assets and activities is not a business. The screen specifies that an integrated set of assets and activities is not a business if substantially all of the fair value of the gross assets acquired or disposed of is concentrated in a single or a group of similar identifiable assets. This update was applied prospectively. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

ASU 2017-07: Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost
The Company adopted this standard as of the beginning of the fiscal year 2018. This update requires that an employer disaggregate the service cost component from the other components of net periodic benefit cost (NPBC). In addition, only the service cost component will be eligible for capitalization. The amendments in this update are required to be applied retrospectively for the presentation of the service cost component and the other components of NPBC in the Consolidated Statement of Earnings and prospectively, on and after the adoption date, for the capitalization of the service cost component of NPBC in assets. As required by the transition provisions of this update, the following table shows the impact of the adoption on the respective line items in the Consolidated Statement of Earnings for 2018 and the reclassifications to the 2017 and 2016 fiscal year Consolidated Statement of Earnings to retroactively apply classification of the service cost component and the other components of NPBC:

(Dollars In millions)	Increase (Decrease) to Net Expense		
	2018	2017	2016
Cost of products sold	$ 51	85	104
Selling, marketing and administrative expenses	55	100	122
Research and development expense	21	40	48
Other (income) expense, net	(127)	(225)	(274)
Earnings before provision for taxes on income	$ —	—	—

The following table summarizes the cumulative effect adjustments made to the 2018 opening balance of retained earnings upon adoption of the new accounting standards mentioned above:

(Dollars in Millions)	Cumulative Effect Adjustment Increase (Decrease) to Retained Earnings
ASU 2014-09 - Revenue from Contracts with Customers	$ (47)
ASU 2016-01 - Financial Instruments	232
ASU 2016-16 - Income Taxes: Intra-Entity Transfers	(439)
Total	$ (254)

ASU 2017-12: Targeted Improvements to Accounting for Hedging Activities
The Company elected to early adopt this standard as of the beginning of the fiscal second quarter of 2018. This update makes more financial and nonfinancial hedging strategies eligible for hedge accounting. It also amends the presentation and disclosure requirements and changes how companies assess effectiveness. The adoption of this standard did not have a material impact on the Company's consolidated financial statements. For additional required disclosures see Note 6 to the Consolidated Financial Statements.

Recently Issued Accounting Standards
Not Adopted as of December 30, 2018
ASU 2018-18: Collaborative Arrangements
This update clarifies the interaction between ASC 808, Collaborative Arrangements and ASC 606, Revenue from Contracts with Customers. The update clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer. In addition, the update precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue if the counterparty is not a customer for that transaction. This update will be effective for the Company for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. ASU 2018-18 should be applied retrospectively to the date of initial application of ASC 606 and early adoption is permitted. The Company is currently assessing the impact of this update on the Company’s consolidated financial statements and related disclosures.

ASU 2018-16: Derivatives and Hedging (Topic ASC 815)
This update adds the Overnight Index Swap (OIS) rate based on the Secured Overnight Financing Rate (SOFR) as an eligible benchmark interest rate permitted in the application of hedge accounting. This update will be effective for the Company for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early adoption is permitted if an entity has adopted ASU 2017-12. The Company is currently assessing the impact of this update on the Company’s consolidated financial statements and related disclosures.

ASU 2018-02: Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income
This update allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Job Act enacted in December 2017. This update will be effective for the Company for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. The Company does not expect this standard to have a material impact on the Company's consolidated financial statements.

ASU 2016-13: Financial Instruments - Credit Losses
This update introduces the current expected credit loss (CECL) model, which will require an entity to measure credit losses for certain financial instruments and financial assets, including trade receivables. Under this update, on initial recognition and at each reporting period, an entity will be required to recognize an allowance that reflects the entity’s current estimate of credit losses expected to be incurred over the life of the financial instrument. This update will be effective for the Company for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. Early adoption is permitted. The Company is currently assessing the impact of this update on the Company’s consolidated financial statements and related disclosures.

ASU 2016-02: Leases
This update requires the recognition of lease assets and lease liabilities on the balance sheet for all lease obligations and disclosing key information about leasing arrangements. This update requires the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under current generally accepted accounting principles. This update will be effective for the Company for all annual periods beginning after December 15, 2018, including interim periods within those fiscal years. The Company will apply the new standard at its adoption date rather than at the earliest comparative period

presented in the financial statements. The Company's operating leases will result in the recognition of additional assets and the corresponding liabilities on its Consolidated Balance Sheets. The adoption of this standard will not have a material impact on the Company's consolidated financial statements.

Cash Equivalents

The Company classifies all highly liquid investments with stated maturities of three months or less from date of purchase as cash equivalents and all highly liquid investments with stated maturities of greater than three months from the date of purchase as current marketable securities. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating. The Company invests its cash primarily in government securities and obligations, corporate debt securities, money market funds and reverse repurchase agreements (RRAs).

RRAs are collateralized by deposits in the form of Government Securities and Obligations for an amount not less than 102% of their value. The Company does not record an asset or liability as the Company is not permitted to sell or repledge the associated collateral. The Company has a policy that the collateral has at least an A (or equivalent) credit rating. The Company utilizes a third party custodian to manage the exchange of funds and ensure that collateral received is maintained at 102% of the value of the RRAs on a daily basis. RRAs with stated maturities of greater than three months from the date of purchase are classified as marketable securities.

Investments

Investments classified as held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings. Investments classified as available-for-sale are carried at estimated fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income. Available-for-sale securities available for current operations are classified as current assets otherwise, they are classified as long term. Management determines the appropriate classification of its investment in debt and equity securities at the time of purchase and re-evaluates such determination at each balance sheet date. The Company reviews its investments in equity securities for impairment and adjusts these investments to fair value through earnings, as required.

Property, Plant and Equipment and Depreciation

Property, plant and equipment are stated at cost. The Company utilizes the straight-line method of depreciation over the estimated useful lives of the assets:

Building and building equipment	20 - 30 years
Land and leasehold improvements	10 - 20 years
Machinery and equipment	2 - 13 years

The Company capitalizes certain computer software and development costs, included in machinery and equipment, when incurred in connection with developing or obtaining computer software for internal use. Capitalized software costs are amortized over the estimated useful lives of the software, which generally range from 3 to 8 years.

The Company reviews long-lived assets to assess recoverability using undiscounted cash flows. When certain events or changes in operating or economic conditions occur, an impairment assessment may be performed on the recoverability of the carrying value of these assets. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows.

Revenue Recognition

The Company recognizes revenue from product sales when obligations under the terms of a contract with the customer are satisfied; generally, this occurs with the transfer of control of the goods to customers. The Company's global payment terms are typically between 30 to 90 days. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns and discounts to customers are accounted for as variable consideration and recorded as a reduction in sales.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including consideration of competitor pricing. Rebates are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns are estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales return accruals.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The sales returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to

customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual net trade sales during the fiscal reporting years 2018, 2017 and 2016.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the same period as related sales. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue. The Company also earns profit-share payments through collaborative arrangements for certain products, which are included in sales to customers. For all years presented, profit-share payments were less than 2.0% of the total revenues and are included in sales to customers.

Shipping and Handling

Shipping and handling costs incurred were $1,090 million, $1,042 million and $974 million in 2018, 2017 and 2016, respectively, and are included in selling, marketing and administrative expense. The amount of revenue received for shipping and handling is less than 0.5% of sales to customers for all periods presented.

Inventories

Inventories are stated at the lower of cost or net realizable value determined by the first-in, first-out method.

Intangible Assets and Goodwill

The authoritative literature on U.S. GAAP requires that goodwill and intangible assets with indefinite lives be assessed annually for impairment. The Company completed the annual impairment test for 2018 in the fiscal fourth quarter. Future impairment tests will be performed annually in the fiscal fourth quarter, or sooner if warranted. Purchased in-process research and development is accounted for as an indefinite lived intangible asset until the underlying project is completed, at which point the intangible asset will be accounted for as a definite lived intangible asset, or abandoned, at which point the intangible asset will be written off or partially impaired.

Intangible assets that have finite useful lives continue to be amortized over their useful lives, and are reviewed for impairment when warranted by economic conditions. See Note 5 for further details on Intangible Assets and Goodwill.

Financial Instruments

As required by U.S. GAAP, all derivative instruments are recorded on the balance sheet at fair value. Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value, with Level 1 having the highest priority and Level 3 having the lowest. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The Company documents all relationships between hedged items and derivatives. The overall risk management strategy includes reasons for undertaking hedge transactions and entering into derivatives. The objectives of this strategy are: (1) minimize foreign currency exposure's impact on the Company's financial performance; (2) protect the Company's cash flow from adverse movements in foreign exchange rates; (3) ensure the appropriateness of financial instruments; and (4) manage the enterprise risk associated with financial institutions. See Note 6 for additional information on Financial Instruments.

Product Liability

Accruals for product liability claims are recorded, on an undiscounted basis, when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated based on existing information and actuarially determined estimates where applicable. The accruals are adjusted periodically as additional information becomes available. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

As a result of cost and availability factors, effective November 1, 2005, the Company ceased purchasing third-party product liability insurance. The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated.

Research and Development

Research and development expenses are expensed as incurred in accordance with ASC 730, Research and Development. Upfront and milestone payments made to third parties in connection with research and development collaborations are expensed as incurred up to the point of regulatory approval. Payments made to third parties subsequent to regulatory approval are capitalized and amortized over the remaining useful life of the related product. Amounts capitalized for such payments are included in other intangibles, net of accumulated amortization.

The Company enters into collaborative arrangements, typically with other pharmaceutical or biotechnology companies, to develop and commercialize drug candidates or intellectual property. These arrangements typically involve two (or more) parties who are active participants in the collaboration and are exposed to significant risks and rewards dependent on the commercial success of the activities. These collaborations usually involve various activities by one or more parties, including research and development, marketing and selling and distribution. Often, these collaborations require upfront, milestone and royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development. Amounts due from collaborative partners related to development activities are generally reflected as a reduction of research and development expense because the performance of contract development services is not central to the Company's operations. In general, the income statement presentation for these collaborations is as follows:

Nature/Type of Collaboration	Statement of Earnings Presentation
Third-party sale of product & profit share payments received	Sales to customers
Royalties/milestones paid to collaborative partner (post-regulatory approval)*	Cost of products sold
Royalties received from collaborative partner	Other income (expense), net
Upfront payments & milestones paid to collaborative partner (pre-regulatory approval)	Research and development expense
Research and development payments to collaborative partner	Research and development expense
Research and development payments received from collaborative partner	Reduction of Research and development expense

* Milestones are capitalized as intangible assets and amortized to cost of products sold over the useful life.

For all years presented, there was no individual project that represented greater than 5% of the total annual consolidated research and development expense.

The Company has a number of products and compounds developed in collaboration with strategic partners including XARELTO®, co-developed with Bayer HealthCare AG and IMBRUVICA®, developed in collaboration and co-marketed with Pharmacyclics LLC, an AbbVie company.

The Company has a number of licensing arrangements for products and compounds including DARZALEX®, licensed from Genmab A/S.

Advertising

Costs associated with advertising are expensed in the year incurred and are included in selling, marketing and administrative expenses. Advertising expenses worldwide, which comprised television, radio, print media and Internet advertising, were $2.6 billion, $2.5 billion and $2.4 billion in 2018, 2017 and 2016, respectively.

Income Taxes

Income taxes are recorded based on amounts refundable or payable for the current year and include the results of any difference between U.S. GAAP accounting and tax reporting, recorded as deferred tax assets or liabilities. The Company estimates deferred tax assets and liabilities based on enacted tax regulations and rates. Future changes in tax laws and rates may affect recorded deferred tax assets and liabilities in the future.

The Company has unrecognized tax benefits for uncertain tax positions. The Company follows U.S. GAAP which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Management believes that changes in these estimates would not have a material effect on the Company's results of operations, cash flows or financial position.

In the fourth fiscal quarter of 2018, the Company has elected to account for the GILTI tax under the deferred method. The deferred tax amounts recorded are based on the evaluation of temporary differences that are expected to reverse as GILTI is incurred.

The Company has recorded deferred tax liabilities on all undistributed earnings prior to December 31, 2017 from its international subsidiaries. The Company has not provided deferred taxes on the undistributed earnings subsequent to January 1, 2018 from certain international subsidiaries where the earnings are considered to be indefinitely reinvested. The Company intends to continue to reinvest these earnings in those international operations. If the Company decides at a later date to

repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company estimates that the total tax effect of this repatriation would be approximately $0.7 billion under current enacted tax laws and regulations and at current currency exchange rates.

See Note 8 for further information regarding income taxes.

Net Earnings Per Share

Basic earnings per share is computed by dividing net earnings available to common shareholders by the weighted average number of common shares outstanding for the period. Diluted earnings per share reflects the potential dilution that could occur if securities were exercised or converted into common stock using the treasury stock method.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the amounts reported. Estimates are used when accounting for sales discounts, rebates, allowances and incentives, product liabilities, income taxes, withholding taxes, depreciation, amortization, employee benefits, contingencies and intangible asset and liability valuations. Actual results may or may not differ from those estimates.

The Company follows the provisions of U.S. GAAP when recording litigation related contingencies. A liability is recorded when a loss is probable and can be reasonably estimated. The best estimate of a loss within a range is accrued; however, if no estimate in the range is better than any other, the minimum amount is accrued.

Annual Closing Date

The Company follows the concept of a fiscal year, which ends on the Sunday nearest to the end of the month of December. Normally each fiscal year consists of 52 weeks, but every five or six years the fiscal year consists of 53 weeks, and therefore includes additional shipping days, as was the case in 2015, and will be the case again in 2020.

Reclassification

Certain prior period amounts have been reclassified to conform to current year presentation.

2. Cash, Cash Equivalents and Current Marketable Securities

At the end of 2018 and 2017, cash, cash equivalents and current marketable securities were comprised of:

(Dollars in Millions)	2018			
	Carrying Amount	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	$ 2,619	2,619	2,619	—
U.S. Reverse repurchase agreements	3,009	3,009	3,009	—
Other Reverse repurchase agreements	443	443	443	—
Money market funds	3,397	3,397	3,397	—
Time deposits[1]	485	485	485	—
Subtotal	$ 9,953	9,953	9,953	—
Gov't Securities	$ 9,474	9,474	8,144	1,330
Corporate debt securities	260	260	10	250
Subtotal available for sale[2]	$ 9,734	9,734	8,154	1,580
Total cash, cash equivalents and current marketable securities			**$ 18,107**	**1,580**

In 2018, the carrying amount was the same as the estimated fair value.
In 2017, the carrying amount was the same as the estimated fair value.

(Dollars in Millions)	2017			
	Carrying Amount	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	$ 2,929	2,929	2,929	—
Other Sovereign Securities[1]	279	279	219	60
U.S. Reverse repurchase agreements	4,025	4,025	4,025	—
Corporate debt securities[1]	289	289	244	45
Money market funds	4,288	4,288	4,288	—
Time deposits[1]	1,176	1,176	1,175	1
Subtotal	$ 12,986	12,986	12,880	106
Gov't Securities	$ 4,864	4,864	4,833	31
Other Sovereign Securities	186	186	80	106
Corporate debt securities	260	260	31	229
Subtotal available for sale[2]	$ 5,310	5,310	4,944	366
Total cash, cash equivalents and current marketable securities			**$ 17,824**	**472**

[1] Held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings.
[2] Available for sale debt securities are reported at fair value with unrealized gains and losses reported net of taxes in other comprehensive income.

Fair value of government securities and obligations and corporate debt securities were estimated using quoted broker prices and significant other observable inputs.

The contractual maturities of the available for sale debt securities at December 30, 2018 are as follows:

(Dollars in Millions)	Cost Basis	Fair Value
Due within one year	$ 9,670	9,670
Due after one year through five years	64	64
Due after five years through ten years	—	—
Total debt securities	$ 9,734	9,734

The Company invests its excess cash in both deposits with major banks throughout the world and other high-quality money market instruments. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating.

3. Inventories

At the end of 2018 and 2017, inventories were comprised of:

(Dollars in Millions)	2018	2017
Raw materials and supplies	$ 1,114	1,140
Goods in process	2,109	2,317
Finished goods	5,376	5,308
Total inventories	**$ 8,599** (1)	**8,765**

(1) Net of assets held for sale on the Consolidated Balance Sheet for approximately $0.2 billion related to the divestiture of the Advanced Sterilization Products business and $0.3 billion related to the strategic collaboration with Jabil Inc., both of which were pending as of December 30, 2018.

4. Property, Plant and Equipment

At the end of 2018 and 2017, property, plant and equipment at cost and accumulated depreciation were:

(Dollars in Millions)	2018		2017
Land and land improvements	$ 807		829
Buildings and building equipment	11,176		11,240
Machinery and equipment	25,992		25,949
Construction in progress	3,876		3,448
Total property, plant and equipment, gross	$ 41,851		41,466
Less accumulated depreciation	24,816		24,461
Total property, plant and equipment, net	**$ 17,035**	(1)	**17,005**

(1) Net of assets held for sale on the Consolidated Balance Sheet for approximately $0.1 billion related to the divestiture of the Advanced Sterilization Products business and $0.1 billion related to the strategic collaboration with Jabil Inc., both of which were pending as of December 30, 2018.

The Company capitalizes interest expense as part of the cost of construction of facilities and equipment. Interest expense capitalized in 2018, 2017 and 2016 was $86 million, $94 million and $102 million, respectively.

Depreciation expense, including the amortization of capitalized interest in 2018, 2017 and 2016 was $2.6 billion, $2.6 billion and $2.5 billion, respectively.

Upon retirement or other disposal of property, plant and equipment, the costs and related amounts of accumulated depreciation or amortization are eliminated from the asset and accumulated depreciation accounts, respectively. The difference, if any, between the net asset value and the proceeds are recorded in earnings.

5. Intangible Assets and Goodwill

At the end of 2018 and 2017, the gross and net amounts of intangible assets were:

(Dollars in Millions)	2018	2017
Intangible assets with definite lives:		
Patents and trademarks — gross	$ 35,194	36,427
Less accumulated amortization	9,784	7,223
Patents and trademarks — net	**$ 25,410**	**29,204**
Customer relationships and other intangibles — gross	$ 21,334	20,204
Less accumulated amortization	8,323	7,463
Customer relationships and other intangibles — net	**$ 13,011**	**12,741**
Intangible assets with indefinite lives:		
Trademarks	$ 6,937	7,082
Purchased in-process research and development(1)	2,253	4,201
Total intangible assets with indefinite lives	**$ 9,190**	**11,283**
Total intangible assets — net	**$ 47,611**	**53,228**

(1) The decrease was primarily attributable to the write-down of $1.1 billion related to the assets acquired in the acquisitions of Alios Biopharma Inc. (Alios) and XO1 Limited (XO1). Of the $1.1 billion, the Company recorded a partial impairment charge of $0.8 billion related to the development program of AL-8176, an investigational drug for the treatment of Respiratory Syncytial Virus (RSV) and human metapneumovirus (hMPV) acquired with the 2014 acquisition of Alios. The impairment charge was calculated based on updated cash flow projections discounted for the inherent risk in the asset development and reflects the impact of the phase 2b clinical trial suspension, a decrease in the probability of success factors and the ongoing analysis of asset development activities. In addition, an impairment charge of $0.3 billion was recorded for the discontinuation of the development project for an anti-thrombin antibody associated with the 2015 acquisition of XO1. Additionally, $0.8 billion of IPR&D related to ERLEADA™ was reclassified to definite lived intangible assets upon commercialization.

Goodwill as of December 30, 2018 and December 31, 2017, as allocated by segment of business, was as follows:

(Dollars in Millions)	Consumer	Pharmaceutical	Medical Devices	Total
Goodwill at January 1, 2017	$ 8,263	2,840	11,702	22,805
Goodwill, related to acquisitions [1]	102	6,161	2,200	8,463
Goodwill, related to divestitures	(74)	(1)	(102)	(177)
Currency translation/other	584	109	122	815
Goodwill at December 31, 2017	$ 8,875	9,109	13,922	31,906
Goodwill, related to acquisitions	168	51	184	403
Goodwill, related to divestitures	—	—	(1,348) [2]	(1,348)
Currency translation/other	(373)	(97)	(38)	(508)
Goodwill at December 30, 2018	**$ 8,670**	**9,063**	**12,720**	**30,453**

[1] Goodwill of $6.2 billion related to the Actelion acquisition acquired in the fiscal second quarter of 2017, within the Pharmaceutical segment and $1.7 billion related to the AMO acquisition acquired in the fiscal first quarter of 2017, within the Medical Devices segment.
[2] Goodwill of $1.0 billion is related to the divestiture of the LifeScan business. Goodwill of $0.3 billion is related to the divestiture of the Advanced Sterilization Products business, which was pending and classified as assets held for sale on the Consolidated Balance Sheet as of December 30, 2018.

The weighted average amortization periods for patents and trademarks and customer relationships and other intangible assets are 11 years and 22 years, respectively. The amortization expense of amortizable assets included in cost of products sold was $4.4 billion, $3.0 billion and $1.2 billion before tax, for the fiscal years ended December 30, 2018, December 31, 2017 and January 1, 2017, respectively. The estimated amortization expense for the five succeeding years approximates $4.3 billion before tax, per year. Intangible asset write-downs are included in Other (income) expense, net.

See Note 20 to the Consolidated Financial Statements for additional details related to acquisitions and divestitures.

6. Fair Value Measurements

The Company uses forward foreign exchange contracts to manage its exposure to the variability of cash flows, primarily related to the foreign exchange rate changes of future intercompany products and third-party purchases of materials denominated in a foreign currency. The Company uses cross currency interest rate swaps to manage currency risk primarily related to borrowings. Both types of derivatives are designated as cash flow hedges.

Additionally, the Company uses interest rate swaps as an instrument to manage interest rate risk related to fixed rate borrowings. These derivatives are designated as fair value hedges. The Company uses cross currency interest rate swaps and forward foreign exchange contracts designated as net investment hedges. Additionally, the Company uses forward foreign exchange contracts to offset its exposure to certain foreign currency assets and liabilities. These forward foreign exchange contracts are not designated as hedges and therefore, changes in the fair values of these derivatives are recognized in earnings, thereby offsetting the current earnings effect of the related foreign currency assets and liabilities.

The Company early adopted ASU 2017-12: Targeted Improvements to Accounting for Hedge Activities effective as of the beginning of fiscal second quarter of 2018.

The Company does not enter into derivative financial instruments for trading or speculative purposes, or that contain credit risk related contingent features. During the fiscal second quarter of 2017, the Company entered into credit support agreements (CSA) with certain derivative counterparties establishing collateral thresholds based on respective credit ratings and netting agreements. As of December 30, 2018, the total amount of collateral paid under the credit support agreements (CSA) amounted to $182 million net. On an ongoing basis, the Company monitors counter-party credit ratings. The Company considers credit non-performance risk to be low, because the Company primarily enters into agreements with commercial institutions that have at least an investment grade credit rating. Refer to the table on significant financial assets and liabilities measured at fair value contained in this footnote for receivables and payables with these commercial institutions. As of December 30, 2018, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of $41.1 billion, $7.3 billion, and $0.5 billion respectively. As of December 31, 2017, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of $34.5 billion, $2.3 billion, and $1.1 billion respectively.

All derivative instruments are recorded on the balance sheet at fair value. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The designation as a cash flow hedge is made at the entrance date of the derivative contract. At inception, all derivatives are expected to be highly effective. Foreign exchange contracts designated as cash flow hedges are accounted for under the forward method and all gains/losses associated with these contracts will be recognized in the income statement when the hedged item impacts earnings. Changes in the fair value of these derivatives are recorded in accumulated other comprehensive income until the underlying transaction affects earnings, and are then reclassified to earnings in the same account as the hedged transaction.

Gains and losses associated with interest rate swaps and changes in fair value of hedged debt attributable to changes in interest rates are recorded to interest expense in the period in which they occur. Gains and losses on net investment hedge are accounted through the currency translation account within accumulated other comprehensive income. The portion excluded from effectiveness testing is recorded through interest (income) expense using the spot method. On an ongoing basis, the Company assesses whether each derivative continues to be highly effective in offsetting changes of hedged items. If and when a derivative is no longer expected to be highly effective, hedge accounting is discontinued.

During the fiscal second quarter of 2016, the Company designated its Euro denominated notes issued in May 2016 with due dates ranging from 2022 to 2035 as a net investment hedge of the Company's investments in certain of its international subsidiaries that use the Euro as their functional currency in order to reduce the volatility caused by changes in exchange rates.

As of December 30, 2018, the balance of deferred net loss on derivatives included in accumulated other comprehensive income was $195 million after-tax. For additional information, see the Consolidated Statements of Comprehensive Income and Note 13. The Company expects that substantially all of the amounts related to forward foreign exchange contracts will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months, excluding interest rate contracts, net investment hedges and equity collar contracts. The amount ultimately realized in earnings may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity of the derivative.

The following table is a summary of the activity related to derivatives and hedges for the fiscal years ended December 30, 2018 and December 31, 2017:

	December 30, 2018					December 31, 2017				
(Dollars in Millions)	Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense	Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense
The effects of fair value, net investment and cash flow hedging:										
Gain (Loss) on fair value hedging relationship:										
Interest rate swaps contracts:										
Hedged items	$ —	—	—	5	—	—	—	—	5	—
Derivatives designated as hedging instruments	—	—	—	(5)	—	—	—	—	(5)	—
Gain (Loss) on net investment hedging relationship:										
Cross currency interest rate swaps contracts:										
Amount of gain or (loss) recognized in income on derivative amount excluded from effectiveness testing	—	—	—	56	—	—	—	—	—	—
Amount of gain or (loss) recognized in AOCI	—	—	—	56	—	—	—	—	—	—
Gain (Loss) on cash flow hedging relationship:										
Forward foreign exchange contracts:										
Amount of gain or (loss) reclassified from AOCI into income [1]	47	200	(220)	—	(24)	(31)	(159)	(165)	—	(87)
Amount of gain or (loss) recognized in AOCI [1]	(32)	(17)	(193)	—	(4)	49	96	(199)	—	(60)
Cross currency interest rate swaps contracts:										
Amount of gain or (loss) reclassified from AOCI into income	—	—	—	133	—	—	—	—	83	—
Amount of gain or (loss) recognized in AOCI	$ —	—	—	117	—	—	—	—	110	—

[1] Includes equity collar contracts. The equity collar contracts expired in December of 2017.

For the fiscal years ended December 30, 2018 and December 31, 2017, the following amounts were recorded on the Consolidated Balance Sheet

Line item in the Consolidated Balance Sheet in which the hedged item is included	**Carrying Amount of the Hedged Liability**		**Cumulative Amount of Fair Value Hedging Adjustment Included in the Carrying Amount of the Hedged Liability**	
(Dollars in Millions)	December 30, 2018	December 31, 2017	December 30, 2018	December 31, 2017
Current Portion of Long-term Debt	$ 494	597	5	2
Long-term Debt	—	496	—	3

The following table is the effect of derivatives not designated as hedging instrument for the fiscal years ended December 30, 2018 and December 31, 2017:

(Dollars in Millions)	Location of Gain /(Loss) Recognized in Income on Derivative	Gain/(Loss) Recognized In Income on Derivative	
Derivatives Not Designated as Hedging Instruments		December 30, 2018	December 31, 2017
Foreign Exchange Contracts	Other (income) expense	(68)	(5)

The following table is the effect of net investment hedges for the fiscal years ended December 30, 2018 and December 31, 2017:

(Dollars in Millions)	Gain/(Loss) Recognized In Accumulated OCI		Location of Gain or (Loss) Reclassified from Accumulated Other Comprehensive Income Into Income	Gain/(Loss) Reclassified From Accumulated OCI Into Income	
			Fiscal Nine Months Ended		
	December 30, 2018	December 31, 2017		December 30, 2018	December 31, 2017
Debt	$ 218	(597)	Other (income) expense	—	—
Cross Currency interest rate swaps	$ 150	—	Other (income) expense	—	—

The Company adopted ASU 2016-01: Financial Instruments: Recognition and Measurement of Financial Assets and Financial Liabilities as of the beginning of the fiscal year 2018. This ASU amends prior guidance to classify equity investments with readily determinable market values into different categories (that is, trading or available-for-sale) and require equity investments to be measured at fair value with changes in fair value recognized through net earnings. The Company made a cumulative effect adjustment to the opening balance of retained earnings upon adoption of ASU 2016-01 which increased retained earnings by $232 million, net of tax, and decreased accumulated other comprehensive income for previously net unrealized gains from equity investments.

The Company holds equity investments with readily determinable fair values and equity investments without readily determinable fair values. The Company has elected to measure equity investments that do not have readily determinable fair values at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer.

The following table is a summary of the activity related to equity investments as of December 30, 2018:

(Dollars in Millions)	December 31, 2017			December 30, 2018	
	Carrying Value	Changes in Fair Value Reflected in Net Income (1)	Sales/ Purchases/Other (2)	Carrying Value	Non Current Other Assets
Equity Investments with readily determinable value	$ 751	(247)	7	511	511
Equity Investments without readily determinable value	$ 510	13	158	681	681

(1) Recorded in Other Income/Expense
(2) Other includes impact of currency

For equity investments without readily determinable market values, $54 million of the changes in fair value reflected in net income were the result of impairments. There were $67 million of changes in fair value reflected in net income due to changes in observable prices.

For the fiscal years ended December 31, 2017, changes in fair value reflected within other comprehensive income due to previously unrealized gains on equity investments with readily determinable fair values net of tax was a net gain of $232 million.

Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described below with Level 1 having the highest priority and Level 3 having the lowest.

The fair value of a derivative financial instrument (i.e., forward foreign exchange contracts, interest rate contracts) is the aggregation by currency of all future cash flows discounted to its present value at the prevailing market interest rates and subsequently converted to the U.S. Dollar at the current spot foreign exchange rate. The Company does not believe that fair values of these derivative instruments materially differ from the amounts that could be realized upon settlement or maturity, or that the changes in fair value will have a material effect on the Company's results of operations, cash flows or financial position. The Company also holds equity investments which are classified as Level 1 and debt securities which are classified as Level 2. The Company did not have any other significant financial assets or liabilities which would require revised valuations under this standard that are recognized at fair value.

The following three levels of inputs are used to measure fair value:

Level 1 — Quoted prices in active markets for identical assets and liabilities.

Level 2 — Significant other observable inputs.

Level 3 — Significant unobservable inputs.

The Company's significant financial assets and liabilities measured at fair value as of December 30, 2018 and December 31, 2017 were as follows:

	2018				2017
(Dollars in Millions)	Level 1	Level 2	Level 3	Total	Total [1]
Derivatives designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	$ —	501	—	501	418
Interest rate contracts [2][4]	—	161	—	161	7
Total	—	**662**	—	**662**	**425**
Liabilities:					
Forward foreign exchange contracts	—	548	—	548	402
Interest rate contracts [3][4]	—	292	—	292	165
Total	—	**840**	—	**840**	**567**
Derivatives not designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	—	32	—	32	38
Liabilities:					
Forward foreign exchange contracts	—	32	—	32	38
Available For Sale Other Investments:					
Equity investments [5]	511	—	—	511	751
Debt securities [6]	$ —	9,734	—	9,734	5,310

Gross to Net Derivative Reconciliation		2018	2017
(Dollars in Millions)			
Total Gross Assets	$	694	463
Credit Support Agreement (CSA)		(423)	(76)
Total Net Asset		271	387
Total Gross Liabilities		872	605
Credit Support Agreement (CSA)		(605)	(238)
Total Net Liabilities	$	267	367

(1) 2017 assets and liabilities are all classified as Level 2 with the exception of equity investments of $751 million, which are classified as Level 1.
(2) Includes $6 million and $7 million of non-current assets for the fiscal years ending December 30, 2018 and December 31, 2017, respectively.
(3) Includes $3 million and $9 million of non-current liabilities for the fiscal years ending December 30, 2018 and December 31, 2017, respectively.
(4) Includes cross currency interest rate swaps and interest rate swaps.
(5) Classified as non-current other assets. The carrying amount of the equity investments were $511 million and $751 million as of December 30, 2018 and December 31, 2017, respectively.
(6) Classified as cash equivalents and current marketable securities.

See Notes 2 and 7 for financial assets and liabilities held at carrying amount on the Consolidated Balance Sheet.

7. Borrowings

The components of long-term debt are as follows:

(Dollars in Millions)	2018	Effective Rate %	2017	Effective Rate %
5.15% Debentures due 2018	$ —		900	5.18
1.65% Notes due 2018	—		597	1.70
4.75% Notes due 2019 (1B Euro 1.14)[2]/(1B Euro 1.1947)[3]	1,139 [2]	5.83	1,192 [3]	5.83
1.875% Notes due 2019	494	1.93	496	1.93
0.89% Notes due 2019	300	1.32	300	1.75
1.125% Notes due 2019	699	1.13	699	1.13
3% Zero Coupon Convertible Subordinated Debentures due 2020	51	3.00	60	3.00
2.95% Debentures due 2020	548	3.15	547	3.15
1.950% Notes due 2020	499	1.99	499	1.99
3.55% Notes due 2021	449	3.67	448	3.67
2.45% Notes due 2021	349	2.48	349	2.48
1.65% Notes due 2021	998	1.65	998	1.65
0.250% Notes due 2022 (1B Euro 1.14)[2]/(1B Euro 1.1947)[3]	1,137 [2]	0.26	1,191 [3]	0.26
2.25% Notes due 2022	996	2.31	995	2.31
6.73% Debentures due 2023	250	6.73	250	6.73
3.375% Notes due 2023	805	3.17	806	3.17
2.05% Notes due 2023	498	2.09	498	2.09
0.650% Notes due 2024 (750MM Euro 1.14)[2]/(750MM Euro 1.1947)[3]	851 [2]	0.68	891 [3]	0.68
5.50% Notes due 2024 (500MM GBP 1.2636)[2]/(500MM GBP 1.3444)[3]	627 [2]	6.75	666 [3]	6.75
2.625% Notes due 2025	748	2.63	747	2.63
2.45% Notes due 2026	1,992	2.47	1,990	2.47
2.95% Notes due 2027	996	2.96	995	2.96
1.150% Notes due 2028 (750MM Euro 1.14)[2]/(750MM Euro 1.1947)[3]	847 [2]	1.21	887 [3]	1.21
2.900% Notes due 2028	1,493	2.91	1,492	2.91
6.95% Notes due 2029	297	7.14	296	7.14
4.95% Debentures due 2033	498	4.95	498	4.95
4.375% Notes due 2033	856	4.24	856	4.24
1.650% Notes due 2035 (1.5B Euro 1.14)[2]/(1.5B Euro 1.1947)[3]	1,693 [2]	1.68	1,774 [3]	1.68
3.55% Notes due 2036	988	3.59	987	3.59
5.95% Notes due 2037	991	5.99	991	5.99
3.625% Notes due 2037	1,486	3.64	1,486	3.64
5.85% Debentures due 2038	696	5.85	696	5.85
3.400% Notes due 2038	990	3.42	990	3.42
4.50% Debentures due 2040	538	4.63	538	4.63
4.85% Notes due 2041	297	4.89	296	4.89
4.50% Notes due 2043	495	4.52	495	4.52
3.70% Notes due 2046	1,972	3.74	1,971	3.74
3.75% Notes due 2047	991	3.76	990	3.76

3.500% Notes due 2048	742	3.52	742	3.52
Other	24	—	75	—
Subtotal	**30,320** (4)	**3.19%** (1)	**32,174** (4)	**3.19** (1)
Less current portion	2,636		1,499	
Total long-term debt	**$ 27,684**		**30,675**	

(1) Weighted average effective rate.
(2) Translation rate at December 30, 2018.
(3) Translation rate at December 31, 2017.
(4) The excess of the fair value over the carrying value of debt was $0.3 billion in 2018 and $2.0 billion in 2017.

Fair value of the long-term debt was estimated using market prices, which were corroborated by quoted broker prices and significant other observable inputs.(Level 2)

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2018, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 12, 2019. Interest charged on borrowings under the credit line agreements is based on either bids provided by banks, the prime rate or London Interbank Offered Rates (LIBOR), plus applicable margins. Commitment fees under the agreements are not material.

Throughout 2018, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $2.8 billion at the end of 2018, of which $2.6 billion is the current portion of the long term debt, and the remainder principally represents local borrowing by international subsidiaries.

Throughout 2017, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $3.9 billion at the end of 2017, of which $2.3 billion was borrowed under the Commercial Paper Program, $1.5 billion is the current portion of the long-term debt, and the remainder principally represents local borrowing by international subsidiaries.

Aggregate maturities of long-term obligations commencing in 2019 are:

(Dollars in Millions)

2019	2020	2021	2022	2023	After 2023
$2,636	1,098	1,796	2,134	1,553	21,103

8. Income Taxes

The provision for taxes on income consists of:

(Dollars in Millions)	2018	2017	2016
Currently payable:			
U.S. taxes	$ 1,081	11,969	1,896
U.S. taxes on international operations	203	126	49
International taxes	2,434	1,872	1,659
Total currently payable	3,718	13,967	3,604
Deferred:			
U.S. taxes	(148)	(1,956)	294
U.S. taxes on international operations	1,358		
International taxes	(2,226)	4,362	(635)
Total deferred	(1,016)	2,406	(341)
Provision for taxes on income	**$ 2,702**	**16,373**	**3,263**

A comparison of income tax expense at the U.S. statutory rate of 21% in 2018 and 35% in 2017 and 2016, to the Company's effective tax rate is as follows:

(Dollars in Millions)	2018	2017	2016
U.S.	$ 5,575	4,865	7,457
International	12,424	12,808	12,346
Earnings before taxes on income:	$ 17,999	17,673	19,803
Tax rates:			
U.S. statutory rate	21.0 %	35.0	35.0
International operations (1)	(3.7)	(12.8)	(17.2)
Research and orphan drug tax credits	(1.0)	(0.4)	(0.4)
U.S. state and local	0.8	0.6	(0.1)
U.S. manufacturing deduction	—	(0.8)	(0.6)
U.S. tax on international income (2)	1.4	0.7	1.3
Tax benefits on share-based compensation	(1.5)	(2.1)	(1.8)
U.S. tax benefit on asset/business disposals	0.5	(0.8)	—
All other	(0.6)	(0.1)	0.3
TCJA and related impacts (3)	(1.9) (3)	73.3 (4)	—
Effective Rate	15.0 %	92.6	16.5

(1) For all periods presented the Company has subsidiaries operating in Puerto Rico under various tax incentives. International operations reflects the impacts of operations in jurisdictions with statutory tax rates different than the U.S., particularly Ireland, Switzerland and Puerto Rico, which is a favorable impact on the effective tax rate as compared with the U.S. statutory rate. The 2017 amount also includes tax cost related to the revaluation of deferred tax balances related to the change in the Belgian statutory tax rate increasing the tax provision by approximately 3.4%.
(2) Includes the impact of the GILTI tax, the Foreign-Derived Intangible Income deduction and other foreign income that is taxable under the U.S. tax code.
(3) Represents impact of adjustments to the 2017 TCJA provisional tax charge. This also includes a net tax benefit from the reduction of a deferred tax liability related to foreign withholding taxes originally accrued as part of the provisional charge. This benefit reduced the Company's effective tax rate by approximately 11%. Further description is included below.
(4) Includes U.S. state and local taxes provisionally recorded as part TCJA provisional charge which was approximately 0.6% of the total effective tax rate.

On December 22, 2017, the United States enacted into law new U.S. tax legislation, the Tax Cuts and Jobs Act (TCJA). This law included provisions for a comprehensive overhaul of the corporate income tax code, including a reduction of the statutory corporate tax rate from 35% to 21%, effective on January 1, 2018. This legislation also eliminated or reduced certain corporate income tax deductions as well as introduced new provisions that taxed certain foreign income not previously taxed by the United States. The TCJA also included a provision for a tax on all previously undistributed earnings of U.S. companies located in foreign jurisdictions. Undistributed earnings in the form of cash and cash equivalents were taxed at a rate of 15.5% and all other earnings are taxed at a rate of 8.0%. This tax is payable over 8 years and will not accrue interest and these payments began in 2018 and will continue through 2025. The remaining balance at the end of the fiscal year 2018 was approximately $8.2 billion.

In December 2017, the SEC provided regulatory guidance for accounting of the impacts of the TCJA, referred to as SAB 118. Under the guidance in SAB 118, the income tax effects, which the accounting under ASC 740 is incomplete, are reported as a provisional amount based on a reasonable estimate. The reasonable estimate is subject to adjustment during a "measurement period", not to exceed one year, until the accounting is complete. The estimate is also subject to the finalization of management's analysis related to certain matters, such as developing interpretations of the provision of the TCJA, changes to certain estimates and amounts related to the earnings and profits of certain subsidiaries and the filing of tax returns.

In the fourth quarter of 2017, the Company recorded a provisional tax cost of approximately $13.0 billion which consisted primarily of the following components:

- a $10.1 billion charge on previously undistributed foreign earnings as of December 31, 2017
- a $4.5 billion deferred tax liability for foreign local and withholding taxes, offset by a $1.1 billion deferred tax asset for U.S. foreign tax credits, for repatriation of substantially all those earnings
- a $0.6 billion tax benefit relating to the remeasurement of U.S. deferred tax assets and liabilities and the impact of the TCJA on unrecognized tax benefits
- a $0.1 billion charge for U.S. state and local taxes on the repatriation of these foreign earnings

During the fourth quarter of 2018, the Company completed its full assessment and finalized the accounting for the impact of TCJA. The Company recorded net adjustments to the above components of the provisional charge of approximately $0.2 billion. These revisions were based on updated estimates and additional analysis by management as well as applying

interpretative guidance issued by the U.S. Department of Treasury to the facts and circumstances that existed as of the TCJA enactment date. This change was primarily related to additional deferred tax liabilities for foreign local and withholding taxes for the remaining balance of undistributed foreign earnings as of December 31, 2017 that were not provided for in the provisional charge in the fourth quarter of 2017.

The TCJA also includes provisions for a tax on global intangible low-taxed income (GILTI). GILTI is described as the excess of a U.S. shareholder's total net foreign income over a deemed return on tangible assets, as provided by the TCJA. In January 2018, the FASB issued guidance that allows companies to elect as an accounting policy whether to record the tax effects of GILTI in the period the tax liability is generated (i.e., "period cost") or provide for deferred tax assets and liabilities related to basis differences that exist and are expected to effect the amount of GILTI inclusion in future years upon reversal (i.e., "deferred method"). Through the third fiscal quarter of 2018, the Company had provisionally elected to treat GILTI as a period expense. Upon further analysis of this new tax provision, the Company has elected to account for GILTI under the deferred method. The deferred tax amounts recorded are based on the evaluation of temporary differences that are expected to reverse as GILTI is incurred. As a result of this election, the Company recorded a deferred tax cost related to GILTI of approximately $1.4 billion in the fourth fiscal quarter of 2018 related to facts and circumstances that existed on the date of TCJA enactment.

As a result of the GILTI deferred tax charge and the other adjustments to the provisional amount, the Company recorded a total of $1.6 billion of adjustments to the 2017 provisional charge increasing the Company's annual effective tax rate by approximately 9%.

During 2018, the Company reorganized the ownership structure of certain foreign subsidiaries which resulted in a reduction of certain foreign withholding taxes that it had recognized as part of the provisional TCJA tax charge in the fourth quarter of 2017. Following the completion of this restructuring in the fourth quarter 2018, and as a result of clarification by Swiss tax authorities regarding the applicability of withholding tax to repatriation of certain earnings, the Company reversed a deferred tax liability of $2.8 billion and a related deferred tax asset of $0.9 billion for U.S. foreign tax credits, for a net deferred tax benefit of $1.9 billion. As this restructuring occurred after the TCJA enactment date, the benefit is not considered an adjustment to the provisional amount recorded in 2017 under SAB118. This benefit with the SAB 118 adjustments has been reflected as "TCJA and related impacts" on the Company's effective tax rate reconciliation.

As described in Note 1 to the Consolidated Financial Statements, in 2018 the Company adopted ASU 2016-16: *Income Taxes: Intra-Entity Transfers of Assets Other Than Inventory*. This standard requires entities to recognize deferred tax assets and liabilities related to transfer of assets, other than inventory, within the consolidated entity. At the beginning of fiscal 2018, the Company recorded a net adjustment to deferred tax assets of approximately $2.0 billion. In the fourth quarter of 2018, as a result of the election to record GILTI on the deferred method, the Company recorded a GILTI deferred tax liability of $1.7 billion related to the adoption provisions of ASU 2016-16 as an adjustment to retained earnings.

The 2018 effective tax rate decreased by 77.6% compared to 2017. The 2017 effective tax rate was primarily driven by the approximately $13 billion provisional tax charge recorded in the fourth quarter of 2017 and the impact of a Belgian statutory tax rate change which increased the 2017 effective rate by 3.4%. Additional drivers of the 2018 annual effective tax were:

- the reduction of the U.S. statutory corporate tax rate including the effects of tax elections which resulted in the acceleration of certain deductions into the 2017 tax return. The impact of these accelerated deductions decreased the annual effective tax rate by approximately 1.7%
- the impact of the adjustments to the 2017 provisional TCJA charge, including both SAB 118 adjustments and the internal restructuring, decreased the effective tax rate by approximately 1.9%
- GILTI tax which increased the annual effective tax rate by approximately 1.6%, which excludes the impact of the SAB 118 adjustment for the adoption of the deferred method for GILTI
- tax benefits received from stock-based compensation during fiscal 2018 and 2017, reduced the effective tax rate by 1.5% and 2.0%, respectively
- in the fourth quarter of 2018, the Company completed the divestiture of its LifeScan business (Note 20), which increased the Company annual effective tax rate by approximately 0.8%
- more income in higher tax jurisdictions relative to lower tax jurisdictions as compared to 2017

The 2017 effective tax rate increased by 76.1% as compared to 2016, primarily driven by the enactment of the TCJA in the U.S. in December 2017. The enactment of the TCJA resulted in a provisional tax charge in the fourth quarter of 2017, of approximately $13.0 billion or approximately 73.3 percentage point increase to the effective tax rate.

The remainder of the increase in the tax rate for 2017 was related to the remeasurement of the Company's deferred tax assets in Belgium, as a result of changes in the Belgian statutory corporate tax rate enacted in December 2017, offset by a tax benefit for the closure of the Company's Animas insulin pump business.

Temporary differences and carryforwards for 2018 and 2017 were as follows:

	2018 Deferred Tax		2017 Deferred Tax	
(Dollars in Millions)	**Asset**	**Liability**	**Asset**	**Liability**
Employee related obligations	$ 2,398		2,259	
Stock based compensation	639		507	
Depreciation & amortization	1,784			(9)
Non-deductible intangibles		(5,967)		(6,506)
International R&D capitalized for tax	1,282		1,307	
Reserves & liabilities	1,647		1,718	
Income reported for tax purposes	1,104		1,316	
Net operating loss carryforward international	786		762	
Undistributed foreign earnings	693	(2,240)	1,101	(4,457)
Global intangible low-taxed income		(2,971)		
Miscellaneous international	603	(93)	755	(194)
Miscellaneous U.S.	469		177	
Total deferred income taxes	**$ 11,405**	**(11,271)**	**9,902**	**(11,166)**

The Company has wholly-owned international subsidiaries that have cumulative net losses. The Company believes that it is more likely than not that these subsidiaries will generate future taxable income sufficient to utilize these deferred tax assets.

The following table summarizes the activity related to unrecognized tax benefits:

(Dollars in Millions)	**2018**	**2017**	**2016**
Beginning of year	$ 3,151	3,041	3,080
Increases related to current year tax positions	242	332	348
Increases related to prior period tax positions	145	232	11
Decreases related to prior period tax positions	(137)	(416) [1]	(338)
Settlements	(40)	(2)	(37)
Lapse of statute of limitations	(35)	(36)	(23)
End of year	**$ 3,326**	**3,151**	**3,041**

[1] In 2017, $347 million of this decrease is related to the TCJA

The unrecognized tax benefits of $3.3 billion at December 30, 2018, if recognized, would affect the Company's annual effective tax rate. The Company conducts business and files tax returns in numerous countries and currently has tax audits in progress with a number of tax authorities. The IRS has completed its audit for the tax years through 2009 and is currently auditing the tax years 2010-2012. The Company currently expects completion of this audit during 2019. Final conclusion of the tax audit may result in an outcome that is different than the Company's estimates and may result in a material impact on the Company's current and future operating results or cash flows in the period that the audit is concluded. In other major jurisdictions where the Company conducts business, the years that remain open to tax audit go back to the year 2006. The Company believes it is possible that audits may be completed by tax authorities in some jurisdictions over the next twelve months. However, the Company is not able to provide a reasonably reliable estimate of the timing of any other future tax payments relating to uncertain tax positions.

The Company classifies liabilities for unrecognized tax benefits and related interest and penalties as long-term liabilities. Interest expense and penalties related to unrecognized tax benefits are classified as income tax expense. The Company recognized after tax interest expense of $53 million, $60 million and $7 million in 2018, 2017 and 2016, respectively. The total amount of accrued interest was $503 million and $436 million in 2018 and 2017, respectively.

9. Employee Related Obligations

At the end of 2018 and 2017, employee related obligations recorded on the Consolidated Balance Sheets were:

(Dollars in Millions)	2018	2017
Pension benefits	$ 5,327	5,343
Postretirement benefits	2,283	2,331
Postemployment benefits	2,330	2,250
Deferred compensation	410	475
Total employee obligations	10,350	10,399
Less current benefits payable	399	325
Employee related obligations — non-current	**$ 9,951**	**10,074**

Prepaid employee related obligations of $475 million and $526 million for 2018 and 2017, respectively, are included in Other assets on the Consolidated Balance Sheets.

10. Pensions and Other Benefit Plans

The Company sponsors various retirement and pension plans, including defined benefit, defined contribution and termination indemnity plans, which cover most employees worldwide. The Company also provides post-retirement benefits, primarily health care, to all eligible U.S. retired employees and their dependents.

Many international employees are covered by government-sponsored programs and the cost to the Company is not significant.

Retirement plan benefits for employees hired before January 1, 2015 are primarily based on the employee's compensation during the last three to five years before retirement and the number of years of service. In 2014, the Company announced that the U.S. Defined Benefit Plan was amended to adopt a new benefit formula, effective for employees hired on or after January 1, 2015. The benefits are calculated using a new formula based on employee compensation over total years of service.

International subsidiaries have plans under which funds are deposited with trustees, annuities are purchased under group contracts, or reserves are provided.

The Company does not typically fund retiree health care benefits in advance, but may do so at its discretion. The Company also has the right to modify these plans in the future.

In 2018 and 2017 the Company used December 31, 2018 and December 31, 2017, respectively, as the measurement date for all U.S. and international retirement and other benefit plans.

Net periodic benefit costs for the Company's defined benefit retirement plans and other benefit plans for 2018, 2017 and 2016 include the following components:

	Retirement Plans			Other Benefit Plans		
(Dollars in Millions)	2018	2017	2016	2018	2017	2016
Service cost	$ 1,283	1,080	949	269	247	224
Interest cost	996	927	927	148	159	158
Expected return on plan assets	(2,212)	(2,041)	(1,962)	(7)	(6)	(6)
Amortization of prior service cost (credit)	3	2	1	(31)	(30)	(34)
Recognized actuarial losses	852	609	496	123	138	135
Curtailments and settlements	1	17	11	—	—	—
Net periodic benefit cost	**$ 923**	**594**	**422**	**502**	**508**	**477**

In 2018, as per the adoption of ASU 2017-07, the service cost component of net periodic benefit cost was presented in the same line items on the Consolidated Statement of Earnings where other employee compensation costs are reported. All other components of net periodic benefit cost are presented as part of Other (income) expense, net on the Consolidated Statement of Earnings.

Amounts expected to be recognized in net periodic benefit cost in the coming year for the Company's defined benefit retirement plans and other post-retirement plans:

(Dollars in Millions)	
Amortization of net transition obligation	$ —
Amortization of net actuarial losses	656
Amortization of prior service credit	27

Unrecognized gains and losses for the U.S. pension plans are amortized over the average remaining future service for each plan. For plans with no active employees, they are amortized over the average life expectancy. The amortization of gains and losses for the other U.S. benefit plans is determined by using a 10% corridor of the greater of the market value of assets or the accumulated postretirement benefit obligation. Total unamortized gains and losses in excess of the corridor are amortized over the average remaining future service.

Prior service costs/benefits for the U.S. pension plans are amortized over the average remaining future service of plan participants at the time of the plan amendment. Prior service cost/benefit for the other U.S. benefit plans is amortized over the average remaining service to full eligibility age of plan participants at the time of the plan amendment.

The following table represents the weighted-average actuarial assumptions:

	Retirement Plans			Other Benefit Plans		
Worldwide Benefit Plans	**2018**	**2017**	**2016**	**2018**	**2017**	**2016**
Net Periodic Benefit Cost						
Service cost discount rate	3.20%	3.59	3.98	3.85	4.63	4.77
Interest cost discount rate	3.60%	3.98	4.24	3.62	3.94	4.10
Rate of increase in compensation levels	3.98%	4.01	4.02	4.29	4.31	4.32
Expected long-term rate of return on plan assets	8.46%	8.43	8.55			
Benefit Obligation						
Discount rate	3.76%	3.30	3.78	4.40	3.78	4.42
Rate of increase in compensation levels	3.97%	3.99	4.02	4.29	4.30	4.29

The Company's discount rates are determined by considering current yield curves representing high quality, long-term fixed income instruments. The resulting discount rates are consistent with the duration of plan liabilities. In the fiscal year 2016, the Company changed its methodology in determining service and interest cost from the single weighted average discount rate approach to duration specific spot rates along that yield curve to the plans' liability cash flows, which management has concluded is a more precise estimate. Prior to this change in methodology, the Company measured service and interest costs utilizing a single weighted-average discount rate derived from the yield curve used to measure the plan obligations. The Company has accounted for this change as a change in accounting estimate and, accordingly, has accounted for it on a prospective basis. This change does not impact the benefit obligation and did not have a material impact to the 2016 full year results.

The expected rates of return on plan asset assumptions represent the Company's assessment of long-term returns on diversified investment portfolios globally. The assessment is determined using projections from external financial sources, long-term historical averages, actual returns by asset class and the various asset class allocations by market.

The following table displays the assumed health care cost trend rates, for all individuals:

Health Care Plans	2018	2017
Health care cost trend rate assumed for next year	6.12%	6.33%
Rate to which the cost trend rate is assumed to decline (ultimate trend)	4.55%	4.55%
Year the rate reaches the ultimate trend rate	2038	2038

A one-percentage-point change in assumed health care cost trend rates would have the following effect:

(Dollars in Millions)	One-Percentage-Point Increase	One-Percentage-Point Decrease
Health Care Plans		
Total interest and service cost	$ 28	(22)
Post-retirement benefit obligation	$ 340	(280)

The following table sets forth information related to the benefit obligation and the fair value of plan assets at year-end 2018 and 2017 for the Company's defined benefit retirement plans and other post-retirement plans:

	Retirement Plans		Other Benefit Plans	
(Dollars in Millions)	**2018**	**2017**	**2018**	**2017**
Change in Benefit Obligation				
Projected benefit obligation — beginning of year	$ 33,221	28,116	4,582	4,605
Service cost	1,283	1,080	269	247
Interest cost	996	927	148	159
Plan participant contributions	66	60	—	—
Amendments	26	(7)	—	(17)
Actuarial (gains) losses	(2,326)	2,996	(119)	(166)
Divestitures & acquisitions	(29)	201	—	88
Curtailments, settlements & restructuring	(21)	(35)	—	2
Benefits paid from plan	(1,018)	(1,050)	(383)	(351)
Effect of exchange rates	(528)	933	(17)	15
Projected benefit obligation — end of year	**$ 31,670**	**33,221**	**4,480**	**4,582**
Change in Plan Assets				
Plan assets at fair value — beginning of year	$ 28,404	23,633	281	75
Actual return on plan assets	(1,269)	4,274	—	12
Company contributions	1,140	664	282	545
Plan participant contributions	66	60	—	—
Settlements	(13)	(32)	—	—
Divestitures & acquisitions	(17)	173	—	—
Benefits paid from plan assets	(1,018)	(1,050)	(383)	(351)
Effect of exchange rates	(475)	682	—	—
Plan assets at fair value — end of year	**$ 26,818**	**28,404**	**180**	**281**
Funded status — end of year	**$ (4,852)**	**(4,817)**	**(4,300)**	**(4,301)**
Amounts Recognized in the Company's Balance Sheet consist of the following:				
Non-current assets	$ 475	526	—	—
Current liabilities	(98)	(92)	(281)	(228)
Non-current liabilities	(5,229)	(5,251)	(4,019)	(4,073)
Total recognized in the consolidated balance sheet — end of year	**$ (4,852)**	**(4,817)**	**(4,300)**	**(4,301)**
Amounts Recognized in Accumulated Other Comprehensive Income consist of the following:				
Net actuarial loss	$ 8,323	8,140	1,263	1,500
Prior service cost (credit)	2	(25)	(106)	(137)
Unrecognized net transition obligation	—	—	—	—
Total before tax effects	**$ 8,325**	**8,115**	**1,157**	**1,363**
Accumulated Benefit Obligations — end of year	**$ 28,533**	**29,793**		

(Dollars in Millions)	Retirement Plans 2018	Retirement Plans 2017	Other Benefit Plans 2018	Other Benefit Plans 2017
Amounts Recognized in Net Periodic Benefit Cost and Other Comprehensive Income				
Net periodic benefit cost	**$ 923**	**594**	**502**	**508**
Net actuarial (gain) loss	1,153	740	(111)	(169)
Amortization of net actuarial loss	(852)	(609)	(123)	(138)
Prior service cost (credit)	26	(7)	—	(17)
Amortization of prior service (cost) credit	(3)	(2)	31	30
Effect of exchange rates	(114)	256	(3)	3
Total loss/(income) recognized in other comprehensive income, before tax	**$ 210**	**378**	**(206)**	**(291)**
Total recognized in net periodic benefit cost and other comprehensive income	**$ 1,133**	**972**	**296**	**217**

The Company plans to continue to fund its U.S. Qualified Plans to comply with the Pension Protection Act of 2006. International Plans are funded in accordance with local regulations. Additional discretionary contributions are made when deemed appropriate to meet the long-term obligations of the plans. For certain plans, funding is not a common practice, as funding provides no economic benefit. Consequently, the Company has several pension plans that are not funded.

In 2018, the Company contributed $679 million and $461 million to its U.S. and international pension plans, respectively.

The following table displays the funded status of the Company's U.S. Qualified & Non-Qualified pension plans and international funded and unfunded pension plans at December 31, 2018 and December 31, 2017, respectively:

	U.S. Plans				International Plans			
	Qualified Plans		Non-Qualified Plans		Funded Plans		Unfunded Plans	
(Dollars in Millions)	2018	2017	2018	2017	2018	2017	2018	2017
Plan Assets	$ 17,725	18,681	—	—	9,093	9,723	—	—
Projected Benefit Obligation	18,609	19,652	2,176	2,257	10,467	10,863	418	449
Accumulated Benefit Obligation	16,851	17,654	1,793	1,849	9,510	9,893	379	397
Over (Under) Funded Status								
Projected Benefit Obligation	$ (884)	(971)	(2,176)	(2,257)	(1,374)	(1,140)	(418)	(449)
Accumulated Benefit Obligation	874	1,027	(1,793)	(1,849)	(417)	(170)	(379)	(397)

Plans with accumulated benefit obligations in excess of plan assets have an accumulated benefit obligation, projected benefit obligation and plan assets of $7.5 billion, $8.8 billion and $4.3 billion, respectively, at the end of 2018, and $3.8 billion, $4.6 billion and $0.7 billion, respectively, at the end of 2017.

The following table displays the projected future benefit payments from the Company's retirement and other benefit plans:

(Dollars in Millions)	2019	2020	2021	2022	2023	2024-2028
Projected future benefit payments						
Retirement plans	$ 1,062	1,104	1,182	1,257	1,332	7,679
Other benefit plans	$ 375	397	411	428	413	2,273

The following table displays the projected future minimum contributions to the unfunded retirement plans. These amounts do not include any discretionary contributions that the Company may elect to make in the future.

(Dollars in Millions)	2019	2020	2021	2022	2023	2024-2028
Projected future contributions	$ 92	95	101	108	115	697

Each pension plan is overseen by a local committee or board that is responsible for the overall administration and investment of the pension plans. In determining investment policies, strategies and goals, each committee or board considers factors including, local pension rules and regulations; local tax regulations; availability of investment vehicles (separate accounts, commingled accounts, insurance funds, etc.); funded status of the plans; ratio of actives to retirees; duration of liabilities; and other relevant factors including: diversification, liquidity of local markets and liquidity of base currency. A majority of the Company's pension funds are open to new entrants and are expected to be on-going plans. Permitted investments are primarily liquid and/or listed, with little reliance on illiquid and non-traditional investments such as hedge funds.

The Company's retirement plan asset allocation at the end of 2018 and 2017 and target allocations for 2019 are as follows:

	Percent of Plan Assets		Target Allocation
	2018	2017	2019
Worldwide Retirement Plans			
Equity securities	71%	76%	70%
Debt securities	29	24	30
Total plan assets	**100%**	**100%**	**100%**

Determination of Fair Value of Plan Assets

The Plan has an established and well-documented process for determining fair values. Fair value is based upon quoted market prices, where available. If listed prices or quotes are not available, fair value is based upon models that primarily use, as inputs, market-based or independently sourced market parameters, including yield curves, interest rates, volatilities, equity or debt prices, foreign exchange rates and credit curves.

While the Plan believes its valuation methods are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

Valuation Hierarchy

The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described in the table below with Level 1 having the highest priority and Level 3 having the lowest.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Following is a description of the valuation methodologies used for the investments measured at fair value.

- *Short-term investment funds* — Cash and quoted short-term instruments are valued at the closing price or the amount held on deposit by the custodian bank. Other investments are through investment vehicles valued using the Net Asset Value (NAV) provided by the administrator of the fund. The NAV is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding. The NAV is a quoted price in a market that is not active and classified as Level 2.
- *Government and agency securities* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified within Level 1 of the valuation hierarchy. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows. When quoted market prices for a security are not available in an active market, they are classified as Level 2.
- *Debt instruments* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified as Level 1. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows and are classified as Level 2. Level 3 debt instruments are priced based on unobservable inputs.
- *Equity securities* — Equity securities are valued at the closing price reported on the major market on which the individual securities are traded. Substantially all common stock is classified within Level 1 of the valuation hierarchy.
- *Commingled funds* — These investment vehicles are valued using the NAV provided by the fund administrator. The NAV is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding. Assets in the Level 2 category have a quoted market price.

- *Insurance contracts* — The instruments are issued by insurance companies. The fair value is based on negotiated value and the underlying investments held in separate account portfolios as well as considering the credit worthiness of the issuer. The underlying investments are government, asset-backed and fixed income securities. In general, insurance contracts are classified as Level 3 as there are no quoted prices nor other observable inputs for pricing.
- *Other assets* — Other assets are represented primarily by limited partnerships and real estate investments, as well as commercial loans and commercial mortgages that are not classified as corporate debt. Other assets that are exchange listed and actively traded are classified as Level 1, while inactively traded assets are classified as Level 2.

The following table sets forth the Retirement Plans' investments measured at fair value as of December 31, 2018 and December 31, 2017:

	Quoted Prices in Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs[a] (Level 3)		Investments Measured at Net Asset Value		Total Assets	
(Dollars in Millions)	**2018**	**2017**	**2018**	**2017**	**2018**	**2017**	**2018**	**2017**	**2018**	**2017**
Short-term investment funds	$ 122	429	529	427	—	—	—	—	651	856
Government and agency securities	—	—	3,595	3,094	—	—	—	—	3,595	3,094
Debt instruments	—	—	3,105	2,013	—	—	—	—	3,105	2,013
Equity securities	11,298	13,848	4	—	—	—	—	—	11,302	13,848
Commingled funds	—	—	2,304	1,780	133	57	5,201	6,158	7,638	7,995
Insurance contracts	—	—	—	—	193	199	—	—	193	199
Other assets	—	—	33	121	—	—	301	278	334	399
Investments at fair value	**$ 11,420**	**14,277**	**9,570**	**7,435**	**326**	**256**	**5,502**	**6,436**	**26,818**	**28,404**

[a] The activity for the Level 3 assets is not significant for all years presented.

The Company's Other Benefit Plans are unfunded except for U.S. commingled funds (Level 2) of $72 million and $81 million and U.S. short-term investment funds (Level 2) of $108 million and $200 million at December 31, 2018 and December 31, 2017, respectively.

The fair value of Johnson & Johnson Common Stock directly held in plan assets was $876 million (3.3% of total plan assets) at December 31, 2018 and $938 million (3.3% of total plan assets) at December 31, 2017.

11. Savings Plan

The Company has voluntary 401(k) savings plans designed to enhance the existing retirement programs covering eligible employees. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which he/she is eligible. Total Company matching contributions to the plans were $242 million, $214 million and $191 million in 2018, 2017 and 2016, respectively.

12. Capital and Treasury Stock
Changes in treasury stock were:

(Amounts in Millions Except Treasury Stock Shares in Thousands)	Treasury Stock Shares	Treasury Stock Amount
Balance at January 3, 2016	364,681	$ 22,684
Employee compensation and stock option plans	(30,839)	(3,311)
Repurchase of common stock	79,490	8,979
Balance at January 1, 2017	413,332	28,352
Employee compensation and stock option plans	(25,508)	(3,156)
Repurchase of common stock	49,494	6,358
Balance at December 31, 2017	437,318	31,554
Employee compensation and stock option plans	(22,082)	(3,060)
Repurchase of common stock	42,283	5,868
Balance at December 30, 2018	457,519	$ 34,362

Aggregate shares of common stock issued were approximately 3,119,843,000 shares at the end of 2018, 2017 and 2016.

Cash dividends paid were $3.54 per share in 2018, compared with dividends of $3.32 per share in 2017, and $3.15 per share in 2016.

On December 17, 2018, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's shares of common stock. The repurchase program has no time limit and may be suspended for periods or discontinued at any time. Any shares acquired will be available for general corporate purposes. The Company intends to finance the share repurchase program through available cash. As of December 30, 2018, $0.9 billion has been repurchased under the program.

On October 13, 2015, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $10.0 billion of the Company's shares of common stock. This share repurchase program was completed as of July 2, 2017.

13. Accumulated Other Comprehensive Income (Loss)
Components of other comprehensive income (loss) consist of the following:

(Dollars in Millions)	Foreign Currency Translation	Gain/(Loss) On Securities	Employee Benefit Plans	Gain/ (Loss) On Derivatives & Hedges	Total Accumulated Other Comprehensive Income (Loss)
January 3, 2016	$ (8,435)	604	(5,298)	(36)	(13,165)
Net 2016 changes	(612)	(193)	(682)	(249)	(1,736)
January 1, 2017	(9,047)	411	(5,980)	(285)	(14,901)
Net 2017 changes	1,696	(179)	(170)	355	1,702
December 31, 2017	(7,351)	232	(6,150)	70	(13,199)
Cumulative adjustment to retained earnings		(232) [1]			(232)
Net 2018 changes	(1,518)	—	(8)	(265)	(1,791)
December 30, 2018	$ (8,869)	—	(6,158)	(195)	(15,222)

[1] See Note 1 to Consolidated Financial Statements for additional details on the adoption of ASU 2016-01

Amounts in accumulated other comprehensive income are presented net of the related tax impact. Foreign currency translation is not adjusted for income taxes where it relates to permanent investments in international subsidiaries. For additional details on comprehensive income see the Consolidated Statements of Comprehensive Income.

Details on reclassifications out of Accumulated Other Comprehensive Income:
Gain/(Loss) On Securities - reclassifications released to Other (income) expense, net.

Employee Benefit Plans - reclassifications are included in net periodic benefit cost. See Note 10 for additional details.
Gain/(Loss) On Derivatives & Hedges - reclassifications to earnings are recorded in the same account as the hedged transaction. See Note 6 for additional details.

14. International Currency Translation

For translation of its subsidiaries operating in non-U.S. Dollar currencies, the Company has determined that the local currencies of its international subsidiaries are the functional currencies except those in highly inflationary economies, which are defined as those which have had compound cumulative rates of inflation of 100% or more during the past three years, or where a substantial portion of its cash flows are not in the local currency. Beginning in the fiscal third quarter of 2018, the Company accounted for operations in Argentina as highly inflationary. For the majority of the Company's subsidiaries the local currency is the functional currency.

In consolidating international subsidiaries, balance sheet currency effects are recorded as a component of accumulated other comprehensive income. This equity account includes the results of translating certain balance sheet assets and liabilities at current exchange rates and some accounts at historical rates, except for those located in highly inflationary economies. The translation of balance sheet accounts for highly inflationary economies are reflected in the operating results.

A rollforward of the changes during 2018, 2017 and 2016 for foreign currency translation adjustments is included in Note 13.

Net currency transaction gains and losses included in Other (income) expense were losses of $265 million, $216 million and $289 million in 2018, 2017 and 2016, respectively.

15. Earnings Per Share

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal years ended December 30, 2018, December 31, 2017 and January 1, 2017:

(In Millions Except Per Share Amounts)	2018	2017	2016
Basic net earnings per share	$ 5.70	0.48	6.04
Average shares outstanding — basic	2,681.5	2,692.0	2,737.3
Potential shares exercisable under stock option plans	139.0	139.7	142.4
Less: shares repurchased under treasury stock method	(92.5)	(87.3)	(92.1)
Convertible debt shares	0.7	0.9	1.3
Adjusted average shares outstanding — diluted	2,728.7	2,745.3	2,788.9
Diluted net earnings per share	$ 5.61	0.47	5.93

The diluted net earnings per share calculation included the dilutive effect of convertible debt that is offset by the related reduction in interest expense of $1 million after-tax for 2018 and 2017, and $2 million for 2016.

The diluted net earnings per share calculation for 2018, 2017 and 2016 included all shares related to stock options, as the exercise price of all options was less than the average market value of the Company's stock.

16. Rental Expense and Lease Commitments

Rentals of space, vehicles, manufacturing equipment and office and data processing equipment under operating leases were approximately $332 million, $372 million and $330 million in 2018, 2017 and 2016, respectively.

The approximate minimum rental payments required under operating leases that have initial or remaining non-cancelable lease terms in excess of one year at December 30, 2018 are:

(Dollars in Millions)

2019	2020	2021	2022	2023	After 2023	Total
$223	188	154	116	76	139	896

Commitments under capital leases are not significant.

17. Common Stock, Stock Option Plans and Stock Compensation Agreements

At December 30, 2018, the Company had 2 stock-based compensation plans. The shares outstanding are for contracts under the Company's 2005 Long-Term Incentive Plan and the 2012 Long-Term Incentive Plan. The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan. Under the 2012 Long-Term Incentive Plan, the Company may issue up to 650 million shares of common stock, plus any shares canceled, expired, forfeited, or not issued from the 2005 Long-Term Incentive Plan subsequent to April 26, 2012. Shares available for future grants under the 2012 Long-Term Incentive Plan were 351 million at the end of 2018.

The compensation cost that has been charged against income for these plans was $978 million, $962 million and $878 million for 2018, 2017 and 2016, respectively. The total income tax benefit recognized in the income statement for share-based compensation costs was $192 million, $275 million and $256 million for 2018, 2017 and 2016, respectively. An additional tax benefit of $353 million was recognized in 2016 due to the adoption of a new accounting standard for the reporting of additional tax benefits on share-based compensation. The total unrecognized compensation cost was $827 million, $798 million and $749 million for 2018, 2017 and 2016, respectively. The weighted average period for this cost to be recognized was 1.73 years, 1.76 years and 1.09 years for 2018, 2017, and 2016, respectively. Share-based compensation costs capitalized as part of inventory were insignificant in all periods.

The Company settles employee benefit equity issuances with treasury shares. Treasury shares are replenished throughout the year for the number of shares used to settle employee benefit equity issuances.

Stock Options

Stock options expire 10 years from the date of grant and vest over service periods that range from 6 months to 4 years. All options are granted at the average of the high and low prices of the Company's Common Stock on the New York Stock Exchange on the date of grant.

The fair value of each option award was estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the following table. For 2018, 2017 and 2016 grants, expected volatility represents a blended rate of 10-year weekly historical overall volatility rate, and a 5-week average implied volatility rate based on at-the-money traded Johnson & Johnson options with a life of 2 years. For all grants, historical data is used to determine the expected life of the option. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant.

The average fair value of options granted was $17.98, $13.38 and $10.01, in 2018, 2017 and 2016, respectively. The fair value was estimated based on the weighted average assumptions of:

	2018	2017	2016
Risk-free rate	2.77%	2.25%	1.51%
Expected volatility	15.77%	15.30%	15.76%
Expected life (in years)	7.0	7.0	7.0
Expected dividend yield	2.70%	2.90%	3.10%

A summary of option activity under the Plan as of December 30, 2018, December 31, 2017 and January 1, 2017, and changes during the years ending on those dates is presented below:

(Shares in Thousands)	Outstanding Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (Dollars in Millions)
Shares at January 3, 2016	116,517	$ 76.41	$ 3,065
Options granted	22,491	101.87	
Options exercised	(22,547)	65.66	
Options canceled/forfeited	(3,006)	92.83	
Shares at January 1, 2017	113,455	83.16	3,636
Options granted	19,287	115.67	
Options exercised	(18,975)	70.87	
Options canceled/forfeited	(2,461)	101.40	
Shares at December 31, 2017	111,306	90.48	5,480
Options granted	17,115	129.51	
Options exercised	(16,228)	75.44	
Options canceled/forfeited	(2,541)	112.90	
Shares at December 30, 2018	**109,652**	**$ 98.29**	**$ 3,214**

The total intrinsic value of options exercised was $1,028 million, $1,060 million and $980 million in 2018, 2017 and 2016, respectively.

The following table summarizes stock options outstanding and exercisable at December 30, 2018:

(Shares in Thousands)	Outstanding			Exercisable	
Exercise Price Range	Options	Average Life[1]	Average Exercise Price	Options	Average Exercise Price
$52.13-$65.62	13,466	1.8	$62.67	13,466	$62.67
$66.07-$72.54	12,710	4.0	$72.53	12,710	$72.53
$90.44-$100.48	29,162	5.6	$95.34	28,537	$95.23
$101.87-$115.67	37,877	7.6	$108.33	111	$108.04
$115.68-$129.51	16,437	9.1	$129.51	38	$129.51
	109,652	**6.2**	**$98.29**	**54,862**	**$82.03**

[1] Average contractual life remaining in years.

Stock options outstanding at December 31, 2017 and January 1, 2017 were 111,306 and an average life of 6.3 years and 113,455 and an average life of 6.2 years, respectively. Stock options exercisable at December 31, 2017 and January 1, 2017 were 52,421 at an average price of $73.61 and 50,414 at an average price of $65.77, respectively.

Restricted Share Units and Performance Share Units

The Company grants restricted share units which vest over service periods that range from 6 months to 3 years. The Company also grants performance share units, which are paid in shares of Johnson & Johnson Common Stock after the end of a three-year performance period. Whether any performance share units vest, and the amount that does vest, is tied to the completion of service periods that range from 6 months to 3 years and the achievement, over a three-year period, of three equally-weighted goals that directly align with or help drive long-term total shareholder return: operational sales, adjusted operational earnings per share, and relative total shareholder return. The number of shares actually earned at the end of the three-year period will vary, based only on actual performance, from 0% to 200% of the target number of performance share units granted. In the fourth quarter of 2017, the Company modified the restricted share units that are scheduled to vest between January 1, 2018 and March 15, 2018. This modification guaranteed a minimum aggregate value, below the market value of the total expected payout amount, for all awards expected to vest during this period. The amount that was committed was not material to the Company's overall financial position.

A summary of the restricted share units and performance share units activity under the Plans as of December 30, 2018 is presented below:

(Shares in Thousands)	Outstanding Restricted Share Units	Outstanding Performance Share Units
Shares at December 31, 2017	20,161	2,625
Granted	6,074	1,142
Issued	(6,684)	(1,151)
Canceled/forfeited/adjusted	(1,091)	(122)
Shares at December 30, 2018	18,460	2,494

The average fair value of the restricted share units granted was $119.67, $107.69 and $92.45 in 2018, 2017 and 2016, respectively, using the fair market value at the date of grant. The fair value of restricted share units was discounted for dividends, which are not paid on the restricted share units during the vesting period. The fair value of restricted share units issued was $613.7 million, $596.5 million and $587.7 million in 2018, 2017 and 2016, respectively.

The weighted average fair value of the performance share units granted was $120.64, $114.13 and $105.30 in 2018, 2017 and 2016, calculated using the weighted average fair market value for each of the three component goals at the date of grant.

The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. The fair value of performance share units issued was $128.8 million, $132.5 million and $127.7 million in 2018, 2017 and 2016, respectively.

18. **Segments of Business and Geographic Areas**

(Dollars in Millions)	Sales to Customers			% Change	
	2018	2017	2016	'18 vs. '17	'17 vs. '16
CONSUMER					
Baby Care					
U.S.	$ 422	449	488	(6.0)%	(8.0)
International	1,436	1,467	1,513	(2.1)	(3.0)
Worldwide	1,858	1,916	2,001	(3.0)	(4.2)
Beauty					
U.S.	2,403	2,335	2,135	2.9	9.4
International	1,979	1,865	1,762	6.1	5.8
Worldwide	4,382	4,200	3,897	4.3	7.8
Oral Care					
U.S.	637	616	648	3.4	(4.9)
International	918	915	920	0.3	(0.5)
Worldwide	1,555	1,531	1,568	1.6	(2.4)
OTC					
U.S.	1,850	1,716	1,675	7.8	2.4
International	2,484	2,410	2,302	3.1	4.7
Worldwide	4,334	4,126	3,977	5.0	3.7
Women's Health					
U.S.	13	12	19	8.3	(36.8)
International	1,036	1,038	1,048	(0.2)	(1.0)
Worldwide	1,049	1,050	1,067	(0.1)	(1.6)
Wound Care/Other					
U.S.	436	437	455	(0.2)	(4.0)
International	239	342	342	(30.1)	0.0
Worldwide	675	779	797	(13.4)	(2.3)
TOTAL CONSUMER					
U.S.	5,761	5,565	5,420	3.5	2.7
International	8,092	8,037	7,887	0.7	1.9
Worldwide	13,853	13,602	13,307	1.8	2.2
PHARMACEUTICAL					
Immunology					
U.S.	9,073	8,871	8,846	2.3	0.3
International	4,047	3,373	3,122	20.0	8.0
Worldwide	13,120	12,244	11,968	7.2	2.3
REMICADE®					
U.S.	3,664	4,525	4,842	(19.0)	(6.5)
U.S. Exports	436	563	782	(22.6)	(28.0)
International	1,226	1,227	1,342	(0.1)	(8.6)
Worldwide	5,326	6,315	6,966	(15.7)	(9.3)

SIMPONI / SIMPONI ARIA®					
U.S.	1,051	954	959	10.2	(0.5)
International	1,033	879	786	17.5	11.8
Worldwide	2,084	1,833	1,745	13.7	5.0
STELARA®					
U.S.	3,469	2,767	2,263	25.4	22.3
International	1,687	1,244	969	35.6	28.4
Worldwide	5,156	4,011	3,232	28.5	24.1
TREMFAYA®					
U.S.	453	62	—	*	*
International	91	1	—	*	*
Worldwide	544	63	—	*	*
OTHER IMMUNOLOGY					
U.S.	—	—	—	—	—
International	10	22	25	(54.5)	(12.0)
Worldwide	10	22	25	(54.5)	(12.0)
Infectious Diseases					
U.S.	1,378	1,358	1,461	1.5	(7.0)
International	1,926	1,796	1,747	7.2	2.8
Worldwide	3,304	3,154	3,208	4.8	(1.7)
EDURANT® / rilpivirine					
U.S.	58	58	52	0.0	11.5
International	758	656	521	15.5	25.9
Worldwide	816	714	573	14.3	24.6
PREZISTA® / PREZCOBIX® / REZOLSTA® / SYMTUZA®					
U.S.	1,169	1,109	1,143	5.4	(3.0)
International	786	712	708	10.4	0.6
Worldwide	1,955	1,821	1,851	7.4	(1.6)
OTHER INFECTIOUS DISEASES					
U.S.	151	191	266	(20.9)	(28.2)
International	382	428	518	(10.7)	(17.4)
Worldwide	533	619	784	(13.9)	(21.0)
Neuroscience					
U.S.	2,574	2,630	2,628	(2.1)	0.1
International	3,503	3,356	3,457	4.4	(2.9)
Worldwide	6,077	5,986	6,085	1.5	(1.6)
CONCERTA® / Methylphenidate					
U.S.	229	384	468	(40.4)	(17.9)
International	434	407	395	6.6	3.0
Worldwide	663	791	863	(16.2)	(8.3)
INVEGA SUSTENNA® / XEPLION® / INVEGA TRINZA® / TREVICTA®					
U.S.	1,791	1,590	1,343	12.6	18.4
International	1,137	979	871	16.1	12.4
Worldwide	2,928	2,569	2,214	14.0	16.0

RISPERDAL CONSTA®					
U.S.	315	360	381	(12.5)	(5.5)
International	422	445	512	(5.2)	(13.1)
Worldwide	737	805	893	(8.4)	(9.9)
OTHER NEUROSCIENCE					
U.S.	239	296	436	(19.3)	(32.1)
International	1,510	1,525	1,679	(1.0)	(9.2)
Worldwide	1,749	1,821	2,115	(4.0)	(13.9)
Oncology					
U.S.	4,331	3,098	2,335	39.8	32.7
International	5,513	4,160	3,472	32.5	19.8
Worldwide	9,844	7,258	5,807	35.6	25.0
DARZALEX®					
U.S.	1,203	884	471	36.1	87.7
International	822	358	101	*	*
Worldwide	2,025	1,242	572	63.0	*
IMBRUVICA®					
U.S.	1,129	841	613	34.2	37.2
International	1,486	1,052	638	41.3	64.9
Worldwide	2,615	1,893	1,251	38.1	51.3
VELCADE®					
U.S.	—	—	—	—	—
International	1,116	1,114	1,224	0.2	(9.0)
Worldwide	1,116	1,114	1,224	0.2	(9.0)
ZYTIGA®/abiraterone acetate					
U.S.	1,771	1,228	1,089	44.2	12.8
International	1,727	1,277	1,171	35.2	9.1
Worldwide	3,498	2,505	2,260	39.6	10.8
OTHER ONCOLOGY					
U.S.	228	145	162	57.2	(10.5)
International	362	359	338	0.8	6.2
Worldwide	590	504	500	17.1	0.8
Pulmonary Hypertension					
U.S.	1,651	773	—	*	*
International	922	554	—	66.4	*
Worldwide	2,573	1,327	—	93.9	*
OPSUMIT®					
U.S.	700	320	—	*	*
International	515	253	—	*	*
Worldwide	1,215	573	—	*	*
TRACLEER®					
U.S.	268	161	—	66.5	*
International	278	242	—	14.9	*
Worldwide	546	403	—	35.5	*

UPTRAVI®					
U.S.	598	238	—	*	*
International	65	25	—	*	*
Worldwide	663	263	—	*	*
OTHER					
U.S.	85	54	—	57.4	*
International	64	34	—	88.2	*
Worldwide	149	88	—	69.3	*
Cardiovascular / Metabolism / Other					
U.S.	4,279	4,744	4,855	(9.8)	(2.3)
International	1,537	1,543	1,541	(0.4)	0.1
Worldwide	5,816	6,287	6,396	(7.5)	(1.7)
XARELTO®					
U.S.	2,477	2,500	2,288	(0.9)	9.3
International	—	—	—	—	—
Worldwide	2,477	2,500	2,288	(0.9)	9.3
INVOKANA® / INVOKAMET®					
U.S.	711	944	1,273	(24.7)	(25.8)
International	170	167	134	1.8	24.6
Worldwide	881	1,111	1,407	(20.7)	(21.0)
PROCRIT® / EPREX®					
U.S.	674	675	767	(0.1)	(12.0)
International	314	297	338	5.7	(12.1)
Worldwide	988	972	1,105	1.6	(12.0)
OTHER					
U.S.	417	625	527	(33.3)	18.6
International	1,053	1,079	1,069	(2.4)	0.9
Worldwide	1,470	1,704	1,596	(13.7)	6.8
TOTAL PHARMACEUTICAL					
U.S.	23,286	21,474	20,125	8.4	6.7
International	17,448	14,782	13,339	18.0	10.8
Worldwide	40,734	36,256	33,464	12.4	8.3
MEDICAL DEVICES					
Diabetes Care					
U.S.	371	612	739	(39.4)	(17.2)
International	638	1,003	1,050	(36.4)	(4.5)
Worldwide	1,009	1,615	1,789	(37.5)	(9.7)
Diagnostics					
U.S.	—	—	—	—	—
International	—	1	66	*	*
Worldwide	—	1	66	*	*
Interventional Solutions					
U.S.	1,283	1,148	1,031	11.8	11.3
International	1,363	1,148	1,024	18.7	12.1
Worldwide	2,646	2,296	2,055	15.2	11.7

Orthopaedics					
U.S.	5,281	5,404	5,438	(2.3)	(0.6)
International	3,604	3,654	3,690	(1.4)	(1.0)
Worldwide	8,885	9,058	9,128	(1.9)	(0.8)
HIPS					
U.S.	841	827	798	1.7	3.6
International	577	567	563	1.8	0.7
Worldwide	1,418	1,394	1,361	1.7	2.4
KNEES					
U.S.	911	948	943	(3.9)	0.5
International	591	575	581	2.8	(1.0)
Worldwide	1,502	1,523	1,524	(1.4)	(0.1)
TRAUMA					
U.S.	1,599	1,576	1,545	1.5	2.0
International	1,100	1,040	1,024	5.8	1.6
Worldwide	2,699	2,616	2,569	3.2	1.8
SPINE & OTHER					
U.S.	1,930	2,053	2,152	(6.0)	(4.6)
International	1,336	1,472	1,522	(9.2)	(3.3)
Worldwide	3,266	3,525	3,674	(7.3)	(4.1)
Surgery					
U.S.	4,125	4,085	4,026	1.0	1.5
International	5,776	5,474	5,270	5.5	3.9
Worldwide	9,901	9,559	9,296	3.6	2.8
ADVANCED					
U.S.	1,657	1,620	1,524	2.3	6.3
International	2,345	2,136	1,993	9.8	7.2
Worldwide	4,002	3,756	3,517	6.5	6.8
GENERAL					
U.S.	1,751	1,728	1,669	1.3	3.5
International	2,806	2,735	2,693	2.6	1.6
Worldwide	4,557	4,463	4,362	2.1	2.3
SPECIALTY					
U.S.	717	737	833	(2.7)	(11.5)
International	625	603	584	3.6	3.3
Worldwide	1,342	1,340	1,417	0.1	(5.4)
Vision					
U.S.	1,777	1,575	1,032	12.8	52.6
International	2,776	2,488	1,753	11.6	41.9
Worldwide	4,553	4,063	2,785	12.1	45.9
CONTACT LENSES / OTHER					
U.S.	1,237	1,122	1,032	10.2	8.7
International	2,065	1,914	1,753	7.9	9.2
Worldwide	3,302	3,036	2,785	8.8	9.0

SURGICAL					
U.S.	540	453	—	19.2	*
International	711	574	—	23.9	*
Worldwide	1,251	1,027	—	21.8	*
TOTAL MEDICAL DEVICES					
U.S.	12,837	12,824	12,266	0.1	4.5
International	14,157	13,768	12,853	2.8	7.1
Worldwide	26,994	26,592	25,119	1.5	5.9
WORLDWIDE					
U.S.	41,884	39,863	37,811	5.1	5.4
International	39,697	36,587	34,079	8.5	7.4
Worldwide	$ 81,581	76,450	71,890	6.7 %	6.3

*Percentage greater than 100% or not meaningful

	Income Before Tax			Identifiable Assets	
(Dollars in Millions)	**2018 [3]**	**2017 [4]**	**2016 [5]**	**2018**	**2017**
Consumer	$ 2,320	2,524	2,441	$ 25,877	25,030
Pharmaceutical	12,568	11,083	12,827	56,636	59,450
Medical Devices	4,397	5,392	5,578	46,254	45,413
Total	19,285	18,999	20,846	128,767	129,893
Less: Expense not allocated to segments [1]	1,286	1,326	1,043		
General corporate [2]				24,187	27,410
Worldwide total	**$ 17,999**	**17,673**	**19,803**	**$ 152,954**	**157,303**

	Additions to Property, Plant & Equipment			Depreciation and Amortization		
(Dollars in Millions)	**2018**	**2017**	**2016**	**2018**	**2017**	**2016**
Consumer	$ 438	485	486	$ 688	674	608
Pharmaceutical	1,012	936	927	3,802	2,416	886
Medical Devices	1,843	1,566	1,472	2,103	2,216	1,928
Segments total	3,293	2,987	2,885	6,593	5,306	3,422
General corporate	377	292	341	336	336	332
Worldwide total	**$ 3,670**	**3,279**	**3,226**	**$ 6,929**	**5,642**	**3,754**

	Sales to Customers			Long-Lived Assets [6]	
(Dollars in Millions)	**2018**	**2017**	**2016**	**2018**	**2017**
United States	$ 41,884	39,863	37,811	$ 37,117	38,556
Europe	18,753	17,126	15,770	51,433	56,677
Western Hemisphere excluding U.S.	6,113	6,041	5,734	2,752	2,990
Asia-Pacific, Africa	14,831	13,420	12,575	2,733	2,773
Segments total	81,581	76,450	71,890	94,035	100,996
General corporate				1,064	1,143
Other non long-lived assets				57,855	55,164
Worldwide total	**$ 81,581**	**76,450**	**71,890**	**$ 152,954**	**157,303**

See Note 1 for a description of the segments in which the Company operates.

Export sales are not significant. In 2018, the Company had three wholesalers distributing products for all three segments that represented approximately 14.0%, 11.0% and 11.0% of the total consolidated revenues. In 2017, the Company had two wholesalers distributing products for all three segments that represented approximately 14.0% and 10.0% of the total consolidated revenues. In 2016, the Company had two wholesalers distributing products for all three segments that represented approximately 13.5% and 10.7% of the total consolidated revenues.

(1) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.

(2) General corporate includes cash, cash equivalents and marketable securities.

(3) The Consumer segment includes a gain of $0.3 billion from the divestiture of NIZORAL® and litigation expense of $0.3 billion. The Pharmaceutical segment includes an in-process research and development charge of $1.1 billion related to the Alios and XO1 assets and the corresponding XO1 contingent liability reversal of $0.2 billion, Actelion acquisition related costs of $0.2 billion, unrealized loss on securities of $0.2 billion and a gain of $0.2 billion from the divestiture of certain non-strategic Pharmaceutical products. The Medical Devices segment includes net litigation expense of $1.7 billion, a restructuring related charge of $0.6 billion, AMO acquisition related costs of $0.1 billion and a gain of $0.5 billion from the divestiture of the LifeScan business in the fiscal fourth quarter.

(4) The Pharmaceutical segment includes $0.8 billion for Actelion acquisition related costs, an in-process research and development expense of $0.4 billion and litigation expense of $0.1 billion. The Medical Devices segment includes litigation expense of $1.1 billion, a restructuring related charge of $0.8 billion, an asset impairment of $0.2 billion primarily related to the insulin pump business and $0.1 billion for AMO acquisition related costs. The Medical Devices segment includes a gain of $0.7 billion from the divestiture of Codman Neurosurgery. The Consumer segment includes a gain of $0.5 billion from the divestiture of COMPEED®.

(5) Includes net litigation expense of $0.8 billion and a restructuring related charge of $0.7 billion in the Medical Devices segment. The Pharmaceutical segment includes a positive adjustment of $0.5 billion to previous reserve estimates and gains from the divestitures of the controlled substance raw material and active pharmaceutical ingredient (API) business and certain anesthetic products in Europe.

(6) Long-lived assets include property, plant and equipment, net for 2018, and 2017 of $17,035 and $17,005, respectively, and intangible assets and goodwill, net for 2018 and 2017 of $78,064 and $85,134, respectively.

19. Selected Quarterly Financial Data (unaudited)

Selected unaudited quarterly financial data for the years 2018 and 2017 are summarized below:

	2018				2017			
(Dollars in Millions Except Per Share Data)	First Quarter [1]	Second Quarter [2]	Third Quarter [3]	Fourth Quarter [4]	First Quarter [5]	Second Quarter [6]	Third Quarter [7]	Fourth Quarter [8]
Segment sales to customers								
Consumer	$ 3,398	3,504	3,415	3,536	3,228	3,478	3,356	3,540
Pharmaceutical	9,844	10,354	10,346	10,190	8,245	8,635	9,695	9,681
Medical Devices	6,767	6,972	6,587	6,668	6,293	6,726	6,599	6,974
Total sales	20,009	20,830	20,348	20,394	17,766	18,839	19,650	20,195
Gross profit	13,395	13,903	13,759	13,433	12,357	12,993	12,725	12,936
Earnings before provision for taxes on income	5,481	4,973	4,423	3,122	5,575	4,748	4,790	2,560
Net earnings (loss)	4,367	3,954	3,934	3,042	4,422	3,827	3,764	(10,713)
Basic net earnings (loss) per share	$ 1.63	1.47	1.47	1.14	1.63	1.42	1.40	(3.99)
Diluted net earnings (loss) per share	$ 1.60	1.45	1.44	1.12	1.61	1.40	1.37	(3.99)

(1) The first quarter of 2018 includes an Actelion acquisition related cost of $92 million after-tax ($96 million before-tax) and a restructuring related charge of $81 million after-tax ($107 million before-tax).

(2) The second quarter of 2018 includes a litigation expense of $609 million after-tax ($703 million before-tax) and a restructuring related charge of $152 million after-tax ($176 million before-tax).

(3) The third quarter of 2018 includes an in-process research and development expense of $859 million after-tax ($1,126 million before-tax) related to the Alios and XO1 assets and the corresponding XO1 contingent liability reversal of $184 million after and before tax, a restructuring related charge of $162 million after-tax ($190 million before-tax) and a $265 million benefit after-tax from the impact of tax legislation.

(4) The fourth quarter of 2018 includes a litigation expense of $1,113 million after-tax ($1,288 million before-tax), a restructuring related charge of $190 million after-tax ($227 million before-tax) and a $137 million benefit after-tax from the impact of tax legislation.

(5) The first quarter of 2017 includes a restructuring charge of $121 million after-tax ($161 million before-tax) and an AMO acquisition related cost of $251 million after-tax ($38 million before-tax).

(6) The second quarter of 2017 includes a litigation expense of $352 million after-tax ($493 million before-tax), Actelion acquisition related costs of $199 million after-tax ($213 million before-tax) a restructuring charge of $101 million after-tax ($128 million before-tax) and an asset impairment charge of $125 million after-tax ($182 million before-tax).

(7) The third quarter of 2017 includes a litigation expense of $97 million after-tax ($118 million before-tax), Actelion acquisition related costs of $255 million after-tax ($367 million before-tax) and a restructuring charge of $136 million after-tax ($187 million before-tax).

(8) The fourth quarter of 2017 includes a litigation expense of $506 million after-tax ($645 million before-tax), Actelion acquisition related costs of $313 million after-tax ($217 million before-tax), a restructuring charge of $237 million after-tax ($284 million before-tax), an in-process research and development expense of $266 million after-tax ($408 million before-tax) and an after-tax benefit of $116 million related to the insulin pump business. Additionally, the fourth quarter of 2017 includes a provisional charge of $13.6 billion for recently enacted tax legislation.

20. Business Combinations and Divestitures

Certain businesses were acquired for $0.9 billion in cash and $0.1 billion of liabilities assumed during 2018. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2018 acquisitions primarily included: Zarbee's, Inc., a privately held company that is a leader in naturally-based consumer healthcare products; Medical Enterprises Distribution LLC, a privately held healthcare technology firm focused on surgical procedure innovation; BeneVir Biopharm, Inc. (BeneVir), a privately-held, biopharmaceutical company specializing in the development of oncolytic immunotherapies and Orthotaxy, a privately-held developer of software-enabled surgery technologies, including a differentiated robotic-assisted surgery solution.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $1.0 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

On October 23, 2018, the Company entered into an agreement to acquire Ci:z Holdings Co., Ltd., a Japanese company focused on the marketing, development and distribution of a broad range of dermocosmetic, cosmetic and skincare products for a total purchase price of approximately ¥230 billion, which equates to approximately $2.1 billion, using the exchange rate of 109.06 Japanese Yen to each U.S. Dollar on January 16, 2019. The acquisition was completed on January 17, 2019, through a series of transactions that included an all-cash tender offer to acquire the publicly held shares not already held by the Company for ¥5,900 per share. Upon completion of the tender offer and the related transactions, the Company acquired 89% of the outstanding shares. The Company plans to acquire the remaining shares that were not tendered in the tender offer through a share consolidation under Japanese law during the first half of 2019 and take appropriate actions to delist from the Tokyo Stock Exchange. The acquisition will include the range of brands comprising DR.CI:LABO, LABO LABO and GENOMER line of skincare products. The Company expects to treat this transaction as a business combination and will include it in the Consumer segment.

On February 13, 2019, the Company entered into a definitive agreement to acquire Auris Health, Inc. for approximately $3.4 billion in cash. Additional contingent payments of up to$2.35 billion, in the aggregate, may be payable upon reaching certain predetermined milestones. Auris Health is a privately held developer of robotic technologies, initially focused in lung cancer, with an FDA-cleared platform currently used in bronchoscopic diagnostic and therapeutic procedures. The closing is subject to antitrust clearance and other customary closing conditions. The transaction is expected to close by the end of the second quarter of 2019. The Company expects to treat this transaction as a business combination and will include it in the Medical Devices segment.

During 2017 certain businesses were acquired for $35.2 billion in cash and $1.8 billion of liabilities assumed. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2017 acquisitions primarily included: Actelion Ltd, an established leading franchise of differentiated, innovative products for pulmonary arterial hypertension (PAH); Abbott Medical Optics (AMO), a wholly-owned subsidiary of Abbott Laboratories, which included ophthalmic products related to: cataract surgery, laser refractive surgery and consumer eye health; Neuravi Limited, a privately-held medical device company that develops and markets medical devices for neurointerventional therapy; TearScience Inc., a manufacturer of products dedicated to treating meibomian gland dysfunction; Sightbox, Inc., a privately-held company that developed a subscription vision care service that connects consumers with eye care professionals and a supply of contact lenses; Torax Medical, Inc., a privately-held medical device company that manufactures and markets the LINX™ Reflux Management System for the surgical treatment of gastroesophageal reflux disease and Megadyne Medical Products, Inc., a privately-held medical device company that develops, manufactures and markets electrosurgical tools.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $34.4 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately $1.1 billion has been identified as the value of IPR&D, primarily associated with the acquisition of Actelion Ltd. The value of the IPR&D was calculated using cash flow projections discounted for the inherent risk in the projects.

During 2017, the Company completed the acquisition of Actelion Ltd through an all cash tender offer in Switzerland for $280 per share, amounting to $29.6 billion, net of cash acquired. As part of the transaction, immediately prior to the completion of the acquisition, Actelion spun out its drug discovery operations and early-stage clinical development assets into a newly created Swiss biopharmaceutical company, Idorsia Ltd. The shares of Idorsia are listed on the SIX Swiss Exchange (SIX). In 2017 the Company held 9.9% of the shares of Idorsia and had rights to an additional 22.1% of Idorsia equity through a convertible loan with a principal amount of approximately $0.5 billion. As a result of Idorsia raising additional capital in July 2018, the Company currently holds 9.0% of the shares of Idorsia and has rights to an additional 20.8% of Idorsia equity through a convertible loan with a principal amount of approximately $0.5 billion. The convertible loan may be converted into Idorsia shares as follows: (i) up to an aggregate shareholding of 16% of Idorsia shares as a result of certain shareholders holding more than 20% of the issued Idorsia shares, and (ii) up to the balance of the remaining amount within 20 business days of the maturity date of the convertible loan, which has a 10 year term, or if Idorsia undergoes a change of control transaction. The investment in Idorsia was recorded as a cost method investment in Other assets in the Company's consolidated Balance Sheet. The Company also exercised the option acquired on ACT-132577, a product within Idorsia being developed for resistant hypertension currently in phase 2 of clinical development. The Company has also entered into an agreement to provide Idorsia

with a Swiss franc denominated credit facility of approximately $250 million. As of December 30, 2018, Idorsia has not made any draw-downs under the credit facility. Actelion has entered into a transitional services agreement with Idorsia. Actelion has established a leading franchise of differentiated, innovative products for pulmonary arterial hypertension (PAH) that are highly complementary to the existing portfolio of the Company. The addition of Actelion's specialty in-market medicines and late-stage products is consistent with the Company's efforts to grow in attractive and complementary therapeutic areas and serve patients with serious illnesses and significant unmet medical need.

During the fiscal second quarter of 2018, the Company finalized the purchase price allocation to the individual assets acquired and liabilities assumed using the acquisition method. The following table presents the amounts recognized for assets acquired and liabilities assumed as of the acquisition date with adjustments made through the second quarter of 2018:

(Dollars in Millions)	
Cash & Cash equivalents	469
Inventory[(1)]	759
Accounts Receivable	485
Other current assets	93
Property, plant and equipment	104
Goodwill	6,161
Intangible assets	25,010
Deferred Taxes	99
Other non-current assets	19
Total Assets Acquired	33,199
Current liabilities	956
Deferred Taxes	1,776
Other non-current liabilities	413
Total Liabilities Assumed	3,145
Net Assets Acquired	30,054

(1) Includes adjustment of $642 million to write-up the acquired inventory to its estimated fair value.

The adjustments made since the date of acquisition were $0.2 billion to the deferred taxes and $0.4 billion to the current liabilities with the offset to goodwill. The assets acquired are recorded in the Pharmaceutical segment. The acquisition of Actelion resulted in approximately $6.2 billion of goodwill. The goodwill is primarily attributable to synergies expected to arise from the acquisition. The goodwill is not expected to be deductible for tax purposes.

The purchase price allocation to the identifiable intangible assets is as follows:

(Dollars in Millions)		
Intangible assets with definite lives:		
Patents and trademarks*	$	24,230
Total amortizable intangibles		24,230
In-process research and development		780
Total intangible assets	**$**	**25,010**

*Includes $0.4 billion related to VALCHLOR®, one of the acquired products, which was divested in the fiscal second quarter of 2018.

The patents and trademarks acquired are comprised of developed technology with a weighted average life of 9 years and was primarily based on the patent life of the marketed products. The intangible assets with definite lives were assigned asset lives ranging from 4 to 10 years. The in-process research and development intangible assets were valued for technology programs for unapproved products.

The value of the IPR&D was calculated using probability adjusted cash flow projections discounted for the risk inherent in such projects. The discount rate applied was 9%.

The acquisition was accounted for using the acquisition method and, accordingly, the results of operations of Actelion were reported in the Company's financial statements beginning on June 16, 2017, the date of acquisition. For the year ended December 31, 2017, total sales and a net loss for Actelion from the date of acquisition were $1.4 billion and $1.4 billion, respectively.

The following table provides pro forma results of operations for the fiscal year ended December 31, 2017 and January 1, 2017, as if Actelion had been acquired as of January 4, 2016. The pro forma results include the effect of certain purchase accounting adjustments such as the estimated changes in depreciation and amortization expense on the acquired tangible and intangible assets. However, pro forma results do not include any anticipated cost savings or other effects of the planned integration of Actelion. Accordingly, such amounts are not necessarily indicative of the results if the acquisition had occurred on the dates indicated or which may occur in the future.

	Unaudited Pro forma Consolidated Results	
(Dollars in Millions Except Per Share Data)	**2017**	**2016**
Net Sales	77,681	74,339
Net Earnings	1,509	13,916
Diluted Net Earnings per Common Share	0.55	4.99

The Company recorded Actelion acquisition related costs before tax of approximately $0.2 billion and $0.8 billion in 2018 and 2017, respectively, which was recorded in Other (income)/expense and Cost of products sold.

During 2017, the Company acquired Abbott Medical Optics (AMO), a wholly-owned subsidiary of Abbott Laboratories, for $4.3 billion, net of cash acquired. The acquisition included ophthalmic products related to: cataract surgery, laser refractive surgery and consumer eye health. The net purchase price was primarily recorded as amortizable intangible assets for $2.3 billion and goodwill for $1.7 billion. The weighted average life of total amortizable intangibles, the majority being customer relationships, is approximately 14.4 years. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not deductible for tax purposes. The intangible assets and goodwill amounts are based on the final purchase price allocation. The assets acquired were recorded in the Medical Devices segment.

Certain businesses were acquired for $4.5 billion in cash and $0.1 billion of liabilities assumed during 2016. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2016 acquisitions primarily included: Vogue International LLC, a privately-held company focused on the marketing, development and distribution of salon-influenced and nature inspired hair care and other personal products; NeuWave Medical, Inc., a privately-held medical device company that manufactures and markets minimally invasive soft tissue microwave ablation systems; NeoStrata Company, Inc., a global leader in dermocosmetics; and the global rights for the commercialization of RHINOCORT® allergy spray outside the United States.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $4.1 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

The net purchase price for Vogue International LLC of $3.3 billion was primarily recorded as amortizable intangible assets for $2.3 billion and goodwill for $1.1 billion. The weighted average life for the $2.3 billion of total amortizable intangibles is approximately 22 years. The trademark asset values were determined to have definite lives ranging from 10 to 22 years, with the majority being 22 years. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is expected to be deductible for tax purposes. The assets acquired were recorded in the Consumer segment.

In 2012, the Company completed the acquisition of Synthes, Inc. for a purchase price of $20.2 billion in cash and stock. In connection with the acquisition of Synthes, Inc. the Company entered into two accelerated share repurchase (ASR) agreements. In 2013, the Company settled the remaining liabilities under the ASR agreements. While the Company believes that the transactions under each ASR agreement and a series of related internal transactions were consummated in a tax efficient manner in accordance with applicable law, it is possible that the Internal Revenue Service could assert one or more contrary positions to challenge the transactions from a tax perspective. If challenged, an amount up to the total purchase price for the Synthes shares could be treated as subject to applicable U.S. tax at approximately the statutory rate to the Company, plus interest.

With the exception of the Actelion Ltd acquisition, supplemental pro forma information for 2018, 2017 and 2016 in accordance with U.S. GAAP standards related to business combinations, and goodwill and other intangible assets, is not provided, as the impact of the aforementioned acquisitions did not have a material effect on the Company's results of operations, cash flows or financial position.

During 2018, the Company divested the LifeScan Inc business for approximately $2.1 billion and retained certain net liabilities. Other divestitures in 2018 included: NIZORAL®, RoC® and certain non-strategic Pharmaceutical products. In 2018, the pre-tax gains on the divestitures were approximately $1.2 billion. Additionally, in 2018, the Company accepted the binding

offer from Fortive Corporation to acquire its Advanced Sterilization Products (ASP) business for approximately $2.7 billion, subject to customary adjustments. The transaction is expected to close in 2019. As of December 30, 2018, the assets held for sale on the Consolidated Balance Sheet were $0.2 billion of inventory, $0.1 billion of property, plant and equipment and $0.3 billion of goodwill. The Company will retain certain net receivables of approximately $0.1 billion associated with the ASP business.

In 2018, the Company accepted a binding offer to form a strategic collaboration with Jabil Inc., one of the world's leading manufacturing services providers for health care products and technology products. The Company is expanding a 12-year relationship with Jabil to produce a range of products within the Ethicon Endo-Surgery and DePuy Synthes businesses. This transaction includes the transfer of employees and manufacturing sites. As of December 30, 2018, the assets held for sale on the Consolidated Balance Sheet were $0.3 billion of inventory and $0.1 billion of property, plant and equipment, net. For additional details on the global supply chain restructuring see Note 22 to the Consolidated Financial Statements.

During 2017, the Company divestitures primarily included: the Codman Neurosurgery business, to Integra LifeSciences Holdings Corporation and the divestiture of COMPEED® to HRA Pharma. In 2017, the pre-tax gains on the divestitures were approximately $1.3 billion.

During 2016, the Company divestitures included: the controlled substance raw material and active pharmaceutical ingredient (API) business; certain anesthetic products in Europe; and certain non-strategic Consumer brands. In 2016, the pre-tax gains on the divestitures were approximately $0.6 billion.

21. Legal Proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability, intellectual property, commercial, supplier indemnification and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of their business.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of December 30, 2018, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions. The ability to make such estimates and judgments can be affected by various factors, including whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; or there are numerous parties involved.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution of, or increase in accruals for, one or more of these matters in any reporting period may have a material adverse effect on the Company's results of operations and cash flows for that period.

PRODUCT LIABILITY

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While the Company believes it has substantial defenses, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

The most significant of these cases include: the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System; the PINNACLE® Acetabular Cup System; pelvic meshes; RISPERDAL®; XARELTO®; body powders containing talc, primarily JOHNSONS® Baby Powder; INVOKANA®; and ETHICON PHYSIOMESH® Flexible Composite Mesh. As of December 30, 2018, in the United States there were approximately 1,800 plaintiffs with direct claims in pending lawsuits

regarding injuries allegedly due to the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System; 10,500 with respect to the PINNACLE® Acetabular Cup System; 34,800 with respect to pelvic meshes; 13,400 with respect to RISPERDAL®; 25,600 with respect to XARELTO®; 13,000 with respect to body powders containing talc; 1,050 with respect to INVOKANA®; and 2,100 with respect to ETHICON PHYSIOMESH® Flexible Composite Mesh.

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System used in hip replacement surgery. Claims for personal injury have been made against DePuy and Johnson & Johnson. The number of pending lawsuits is expected to fluctuate as certain lawsuits are settled or dismissed and additional lawsuits are filed. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada, Australia, Ireland, Germany and Italy. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR Hip System plaintiffs to establish a program to settle claims with eligible ASR Hip patients in the United States who had surgery to replace their ASR Hips, known as revision surgery, as of August 31, 2013. DePuy reached additional agreements in February 2015 and March 2017, which further extended the settlement program to include ASR Hip patients who had revision surgeries after August 31, 2013 and prior to February 15, 2017. This settlement program has resolved more than 10,000 claims, therefore bringing to resolution significant ASR Hip litigation activity in the United States. However, lawsuits in the United States remain, and the settlement program does not address litigation outside of the United States. In Australia, a class action settlement was reached that resolved the claims of the majority of ASR Hip patients in that country. In Canada, the Company has reached agreements to settle two pending class actions which have been approved by the Québec Superior Court and the Supreme Court of British Columbia. The British Columbia order is currently the subject of an appeal. The Company continues to receive information with respect to potential additional costs associated with this recall on a worldwide basis. The Company has established accruals for the costs associated with the United States settlement program and DePuy ASR™ Hip-related product liability litigation.

Claims for personal injury have also been made against DePuy Orthopaedics, Inc. and Johnson & Johnson (collectively, DePuy) relating to the PINNACLE® Acetabular Cup System used in hip replacement surgery. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Texas. Litigation has also been filed in some state courts and in countries outside of the United States. Several adverse verdicts have been rendered against DePuy, one of which was reversed on appeal and remanded for retrial, the second remains under appeal and the third is pending decision on post-trial motions in the district court. The Company has established an accrual for product liability litigation associated with the PINNACLE® Acetabular Cup System. The Company is negotiating settlements of these cases and the related costs are reflected in the Company’s accruals.

Claims for personal injury have been made against Ethicon, Inc. (Ethicon) and Johnson & Johnson arising out of Ethicon's pelvic mesh devices used to treat stress urinary incontinence and pelvic organ prolapse. The Company continues to receive information with respect to potential costs and additional cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Southern District of West Virginia. The Company has settled or otherwise resolved a majority of the United States cases and the costs associated with these settlements are reflected in the Company's accruals. In addition, class actions and individual personal injury cases or claims have been commenced in various countries outside of the United States, including claims and cases in the United Kingdom, the Netherlands and Belgium, and class actions in Israel, Australia and Canada, seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices. In Australia, a trial of class action issues has been completed and the parties are awaiting a decision. The Company has established accruals with respect to product liability litigation associated with Ethicon's pelvic mesh products.

Following a June 2016 worldwide market withdrawal of ETHICON PHYSIOMESH® Flexible Composite Mesh, claims for personal injury have been made against Ethicon, Inc. and Johnson & Johnson alleging personal injury arising out of the use of this hernia mesh device. Cases filed in federal courts in the United States have been organized as a multi-district litigation (MDL) in the United States District Court for the Northern District of Georgia. A multi county litigation (MCL) has also been formed in New Jersey state court and assigned to Atlantic County for cases pending in New Jersey. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has established accruals with respect to product liability litigation associated with ETHICON PHYSIOMESH® Flexible Composite Mesh.

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and Johnson & Johnson arising out of the use of RISPERDAL®, indicated for the treatment of schizophrenia, acute manic or mixed episodes associated with bipolar I

disorder and irritability associated with autism, and related compounds. Lawsuits have been primarily filed in state courts in Pennsylvania, California, and Missouri. Other actions are pending in various courts in the United States and Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has settled or otherwise resolved many of the United States cases and the costs associated with these settlements are reflected in the Company's accruals.

Claims for personal injury arising out of the use of XARELTO®, an oral anticoagulant, have been made against Janssen Pharmaceuticals, Inc. (JPI); Johnson & Johnson; and JPI's collaboration partner for XARELTO® Bayer AG and certain of its affiliates. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Eastern District of Louisiana. In addition, cases have been filed in state courts across the United States. Many of these cases have been consolidated into a state mass tort litigation in Philadelphia, Pennsylvania; and there are coordinated proceedings in Delaware, California and Missouri. Class action lawsuits also have been filed in Canada. The Company has established an accrual for defense costs only in connection with product liability litigation associated with XARELTO®.

Personal injury claims alleging that talc causes cancer have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSONS® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the District of New Jersey. The Company has successfully defended a number of these cases but there have been verdicts against the Company, including a verdict in July 2018 of $4.7 billion. The Company believes that it has strong grounds on appeal to overturn these verdicts. The Company has established an accrual for defense costs only in connection with product liability litigation associated with body powders containing talc.

In February 2018, a securities class action lawsuit was filed against Johnson & Johnson and certain named officers in the United States District Court for the District of New Jersey, alleging that Johnson & Johnson violated the federal securities laws by failing to adequately disclose the alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S® Baby Powder, and that purchasers of Johnson & Johnson's shares suffered losses as a result. Plaintiffs are seeking damages. In October 2018, a shareholder derivative lawsuit was filed against Johnson & Johnson as the nominal defendant and its current directors as defendants in the United States District Court for the District of New Jersey, alleging a breach of fiduciary duties related to the alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S® Baby Powder, and that Johnson & Johnson has suffered damages as a result of those alleged breaches. Plaintiff is seeking damages and an order for the Company to reform its internal policies and procedures. In January 2019, two ERISA class action lawsuits were filed by participants in the Johnson & Johnson Savings Plan against Johnson & Johnson, its Pension and Benefits Committee, and certain named officers in the United States District Court for the District of New Jersey, alleging that the defendants breached their fiduciary duties by offering Johnson & Johnson stock as a Johnson & Johnson Savings Plan investment option when it was imprudent to do so because of failures to disclose alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S® Baby Powder. Plaintiffs are seeking damages and injunctive relief. Each of these matters will be adjudicated in conjunction with the multi-district litigation referenced in the prior paragraph. In addition, the Company has received preliminary inquiries and subpoenas to produce documents regarding these matters from Senator Murray, a member of the Senate Committee on Health, Education, Labor and Pensions, the Department of Justice and the Securities and Exchange Commission. The Company is cooperating with these government inquiries and will be producing documents in response.

Claims for personal injury have been made against a number of Johnson & Johnson companies, including Janssen Pharmaceuticals, Inc. and Johnson & Johnson, arising out of the use of INVOKANA®, a prescription medication indicated to improve glycemic control in adults with Type 2 diabetes. Lawsuits filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the District of New Jersey. Cases have also been filed in state courts in Pennsylvania, California and New Jersey. Class action lawsuits have been filed in Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has settled or otherwise resolved many of the cases and claims in the United States and the costs associated with these settlements are reflected in the Company's accruals.

INTELLECTUAL PROPERTY

Certain subsidiaries of Johnson & Johnson are subject, from time to time, to legal proceedings and claims related to patent, trademark and other intellectual property matters arising out of their businesses. Many of these matters involve challenges to the coverage and/or validity of the patents on various products and allegations that certain of the Company's products infringe the patents of third parties. Although these subsidiaries believe that they have substantial defenses to these challenges and allegations with respect to all significant patents, there can be no assurance as to the outcome of these matters. A loss in any of these cases could adversely affect the ability of these subsidiaries to sell their products, result in loss of sales due to loss of market exclusivity, require the payment of past damages and future royalties, and may result in a non-cash impairment charge for any associated intangible asset. The most significant of these matters are described below.

Medical Devices

In June 2009, Rembrandt Vision Technologies, L.P. (Rembrandt) filed a patent infringement lawsuit against Johnson & Johnson Vision Care, Inc. (JJVCI) in the United States District Court for the Eastern District of Texas alleging that JJVCI's manufacture and sale of its ACUVUE® ADVANCE and ACUVUE OASYS® Hydrogel Contact Lenses infringed Rembrandt's United States Patent No. 5,712,327 and seeking monetary relief. The case was transferred to the United States District Court for the Middle District of Florida, where a trial in May 2012 resulted in a verdict of non-infringement that was subsequently upheld on appeal. In July 2014, Rembrandt sought a new trial based on alleged new evidence, which the district court denied. In April 2016, the Court of Appeals overturned that ruling and remanded the case to the district court for a new trial. A new trial was held in August 2017, and the jury returned a verdict of non-infringement in favor of JJVCI. Rembrandt has appealed the verdict to the United States Court of Appeals for the Federal Circuit (CAFC). In February 2019, the CAFC affirmed the judgment in favor of JJVCI.

In March 2013, Medinol Ltd. (Medinol) filed a patent infringement lawsuit against Cordis Corporation (Cordis) and Johnson & Johnson in the United States District Court for the Southern District of New York alleging that Cordis's sales of the CYPHER™ and CYPHER SELECT™ stents made in the United States since 2005 willfully infringed four of Medinol's patents directed to the geometry of articulated stents. Medinol is seeking damages and attorneys' fees. Although Johnson & Johnson has since sold Cordis, it has retained liability for this case. After trial in January 2014, the district court dismissed the case, finding Medinol unreasonably delayed bringing its claims (the laches defense). In September 2014, the district court denied a motion by Medinol to vacate the judgment and grant it a new trial. Medinol appealed the decision to the United States Court of Appeals for the Federal Circuit. In March 2017, the United States Supreme Court held that the laches defense is not available in patent cases. In April 2018, the United States Court of Appeals for the Federal Circuit remanded the case back to the district court to reconsider Medinol's motion for a new trial, and briefing in the district court was completed in June 2018.

In November 2016, MedIdea, L.L.C. (MedIdea) filed a patent infringement lawsuit against DePuy Orthopaedics, Inc. in the United States District Court for the Northern District of Illinois alleging infringement by the ATTUNE® Knee System. In April 2017, MedIdea filed an amended complaint adding DePuy Synthes Products, Inc. and DePuy Synthes Sales, Inc. as named defendants. MedIdea alleges infringement of United States Patent Nos. 6,558,426 ('426); 8,273,132 ('132); 8,721,730 ('730) and 9,492,280 ('280) relating to posterior stabilized knee systems. Specifically, MedIdea alleges that the SOFCAM™ Contact feature of the ATTUNE® posterior stabilized knee products infringes the patents-in-suit. MedIdea is seeking monetary damages and injunctive relief. In June 2017, the case was transferred to the United States District Court for the District of Massachusetts. A claim construction hearing was held in October 2018, and a claim construction order was issued in November 2018. In December 2018, MedIdea stipulated to non-infringement of the '132, '730 and '280 patents, based on the district court's claim construction and reserving its right to appeal that construction, leaving only the '426 patent at issue before the district court. In January 2019, the district court stayed the case pending a decision in the Inter Partes Review proceeding on the '426 patent (see below). In December 2017, DePuy Synthes Products, Inc. filed a Petition for Inter Partes Review with the United States Patent and Trademark Office (USPTO), seeking to invalidate the two claims of the '426 patent asserted in the district court litigation, and in June 2018, the USPTO instituted review of those claims. A hearing trial is scheduled for March 2019, and a decision in the proceeding is due by June 2019.

In December 2016, Ethicon Endo-Surgery, Inc. and Ethicon Endo-Surgery, LLC (now known as Ethicon LLC) sued Covidien, Inc. in the United States District Court for the District of Massachusetts seeking a declaration that United States Patent Nos. 6,585,735 (the '735 patent); 7,118,587; 7,473,253; 8,070,748 and 8,241,284 (the '284 patent), are either invalid or not infringed by Ethicon's ENSEAL® X1 Large Jaw Tissue Sealer product. In April 2017, Covidien LP, Covidien Sales LLC, and Covidien AG (collectively, Covidien) answered and counterclaimed, denying the allegations, asserting willful infringement of the '735 patent, the '284 patent and United States Patent Nos. 8,323,310 (the '310 patent); 9,084,608; 9,241,759 (the '759 patent) and 9,113,882, and seeking damages and an injunction. Covidien filed a motion for preliminary injunction, which was denied in

October 2017. The parties have entered joint stipulations such that only the ’735 patent, the ’310 patent and the ’759 patent remain in dispute. Trial is scheduled to begin in September 2019.

In November 2017, Board of Regents, The University of Texas System and Tissuegen, Inc. (collectively, UT) filed a lawsuit in the United States District Court for the Western District of Texas against Ethicon, Inc. and Ethicon US, LLC alleging the manufacture and sale of VICRYL® Plus Antibacterial Sutures, MONOCRYL® Plus Antibacterial Sutures, PDS® Plus Antibacterial Sutures, STRATAFIX® POS® Antibacterial Sutures and STRATAFIX® MONOCRYL®Plus Antibacterial Sutures infringe plaintiffs’ United States Patent Nos. 6,596,296 and 7,033,603 directed to implantable polymer drug releasing biodegradable fibers containing a therapeutic agent. UT is seeking damages and an injunction. In December 2018, Ethicon filed petitions with the USPTO, seeking Inter Partes Review (IPR) of both asserted patents. Those petitions have been stayed by the USPTO pending a decision by the U.S. Court of Appeals for the Federal Circuit in an unrelated case.

Pharmaceutical

In April 2016, MorphoSys AG, a German biotech company, filed a patent infringement lawsuit against Janssen Biotech, Inc. (JBI), Genmab U.S. Inc. and Genmab A/S (collectively, Genmab) in the United States District Court for the District of Delaware. MorphoSys alleged that JBI’s manufacture and sale of DARZALEX® (daratumumab) willfully infringed MorphoSys’ United States Patent Nos. 8,263,746, 9,200,061 and 9,785,590. MorphoSys sought money damages. JBI licenses patents and the commercial rights to DARZALEX® from Genmab. In January 2019, the district court granted summary judgment in JBI and Genmab’s favor, invalidating the asserted claims of the patents-in-suit, and the parties filed a joint stipulation of dismissal of the action.

In August 2016, Sandoz Ltd and Hexal AG (collectively, Sandoz) filed a lawsuit in the English High Court against G.D. Searle LLC, a Pfizer company (Searle) and Janssen Sciences Ireland UC (JSI) alleging that Searle’s supplementary protection certificate SPC/GB07/038 (SPC), which is exclusively licensed to JSI, is invalid and should be revoked. Janssen-Cilag Limited sells PREZISTA® (darunavir) in the United Kingdom pursuant to this license. In October 2016, Searle and JSI counterclaimed against Sandoz for threatened infringement of the SPC based on statements of its plans to launch generic darunavir in the United Kingdom. Sandoz admitted that its generic darunavir product would infringe the SPC if it is found valid. Searle and JSI are seeking an order enjoining Sandoz from marketing its generic darunavir before the expiration of the SPC. Following a trial in April 2017, the court entered a decision holding that the SPC is valid and granting a final injunction. Sandoz has appealed the court’s decision and the injunction is stayed pending the appeal. In January 2018, the court referred the issue on appeal to the Court of Justice for the European Union (CJEU) and stayed the proceedings pending the CJEU’s ruling on the issue.

In April 2018, Acerta Pharma B.V., AstraZeneca UK Ltd and AstraZeneca Pharmaceuticals LP filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Pharmacylics LLC and Abbvie Inc. (collectively, Abbvie), alleging that the manufacture and sale of IMBRUVICA® infringes U.S. Patent No. 7,459,554. Janssen Biotech, Inc., which commercializes IMBRUVICA® jointly with Abbvie, intervened in the action in November 2018. A trial is scheduled to begin in January 2021.

REMICADE® Related Cases

In August 2014, Celltrion Healthcare Co. Ltd. and Celltrion Inc. (collectively, Celltrion) filed an application with the United States Food and Drug Administration (FDA) for approval to make and sell its own infliximab biosimilar. In March 2015, Janssen Biotech, Inc. (JBI) filed a lawsuit in the United States District Court for the District of Massachusetts against Celltrion and Hospira Healthcare Corporation (Hospira), which has exclusive marketing rights for Celltrion’s infliximab biosimilar in the United States, seeking, among other things, a declaratory judgment that their biosimilar product infringes or potentially infringes several JBI patents, including United States Patent No. 6,284,471 relating to REMICADE® (infliximab) (the ’471 patent) and United States Patent No. 7,598,083 (the ’083 patent) directed to the cell culture media used to make Celltrion’s biosimilar. In August 2016, the district court granted both Celltrion’s and Hospira’s motions for summary judgment of invalidity of the ’471 patent. JBI appealed those decisions to the United States Court of Appeals for the Federal Circuit. In January 2018, the Federal Circuit dismissed the appeal as moot based on its affirmance of a decision by the USPTO’s Patent Trial and Appeal Board affirming invalidity of the ’471 patent.

In June 2016, JBI filed two additional patent infringement lawsuits asserting the ’083 patent, one against Celltrion and Hospira in the United States District Court for the District of Massachusetts and the other against HyClone Laboratories, Inc., the manufacturer of the cell culture media that Celltrion uses to make its biosimilar product, in the United States District Court for the District of Utah. On July 30, 2018 the district court granted Celltrion’s motion for summary judgment of non-infringement and entered an order dismissing the ’083 lawsuit against Celltrion and Hospira. JBI appealed to the United States Court of

Appeals for the Federal Circuit. The litigation against HyClone in Utah is stayed pending the outcome of the Massachusetts actions.

The FDA approved the first infliximab biosimilar for sale in the United States in 2016, and a number of such products have been launched.

Litigation Against Filers of Abbreviated New Drug Applications (ANDAs)

The following summarizes lawsuits pending against generic companies that have filed Abbreviated New Drug Applications (ANDAs) with the FDA or undertaken similar regulatory processes outside of the United States, seeking to market generic forms of products sold by various subsidiaries of Johnson & Johnson prior to expiration of the applicable patents covering those products. These ANDAs typically include allegations of non-infringement and invalidity of the applicable patents. In the event the subsidiaries are not successful in an action, or the automatic statutory stay of the ANDAs expires before the United States District Court rulings are obtained, the third-party companies involved would have the ability, upon approval of the FDA, to introduce generic versions of their products to the market, resulting in the potential for substantial market share and revenue losses for the applicable products, and which may result in a non-cash impairment charge in any associated intangible asset. In addition, from time to time, subsidiaries may settle these types of actions and such settlements can involve the introduction of generic versions of the products at issue to the market prior to the expiration of the relevant patents. The Inter Partes Review (IPR) process with the United States Patent and Trademark Office (USPTO), created under the 2011 America Invents Act, is also being used at times by generic companies in conjunction with ANDAs and lawsuits, to challenge the applicable patents.

ZYTIGA®

In July 2015, Janssen Biotech, Inc., Janssen Oncology, Inc. and Janssen Research & Development, LLC (collectively, Janssen) and BTG International Ltd. (BTG) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against a number of generic companies (and certain of their affiliates and/or suppliers) who filed ANDAs seeking approval to market a generic version of ZYTIGA® 250mg before the expiration of United States Patent No. 8,822,438 (the '438 patent). The generic companies include Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC (collectively, Amneal); Apotex Inc. and Apotex Corp. (collectively, Apotex); Citron Pharma LLC (Citron); Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, Dr. Reddy's); Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, Mylan); Par Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc. (collectively, Par); Sun Pharmaceutical Industries Ltd. and Sun Pharmaceuticals Industries, Inc. (collectively, Sun); Teva Pharmaceuticals USA, Inc. (Teva); Wockhardt Bio A.G.; Wockhardt USA LLC and Wockhardt Ltd. (collectively, Wockhardt); West-Ward Pharmaceutical Corp. (West-Ward) and Hikma Pharmaceuticals, LLC (Hikma).

Janssen and BTG also initiated patent infringement lawsuits in the United States District Court for the District of New Jersey against Amerigen Pharmaceuticals Limited (Amerigen) in May 2016, and Glenmark Pharmaceuticals, Inc. (Glenmark) in June 2016, each of whom filed an ANDA seeking approval to market its generic version of ZYTIGA® before the expiration of the '438 patent. These lawsuits have been consolidated with the lawsuit filed in July 2015.

In August 2015, Janssen and BTG filed an additional jurisdictional protective lawsuit against the Mylan defendants in the United States District Court for the Northern District of West Virginia, which has been stayed.

In August 2017, Janssen and BTG initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva, who filed an ANDA seeking approval to market a generic version of ZYTIGA® 500mg before the expiration of the '438 patent. This lawsuit has been consolidated with the lawsuit filed in July 2015.

In February 2018, Janssen and BTG filed a patent infringement lawsuit against MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited (collectively, MSN) in United States District Court for the District of New Jersey based on its ANDA seeking approval for a generic version of ZYTIGA® prior to the expiration of the '438 patent.

In November 2018, Janssen and BTG initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Qilu Pharmaceutical Co., Ltd. and Qilu Pharma, Inc. (collectively, Qilu), who filed an ANDA seeking approval to market a generic version of ZYTIGA® before the expiration of the '438 patent.

In December 2017, Janssen and BTG entered into a settlement agreement with Glenmark. In January 2018, Janssen dismissed its lawsuit against Sun after it withdrew its ANDA. In April 2018, Janssen and BTG entered into a settlement agreement with Apotex.

In October 2018, the United States District Court for the District of New Jersey issued a ruling invalidating all asserted claims of the ’438 patent. The court held that the patent claims would be infringed if the patent were valid. Janssen appealed the court’s decision.

In November 2018, the United States Court of Appeals for the Federal Circuit denied Janssen’s request for an injunction pending appeal. As a result, several generic versions of ZYTIGA® have entered the market. Janssen has appealed the decision of the United States District Court for the District of New Jersey, and the oral argument on the appeal is scheduled for March 2019.

The lawsuits against MSN and Qilu remain pending in the district courts. In each of these lawsuits, Janssen is seeking an order enjoining the defendants from marketing their generic versions of ZYTIGA® before the expiration of the ’438 patent.

Several generic companies including Amerigen, Argentum Pharmaceuticals LLC (Argentum), Mylan, Wockhardt, Actavis, Amneal, Dr. Reddy’s, Sun, Teva, West-Ward and Hikma filed Petitions for Inter Partes Review (IPR) with the USPTO, seeking to invalidate the ’438 patent. In January 2018, the USPTO issued decisions finding the ’438 patent claims unpatentable, and Janssen requested rehearing. In December 2018, the USPTO denied Janssen’s request for rehearing of the IPR decisions. Janssen filed an appeal, which was consolidated with the above-mentioned appeal of the decision of the United States District Court for the District of New Jersey.

In October 2017, Janssen Inc. and Janssen Oncology, Inc. (collectively, Janssen) initiated two Notices of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Teva Canada Limited (Teva) and the Minister of Health in Canada in response to Teva's filing Abbreviated New Drug Submissions (ANDS) and seeking approval to market generic versions of ZYTIGA® 250mg and ZYTIGA® 500mg before the expiration of Canadian Patent No. 2,661,422. In June 2018, the parties entered into a settlement agreement.

In November 2017, Janssen initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex Inc. (Apotex) and the Minister of Health in Canada in response to Apotex’s filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of ZYTIGA® before the expiration of Canadian Patent No. 2,661,422. The federal court of Canada scheduled the Final Hearing for April 2019. Janssen is seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance with respect to Apotex’s ANDS before the expiration of Janssen’s patent.

In January 2019, Janssen initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex and the Minister of Health in Canada in response to Apotex’s filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a film-coated generic version of ZYTIGA® before the expiration of Canadian Patent No. 2,661,422. Janssen is seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance with respect to Apotex’s ANDS before the expiration of Janssen’s patent.

XARELTO®

Beginning in October 2015, Janssen Pharmaceuticals, Inc. (JPI) and Bayer Pharma AG and Bayer Intellectual Property GmbH (collectively, Bayer) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of XARELTO® before expiration of Bayer’s United States Patent Nos. 7,157,456, 7,585,860 and 7,592,339 relating to XARELTO®. JPI is the exclusive sublicensee of the asserted patents. The following generic companies are named defendants: Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. (collectively, Aurobindo); Breckenridge Pharmaceutical, Inc. (Breckenridge); InvaGen Pharmaceuticals Inc. (InvaGen); Micro Labs USA Inc. and Micro Labs Ltd (collectively, Micro); Mylan Pharmaceuticals Inc. (Mylan); Prinston Pharmaceuticals, Inc.; Sigmapharm Laboratories, LLC (Sigmapharm); Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. (collectively, Torrent). Trial concluded in April 2018. In July 2018 the district court entered judgment against Mylan and Sigmapharm, holding that the asserted compound patent is valid and infringed. In September 2018, the district court entered judgment against the remaining defendants. None of the defendants appealed the judgment.

Beginning in April 2017, JPI and Bayer Intellectual Property GmbH and Bayer AG (collectively, Bayer AG) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of XARELTO® before expiration of Bayer AG’s United States Patent No. 9,539,218 (’218) relating to XARELTO®. JPI is the exclusive sublicensee of the asserted patent. The following generic companies are named defendants: Alembic Pharmaceuticals Limited, Alembic Global Holding SA and Alembic Pharmaceuticals, Inc. (Alembic); Aurobindo; Breckenridge; InvaGen; Lupin Limited and Lupin Pharmaceuticals, Inc.

(collectively, Lupin); Micro; Mylan; Sigmapharm; Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals U.S.A., Inc. (collectively, Taro) and Torrent. Lupin counterclaimed for declaratory judgment of noninfringement and invalidity of United States Patent No. 9,415,053, but Lupin dismissed its counterclaims after it was provided a covenant not to sue on that patent. Aurobindo, Taro, Torrent, Micro, Breckenridge, InvaGen, Sigmapharm, Lupin and Alembic have agreed to have their cases stayed and to be bound by the outcome of any final judgment rendered against any of the other defendants. The ’218 cases have been consolidated for discovery and trial, and are currently set for trial in April 2019.

In December 2018, JPI and Bayer AG filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, Teva) who filed an ANDA seeking approval to market a generic version of XARELTO® before expiration of Bayer AG’s ’218 patent.

In each of these lawsuits, JPI is seeking an order enjoining the defendants from marketing their generic versions of XARELTO® before the expiration of the relevant patents.

In May 2018, Mylan filed a Petition for Inter Partes Review with the USPTO, seeking to invalidate the ’218 patent. In December 2018, the USPTO issued a decision denying institution of Mylan’s Petition for Inter Partes Review.

PREZISTA®

In May 2018, Janssen Products, L.P. and Janssen Sciences Ireland UC (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Dr. Reddys Laboratories, Inc., Dr. Reddys Laboratories, Ltd., Laurus Labs, Ltd. and Pharmaq, Inc. (collectively, DRL) who filed an ANDA seeking approval to market generic versions of PREZISTA® before the expiration of United States Patent Nos. 8,518,987; 7,126,015; and 7,595,408. Trial is scheduled to begin in May 2020.

In December 2018, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals Company GmbH, Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals Pvt Ltd., and Raks Pharma Pvt. Ltd. (collectively, Amneal), who filed an ANDA seeking approval to market generic versions of PREZISTA® before the expiration of United States Patent Nos. 8,518,987; 7,126,015; and 7,595,408.

In each of these lawsuits, Janssen is seeking an order enjoining the defendants from marketing its generic versions of PREZISTA® before the expiration of the relevant patents.

INVOKANA®/INVOKAMET®

Beginning in July 2017, Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Cilag GmbH International and Janssen Pharmaceutica NV (collectively, Janssen) and Mitsubishi Tanabe Pharma Corporation (MTPC) filed patent infringement lawsuits in the United States District Court for the District of New Jersey, the United States District Court for the District of Colorado and the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of INVOKANA® and/or INVOKAMET® before expiration of MTPC’s United States Patent Nos. 7,943,582 and/or 8,513,202 relating to INVOKANA® and INVOKAMET®. Janssen is the exclusive licensee of the asserted patents. The following generic companies are named defendants: Apotex Inc. and Apotex Corp. (Apotex); Aurobindo Pharma USA Inc. (Aurobindo); Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc.; InvaGen Pharmaceuticals, Inc. (InvaGen); Prinston Pharmaceuticals Inc.; Dr. Reddy’s Laboratories, Inc. and Dr. Reddy’s Laboratories Ltd; Hetero USA, Inc., Hetero Labs Limited Unit-V and Hetero Labs Limited; MSN Laboratories Private Ltd. and MSN Pharmaceuticals, Inc.; Laurus Labs Ltd.; Indoco Remedies Ltd.; Zydus Pharmaceuticals (USA) Inc. (Zydus); Sandoz, Inc. (Sandoz); Teva Pharmaceuticals USA, Inc.; and Lupin Ltd. and Lupin Pharmaceuticals, Inc.

Beginning in July 2017, Janssen and MTPC filed patent infringement lawsuits in the United States District Court for the District of New Jersey and the United States District Court for the District of Colorado against Sandoz and InvaGen, who filed ANDAs seeking approval to market generic versions of INVOKANA® and/or INVOKAMET® before expiration of MTPC’s United States Patent No. 7,943,788 (the ’788 patent) relating to INVOKANA® and INVOKAMET® and against Zydus, who filed ANDAs seeking approval to market generic versions of INVOKANA® and INVOKAMET® before expiration of the ’788 patent, MTPC's United States Patent No. 8,222,219 relating to INVOKANA® and INVOKAMET® and MTPC’s United States Patent No. 8,785,403 relating to INVOKAMET®, and against Aurobindo, who filed an ANDA seeking approval to market a generic version of INVOKANA® before expiration of the ’788 patent and the ’219 patent relating to INVOKANA®.

Janssen is the exclusive licensee of the asserted patents. In October 2017, the Colorado lawsuits against Sandoz were dismissed. In December 2017, the Delaware lawsuits against Apotex and Teva were dismissed.

In April 2018, Janssen and MTPC filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Prinston, who filed an ANDA seeking approval to market a generic version of INVOKANA® before expiration of the '788 patent relating to INVOKANA®.

In each of these lawsuits, Janssen and MTPC are seeking an order enjoining the defendants from marketing their generic versions of INVOKANA® and/or INVOKAMET® before the expiration of the relevant patents.

OPSUMIT®

In January 2018, Actelion Pharmaceuticals Ltd (Actelion) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Zydus Pharmaceuticals (USA) Inc. (Zydus) and Amneal Pharmaceuticals LLC (Amneal), each of whom filed an ANDA seeking approval to market a generic version of OPSUMIT® before the expiration of United States Patent No. 7,094,781. In the lawsuit, Actelion is seeking an order enjoining Zydus and Amneal from marketing generic versions of OPSUMIT® before the expiration of the patent. In December 2018, the district court entered an order wherein one of the defendants, Amneal, stipulated to infringement. Trial is scheduled to commence in October 2020.

INVEGA SUSTENNA®

In January 2018, Janssen Pharmaceutica NV and Janssen Pharmaceuticals, Inc. (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva Pharmaceuticals USA, Inc. (Teva), who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of United States Patent No. 9,439,906. In the lawsuit, Janssen is seeking an order enjoining Teva from marketing a generic version of INVEGA SUSTENNA® before the expiration of the patent.

In February 2018, Janssen Inc. and Janssen Pharmaceutica NV (collectively, Janssen) initiated a Notices of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Teva Canada Limited (Teva) and the Minister of Health in response to Teva's filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of Canadian Patent Nos. 2,309,629 and 2,655,335. Janssen is seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance with respect to Teva's ANDS before the expiration of these patents. The Final Hearing is scheduled to begin in September 2019.

IMBRUVICA®

Beginning in January 2018, Pharmacyclics LLC (Pharmacyclics) and Janssen Biotech, Inc. (JBI) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of IMBRUVICA® before expiration of Pharmacyclics' United States Patent Nos. 8,008,309, 7,514,444, 8,697,711, 8,735,403, 8,957,079, 9,181,257, 8,754,091, 8,497,277, 8,925,015, 8,476,284, 8,754,090, 8,999,999, 9,125,889, 9,801,881, 9,801,883, 9,814,721, 9,795,604, 9,296,753, 9,540,382, 9,713,617 and/or 9,725,455 relating to IMBRUVICA®. JBI is the exclusive licensee of the asserted patents. The following generic companies are named defendants: Cipla Limited and Cipla USA Inc. (Cipla); Fresenius Kabi USA, LLC, Fresenius Kabi USA, Inc., and Fresenius Kabi Oncology Limited (Fresenius Kabi); Sandoz Inc. and Lek Pharmaceuticals d.d. (Sandoz); Shilpa Medicare Limited (Shilpa); Sun Pharma Global FZE and Sun Pharmaceutical Industries Limited (Sun); Teva Pharmaceuticals USA, Inc. (Teva); and Zydus Worldwide DMCC and Cadila Healthcare Limited (Zydus). Trial is scheduled to begin in October 2020.

In October 2018, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Sun asserting newly issued United States Patent No. 10,004,746.

In each of the lawsuits, Pharmacyclics and JBI are seeking an order enjoining the defendants from marketing generic versions of IMBRUVICA® before the expiration of the relevant patents.

In January 2019, Pharmacyclics and JBI amended their complaints against Fresenius Kabi, Zydus, Teva and Sandoz to further allege infringement of U.S. Patent Nos. 10,106,548, and 10,125,140.

In January 2019, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Zydus, who filed an ANDA seeking approval to market a generic version of IMBRUVICA® 70 mg before the

expiration of U.S. Patent Nos. 514,444, 8,003,309, 8,476,284, 8,497,277, 8,697,711, 8,753,403, 8,754,090, 8,754,091, 8,952,015, 8,957,079, 9,181,257, 9,296,723, 9,340,382, 9,713,617, 9,725,455, 10,106,548, and 10,125,140.

GOVERNMENT PROCEEDINGS

Like other companies in the pharmaceutical and medical devices industries, Johnson & Johnson and certain of its subsidiaries are subject to extensive regulation by national, state and local government agencies in the United States and other countries in which they operate. As a result, interaction with government agencies is ongoing. The most significant litigation brought by, and investigations conducted by, government agencies are listed below. It is possible that criminal charges and substantial fines and/or civil penalties or damages could result from government investigations or litigation.

Average Wholesale Price (AWP) Litigation

Johnson & Johnson and several of its pharmaceutical subsidiaries (the J&J AWP Defendants), along with numerous other pharmaceutical companies, were named as defendants in a series of lawsuits in state and federal courts involving allegations that the pricing and marketing of certain pharmaceutical products amounted to fraudulent and otherwise actionable conduct because, among other things, the companies allegedly reported an inflated Average Wholesale Price (AWP) for the drugs at issue. Payors alleged that they used those AWPs in calculating provider reimbursement levels. The plaintiffs in these cases included three classes of private persons or entities that paid for any portion of the purchase of the drugs at issue based on AWP, and state government entities that made Medicaid payments for the drugs at issue based on AWP. Many of these cases, both federal actions and state actions removed to federal court, were consolidated for pre-trial purposes in a multi-district litigation in the United States District Court for the District of Massachusetts, where all claims against the J&J AWP Defendants were ultimately dismissed. The J&J AWP Defendants also prevailed in a case brought by the Commonwealth of Pennsylvania. Other AWP cases have been resolved through court order or settlement. Two cases remain pending. In a case brought by Illinois, trial has been scheduled for March 2019. In New Jersey, a putative class action based upon AWP allegations is pending against Centocor, Inc. and Ortho Biotech Inc. (both now Janssen Biotech, Inc.), Johnson & Johnson and ALZA Corporation.

Opioids Litigation

Beginning in 2014 and continuing to the present, Johnson & Johnson and Janssen Pharmaceuticals, Inc. (JPI), along with other pharmaceutical companies, have been named in more than 1,600 lawsuits brought by certain state and local governments related to the marketing of opioids, including DURAGESIC®, NUCYNTA® and NUCYNTA® ER. To date, complaints against pharmaceutical companies, including Johnson & Johnson and JPI, have been filed in state court by the state Attorneys General in Arkansas, Florida, Kentucky, Louisiana, Mississippi, Missouri, New Hampshire, New Jersey, New Mexico, Ohio, Oklahoma and South Dakota. Complaints against the manufacturers also have been filed in state or federal court by city, county and local government agencies in the following states: Alabama; Arkansas; California; Connecticut; Florida; Georgia; Illinois; Kentucky; Louisiana; Maine; Maryland; Massachusetts; Mississippi; Missouri; Nevada; New Hampshire; New Jersey; New Mexico; New York; North Carolina; Ohio; Oklahoma; Oregon; Pennsylvania; Rhode Island; South Carolina; South Dakota; Tennessee; Texas; Utah; Virginia; Washington; West Virginia and Wisconsin. The Government of Puerto Rico filed suit in Superior Court of San Juan. In addition, the Province of British Columbia filed suit in Canada. These actions allege a variety of claims related to opioids marketing practices, including false advertising, unfair competition, public nuisance, consumer fraud violations, deceptive acts and practices, false claims and unjust enrichment. The suits generally seek penalties and/or injunctive and monetary relief and, in some of the suits, the plaintiffs are seeking joint and several liability among the defendants. These cases are in early stages of litigation. In October 2017, Johnson & Johnson and JPI were both served with a motion to consolidate 66 pending matters into a federal Multi District Litigation in the Southern District of Ohio. In December 2017, the MDL was approved in the Northern District of Ohio and there are over 1,400 cases that have been transferred to the MDL.

Johnson & Johnson, JPI and other pharmaceutical companies have also received subpoenas or requests for information related to opioids marketing practices from the following state Attorneys General: Alaska, Indiana, Montana, New Hampshire, South Carolina, Tennessee, Texas and Washington. In September 2017, Johnson & Johnson and JPI were contacted by the Texas and Colorado Attorney General's Offices on behalf of approximately 38 states regarding a multi-state Attorney General investigation. The multi-state coalition served Johnson & Johnson and JPI with subpoenas as part of the investigation. Johnson & Johnson and JPI have also received requests for information from the ranking minority member of the United States Senate Committee on Homeland Security and Governmental Affairs regarding the sales, marketing, and educational strategies related to the promotion of opioids use.

Other

In August 2012, DePuy Orthopaedics, Inc., DePuy, Inc. (now known as DePuy Synthes, Inc.), and Johnson & Johnson Services, Inc. (collectively DePuy) received an informal request from the United States Attorney's Office for the District of Massachusetts and the Civil Division of the United States Department of Justice (the United States) for the production of materials relating to the DePuy ASR™ XL Hip device. In July 2014, the United States notified the United States District Court for the District of Massachusetts that it had declined to intervene in a qui tam case filed pursuant to the False Claims Act against the companies. In February 2016, the district court granted the companies' motion to dismiss with prejudice, unsealed the qui tam complaint, and denied the qui tam relators' request for leave to file a further amended complaint. The qui tam relators appealed the case to the United States Court of Appeals for the First Circuit. In July 2017, the First Circuit affirmed the district court's dismissal in part, reversed in part, and affirmed the decision to deny the relators' request to file a third amended complaint. The relators' remaining claims are now pending before the district court, and fact discovery is currently scheduled to close in September 2019. Additionally, DePuy filed a petition for certiorari with the United States Supreme Court, seeking review of the First Circuit's decision. The Supreme Court denied the petition in April 2018.

Since October 2013, a group of State Attorneys General have issued Civil Investigative Demands relating to the development, sales and marketing of several of DePuy Orthopaedics, Inc.'s hip products. In July 2014, the Oregon Department of Justice, which was investigating these matters independently of the other states, announced a settlement of its ASR™ XL Hip device investigation with the State of Oregon. In December 2018, the Company, the remaining states and the District of Columbia agreed to settle all of the investigations, and on January 22, 2019, the states and the Company filed consent judgments resolving the matter.

In October 2012, Johnson & Johnson was contacted by the California Attorney General's office regarding a multi-state Attorney General investigation of the marketing of surgical mesh products for hernia and urogynecological purposes by Johnson & Johnson's subsidiary, Ethicon, Inc. (Ethicon). Johnson & Johnson and Ethicon have since entered into a series of tolling agreements with the 47 states and the District of Columbia participating in the multi-state investigation and have responded to Civil Investigative Demands served by certain of the participating states. The states are seeking monetary and injunctive relief. In May 2016, California and Washington filed civil complaints against Johnson & Johnson, Ethicon and Ethicon US, LLC alleging violations of their consumer protection statutes. Similar complaints were filed against the companies by Kentucky in August 2016 and by Mississippi in October 2017. Johnson & Johnson and Ethicon have entered into a new tolling agreement with the remaining 43 states and the District of Columbia.

In December 2012, Therakos, Inc. (Therakos), formerly a subsidiary of Johnson & Johnson and part of the Ortho-Clinical Diagnostics, Inc. (OCD) franchise, received a letter from the civil division of the United States Attorney's Office for the Eastern District of Pennsylvania informing Therakos that the United States Attorney's Office was investigating the sales and marketing of Uvadex® (methoxsalen) and the Uvar Xts® and Cellex® Systems during the period 2000 to the present. The United States Attorney's Office requested that OCD and Johnson & Johnson preserve documents that could relate to the investigation. Therakos was subsequently acquired by an affiliate of Gores Capital Partners III, L.P. in January 2013, and OCD was divested in June 2014. Following the divestiture of OCD, Johnson & Johnson retains OCD's portion of any liability that may result from the investigation for activity that occurred prior to the sale of Therakos. In March 2014 and March 2016, the United States Attorney's Office requested that Johnson & Johnson produce certain documents, and Johnson & Johnson is cooperating with those requests.

In June 2014, the Mississippi Attorney General filed a complaint in Chancery Court of The First Judicial District of Hinds County, Mississippi against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (now known as Johnson & Johnson Consumer Inc.) (JJCI). The complaint alleges that defendants failed to disclose alleged health risks associated with female consumers' use of talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product divested in 2012) and seeks injunctive and monetary relief. Trial is stayed pending interlocutory appeal of a denial of JJCI's motion for summary judgment.

In March 2016, Janssen Pharmaceuticals, Inc. (JPI) received a Civil Investigative Demand from the United States Attorney's Office for the Southern District of New York related to JPI's contractual relationships with pharmacy benefit managers over the period from January 1, 2006 to the present with regard to certain of JPI's pharmaceutical products. The demand was issued in connection with an investigation under the False Claims Act.

In January 2017, Janssen Pharmaceuticals, Inc. (JPI) received a Civil Investigative Demand from the United States Department of Justice relating to allegations concerning the sales and marketing practices of OLYSIO®. In December 2017, Johnson & Johnson and JPI were served with a whistleblower lawsuit filed in the United States District Court for the Central District of California alleging the off-label promotion of OLYSIO® and additional products, including NUCYNTA®, XARELTO®, LEVAQUIN® and REMICADE®. At this time, the federal and state governments have declined to intervene and the lawsuit, which is related to the Civil Investigative Demand, is being prosecuted by a former company employee. The United States

District Court for the Central District of California dismissed the claim in April 2018. In May 2018, the relator filed a notice of appeal to the United States Court of Appeals for the Ninth Circuit.

In November 2018, a second whistleblower lawsuit was unsealed in the United States District Court for the Central District of California. The lawsuit is substantially similar to the lawsuit under appeal but is brought in the name of the original relator. The federal and state governments have declined to intervene in the second suit at this time.

In February 2017, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts seeking the production of records pertaining to payments to any 501(c)(3) charitable organization that provides financial assistance to Medicare patients. Multiple pharmaceutical companies have publicly reported receipt of subpoenas and ongoing inquiries similar to this one and the one described below. The government has represented that it will not be pursuing action against the company in this matter.

Actelion Pharmaceuticals US, Inc. (Actelion US), received a subpoena in May 2016, with follow-up requests for documents from the United States Attorney's Office for the District of Massachusetts. The subpoena seeks the production of records pertaining to Actelion US' payments to 501(c)(3) charitable organizations that provide financial assistance to Medicare patients. In December 2018, the Company and the United States Department of Justice agreed to a settlement in this matter.

In March 2017, Janssen Biotech, Inc. received a Civil Investigative Demand from the United States Department of Justice regarding a False Claims Act investigation concerning management and advisory services provided to rheumatology and gastroenterology practices that purchased REMICADE® or SIMPONI ARIA®.

In April and September 2017, Johnson & Johnson received subpoenas from the United States Attorney for the District of Massachusetts seeking documents broadly relating to pharmaceutical copayment support programs for DARZALEX®, OLYSIO®, REMICADE®, SIMPONI®, STELARA® and ZYTIGA®. The subpoenas also seek documents relating to Average Manufacturer Price and Best Price reporting to the Center for Medicare and Medicaid Services related to those products, as well as rebate payments to state Medicaid agencies.

In June 2017, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts seeking information regarding practices pertaining to the sterilization of DePuy Synthes, Inc. spinal implants at three hospitals in Boston as well as interactions of employees of Company subsidiaries with physicians at these hospitals. Johnson & Johnson and DePuy Synthes, Inc. have produced documents in response to the subpoena and are fully cooperating with the government's investigation.

In July 2018, Advanced Sterilization Products (ASP) received a Civil Investigative Demand from the United States Department of Justice regarding a False Claims Act investigation concerning the pricing, quality, marketing and promotion of EvoTech ECR, Tyvek Peel Pouches, or Sterrad Cyclesure 24 biological indicators.

In July 2018 the Public Prosecution Service in Rio de Janeiro and representatives from the Brazilian antitrust authority CADE inspected the offices of more than 30 companies including Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda. The authorities appear to be investigating allegations of possible anti-competitive behavior and possible improper payments in the medical device industry. The United States Department of Justice and the United States Securities and Exchange Commission have made additional preliminary inquiries about the inspection in Brazil, and Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda. is cooperating with those requests.

From time to time, the Company has received requests from a variety of United States Congressional Committees to produce information relevant to ongoing congressional inquiries. It is the policy of Johnson & Johnson to cooperate with these inquiries by producing the requested information.

GENERAL LITIGATION

In April 2016, a putative class action was filed against Johnson & Johnson, Johnson & Johnson Sales and Logistics Company, LLC and McNeil PPC, Inc. (now known as Johnson & Johnson Consumer, Inc.) in New Jersey Superior Court, Camden County on behalf of persons who reside in the state of New Jersey who purchased various McNeil over-the-counter products from December 2008 through the present. The complaint alleges violations of the New Jersey Consumer Fraud Act. Following the grant of a motion to dismiss and the filing of an amended complaint, in May 2017, the court denied a motion to dismiss the amended complaint. In December 2018, a settlement was reached and the matter has been dismissed.

In May 2014, two purported class actions were filed in federal court, one in the United States District Court for the Central District of California and one in the United States District Court for the Southern District of Illinois, against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (now known as Johnson & Johnson Consumer Inc.) (JJCI) alleging violations of state consumer fraud statutes based on nondisclosure of alleged health risks associated with talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product no longer sold by JJCI). Both cases seek injunctive relief and monetary damages; neither includes a claim for personal injuries. In October 2016, both cases were transferred to the United States District Court for the District Court of New Jersey as part of a newly created federal multi-district litigation. In July 2017, the district court granted Johnson & Johnson's and JJCI's motion to dismiss one of the cases. In September 2018, the United States Court of Appeals for the Third Circuit affirmed this dismissal. In September 2017, the plaintiff in the second case voluntarily dismissed their complaint. In March 2018, the plaintiff in the second case refiled in Illinois State Court.

In August 2014, United States Customs and Border Protection (US CBP) issued a Penalty Notice against Janssen Ortho LLC (Janssen Ortho), assessing penalties for the alleged improper classification of darunavir ethanolate (the active pharmaceutical ingredient in PREZISTA®) in connection with its importation into the United States. In October 2014, Janssen Ortho submitted a Petition for Relief in response to the Penalty Notice. In May 2015, US CBP issued an Amended Penalty Notice assessing substantial penalties and Janssen Ortho filed a Petition for Relief in July 2015.

In March and April 2015, over 30 putative class action complaints were filed by contact lens patients in a number of courts around the United States against Johnson & Johnson Vision Care, Inc. (JJVCI) and other contact lens manufacturers, distributors, and retailers, alleging vertical and horizontal conspiracies to fix the retail prices of contact lenses. The complaints allege that the manufacturers reached agreements with each other and certain distributors and retailers concerning the prices at which some contact lenses could be sold to consumers. The plaintiffs are seeking damages and injunctive relief. All of the class action cases were transferred to the United States District Court for the Middle District of Florida in June 2015. The plaintiffs filed a consolidated class action complaint in November 2015. In June 2016, the district court denied motions to dismiss filed by JJVCI and other defendants. Discovery is ongoing. In March 2017, the plaintiffs filed a motion for class certification. The district court held a hearing on the motion for class certification in August 2018. In December 2018, the district court granted the plaintiffs motion for class certification.

In August 2015, two third-party payors filed a purported class action in the United States District Court for the Eastern District of Louisiana against Janssen Research & Development, LLC, Janssen Ortho LLC, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Johnson & Johnson (as well as certain Bayer entities), alleging that the defendants improperly marketed and promoted XARELTO® as safer and more effective than less expensive alternative medications while failing to fully disclose its risks. The complaint seeks damages.

In May 2017, Lonza Sales AG (Lonza) filed a Request for Arbitration with the London Court of International Arbitration against Janssen Research & Development, LLC (Janssen R&D). Lonza alleges that Janssen R&D breached a 2005 agreement between the parties by sublicensing certain Lonza technology used in the manufacture of daratumumab without Lonza's consent. Lonza seeks monetary damages. The arbitration hearing was held in September 2018. Post hearing briefing is complete, and the parties are awaiting a decision.

In May 2017, a purported class action was filed in the United States District Court for the Western District of Washington against LifeScan Inc., Johnson & Johnson, other diabetes test strip manufacturers and certain Pharmacy Benefit Managers (PBMs). The complaint alleges that consumers paid inflated prices for glucose monitor test strips as a consequence of undisclosed rebates and other incentives paid by manufacturers to PBMs. The complaint includes RICO, ERISA, and state consumer protection claims. The complaint seeks equitable relief and damages. In November 2017, the case was ordered transferred to United States District Court for the District of New Jersey. The LifeScan business was divested in October 2018 and Johnson & Johnson retained liability that may result from these claims prior to the closing of the divestiture.

In September 2017, Pfizer, Inc. (Pfizer) filed an antitrust complaint against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) in United States District Court for the Eastern District of Pennsylvania. Pfizer alleges that Janssen has violated federal antitrust laws through its contracting strategies for REMICADE®. The complaint seeks damages and injunctive relief.

Beginning in September 2017, multiple purported class actions were filed against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) alleging that Janssen's REMICADE® contracting strategies violated federal and state antitrust and consumer laws and seeking damages and injunctive relief. In November 2017, the cases were consolidated for pre-trial purposes in United States District Court for the Eastern District of Pennsylvania as In re Remicade Antitrust Litigation.

In June 2018, Walgreen Co. and Kroger Co, filed an antitrust complaint against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) in the United States District Court for the Eastern District of Pennsylvania. The complaint alleges that Janssen has violated federal antitrust laws through its contracting strategies for REMICADE®. The complaint seeks damages and injunctive relief.

In October 2017, certain United States service members and their families brought a complaint against a number of pharmaceutical and medical devices companies, including Johnson & Johnson and certain of its subsidiaries, alleging that the defendants violated the United States Anti-Terrorism Act. The complaint alleges that the defendants provided funding for terrorist organizations through their sales practices pursuant to pharmaceutical and medical device contracts with the Iraqi Ministry of Health.

Andover Healthcare, Inc. (Andover) filed a Lanham act case against Johnson & Johnson Consumer Inc. in April 2017 in the United States District Court for the District of Massachusetts. Andover asserts that the claim "not made with natural rubber latex" on COACH® Sports Wrap, BAND-AID® Brand SECURE-FLEX® Wrap and BAND-AID® Brand HURT-FREE® Wrap is false. Andover seeks actual damages and pre-judgment interest thereon, disgorgement of profits, treble damages, attorney's fees and injunctive relief. In December 2018, the parties entered into a settlement agreement.

In October 2018, two separate putative class actions were filed against Actelion Pharmaceutical Ltd., Actelion Pharmaceuticals US, Inc., and Actelion Clinical Research, Inc. (collectively "Actelion") in United States District Court for the District of Maryland and United States District Court for the District of Columbia. The complaints allege that Actelion violated state and federal antitrust and unfair competition laws by allegedly refusing to supply generic pharmaceutical manufacturers with samples of TRACLEER®. TRACLEER® is subject to a Risk Evaluation and Mitigation Strategy, which imposes restrictions on distribution of the product. In January 2019, the plaintiffs dismissed the District of Columbia case and filed a consolidated complaint in federal court in Maryland.

In December 2018, Janssen Biotech, Inc., Janssen Oncology, Inc, Janssen Research & Development, LLC, and Johnson & Johnson (collectively, Janssen) were served with a *qui tam* complaint filed on behalf of the United States, 28 states, and the District of Columbia. The complaint, which was filed in December 2017 in United States District Court for the Northern District of California, alleges that Janssen violated the federal False Claims Act and state law when providing pricing information for ZYTIGA® to the government in connection with direct government sales and government-funded drug reimbursement programs. At this time, the federal and state governments have declined to intervene.

Johnson & Johnson or its subsidiaries are also parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the cost of past and/or future remediation.

22. Restructuring

In the first quarter of 2016, the Company announced restructuring actions in its Medical Devices segment to better serve the needs of patients and customers in today's evolving healthcare marketplace. The Company has undertaken actions to strengthen its go-to-market model, accelerate the pace of innovation, further prioritize key platforms and geographies, and streamline operations while maintaining high quality standards.

In 2018, the Company recorded a pre-tax charge of $462 million, of which $46 million was included in cost of products sold and $227 million was included in other (income) expense. Total project costs of $2.5 billion have been recorded since the restructuring has been announced. This restructuring program was completed in the fiscal fourth quarter of 2018.

On April 17, 2018, the Company announced plans to implement a series of actions across its Global Supply Chain that are intended to focus resources and increase investments in the critical capabilities, technologies and solutions necessary to manufacture and supply its product portfolio, enhance agility and drive growth. The Global Supply Chain actions will include expanding the use of strategic collaborations and bolstering initiatives to reduce complexity, improve cost-competitiveness, enhance capabilities and optimize the Supply Chain network. For additional details on the global supply chain restructuring strategic collaborations see Note 20 to the Consolidated Financial Statements. In 2018, the Company recorded a pre-tax charge of $238 million, of which $59 million was included in cost of products sold and $117 million was included in other (income) expense. See the following table for additional details on the restructuring programs.

In total, the Company expects the Global Supply Chain actions to generate approximately $0.6 billion to $0.8 billion in annual pre-tax cost savings that will be substantially delivered by 2022. The Company expects to record pre-tax restructuring charges of approximately $1.9 billion to $2.3 billion, over the 4 to 5 year period of this activity. These costs are associated with network optimizations, exit costs and accelerated depreciation and amortization.

The following table summarizes the severance charges and the associated spending under these initiatives through the fiscal year ended 2018:985

(Dollars in Millions)		Severance	Asset Write-offs	Other**	Total
Reserve balance, January 3, 2016	$	484	—	17	501
2016 activity		(104)	—	(16)	(120)
Reserve balance, January 1, 2017		380	—	1	381
2017 activity		(151)	—	37	(114)
Reserve balance, December 31, 2017		229	—	38	267
Current year activity:					
Charges		—	132	568	700
Cash payments		(35)	—	(558)	(593)
Settled non cash		—	(132)	—	(132)
Reserve balance, December 30, 2018*	$	194	—	48	242

*Cash outlays for severance are expected to be substantially paid out over the next 2 years in accordance with the Company's plans and local laws.
**Other includes project expense such as salaries for employees supporting the initiative and consulting expenses.

Although the Medical Devices restructuring program was completed in 2018, the Company expects that severance charges will continue beyond that date. The Company continuously reevaluates its severance reserves related to restructuring and the timing of payments has extended due to the planned release of associates regarding several longer-term projects. The Company believes that the existing severance reserves are sufficient to cover the Global Supply Chain plans given the period over which the actions will take place. The Company will continue to assess and make adjustments as necessary if additional amounts become probable and estimable. Approximately 2,375 individuals received separation payments since these restructuring announcements.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Johnson & Johnson

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Johnson & Johnson and its subsidiaries (the "Company") as of December 30, 2018 and December 31, 2017, and the related consolidated statements of earnings, of comprehensive income, of equity, and of cash flows for each of the three years in the period ended December 30, 2018 including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 30, 2018, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 30, 2018 and December 31, 2017**,** and the results of its operations and its cash flows for each of the three years in the period ended December 30, 2018 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 30, 2018, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/PricewaterhouseCoopers LLP

Florham Park, New Jersey
February 20, 2019

We have served as the Company's auditor since at least 1920. We have not been able to determine the specific year we began serving as auditor of the Company.

Management's Report on Internal Control Over Financial Reporting

Under Section 404 of the Sarbanes-Oxley Act of 2002, management is required to assess the effectiveness of the Company's internal control over financial reporting as of the end of each fiscal year and report, based on that assessment, whether the Company's internal control over financial reporting is effective.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is designed to provide reasonable assurance as to the reliability of the Company's financial reporting and the preparation of external financial statements in accordance with generally accepted accounting principles.

Internal controls over financial reporting, no matter how well designed, have inherent limitations. Therefore, internal control over financial reporting determined to be effective can provide only reasonable assurance with respect to financial statement preparation and may not prevent or detect all misstatements. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management has assessed the effectiveness of the Company's internal control over financial reporting as of December 30, 2018. In making this assessment, the Company used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework (2013)." These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. The Company's assessment included extensive documenting, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

Based on the Company's processes and assessment, as described above, management has concluded that, as of December 30, 2018, the Company's internal control over financial reporting was effective.

The effectiveness of the Company's internal control over financial reporting as of December 30, 2018 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which appears herein.

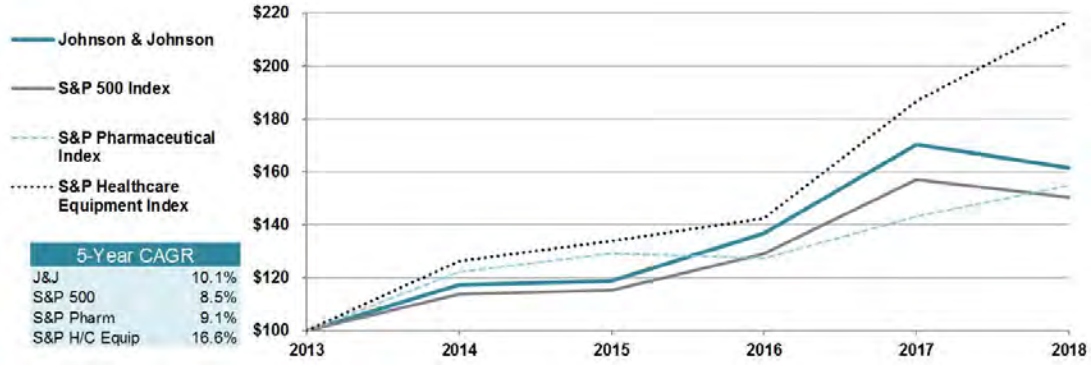
/s/ Alex Gorsky
Alex Gorsky
Chairman, Board of Directors
Chief Executive Officer

/s/ Joseph J. Wolk
Joseph J. Wolk
Executive Vice President, Chief Financial Officer

Shareholder Return Performance Graphs

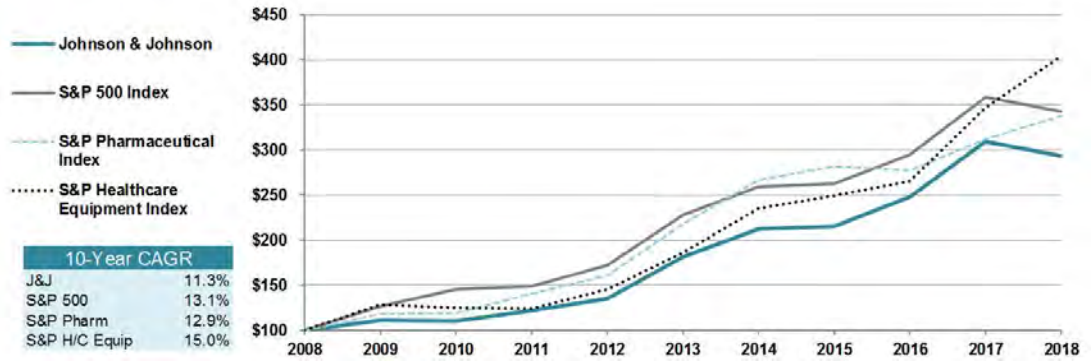
Set forth below are line graphs comparing the cumulative total shareholder return on the Company's Common Stock for periods of five years and ten years ending December 31, 2018, against the cumulative total return of the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index. The graphs and tables assume that $100 was invested on December 31, 2013 and December 31, 2008 in each of the Company's Common Stock, the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index and that all dividends were reinvested.

5 Year Shareholder Return Performance J&J vs. Indices



	2013	2014	2015	2016	2017	2018
Johnson & Johnson	$100.00	$117.34	$118.69	$136.88	$170.29	$161.54
S&P 500 Index	$100.00	$113.68	$115.24	$129.02	$157.17	$150.27
S&P Pharmaceutical Index	$100.00	$122.22	$129.29	$127.27	$143.27	$154.86
S&P Healthcare Equipment Index	$100.00	$126.28	$133.82	$142.50	$186.53	$216.82

10 Year Shareholder Return Performance J&J vs. Indices



	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Johnson & Johnson	$100.00	$111.28	$110.63	$121.57	$134.73	$181.37	$212.81	$215.28	$248.26	$308.85	$292.99
S&P 500 Index	$100.00	$126.45	$145.49	$148.55	$172.31	$228.09	$259.29	$262.86	$294.28	$358.50	$342.75
S&P Pharmaceutical Index	$100.00	$118.62	$119.54	$140.77	$161.07	$217.82	$266.21	$281.62	$277.21	$312.06	$337.32
S&P Healthcare Equipment Index	$100.00	$128.79	$125.30	$124.30	$145.76	$186.12	$235.04	$249.08	$265.23	$347.17	$403.55

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE 990

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures. At the end of the period covered by this Report, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Alex Gorsky, Chairman and Chief Executive Officer, and Joseph J. Wolk, Executive Vice President, Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Gorsky and Wolk concluded that, as of the end of the period covered by this Report, the Company's disclosure controls and procedures were effective

Reports on Internal Control Over Financial Reporting. The information called for by this item is incorporated herein by reference to "Management's Report on Internal Control Over Financial Reporting", and the attestation regarding internal controls over financial reporting included in the "Report of Independent Registered Public Accounting Firm" included in Item 8 of this Report.

Changes in Internal Control Over Financial Reporting. During the fiscal quarter ended December 30, 2018, there were no changes in the Company's internal control over financial reporting identified in connection with the evaluation required under Rules 13a-15 and 15d-15 under the Exchange Act that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

The Company is implementing a multi-year, enterprise-wide initiative to integrate, simplify and standardize processes and systems for the human resources, information technology, procurement, supply chain and finance functions. These are enhancements to support the growth of the Company's financial shared service capabilities and standardize financial systems. This initiative is not in response to any identified deficiency or weakness in the Company's internal control over financial reporting. In response to this initiative, the Company has and will continue to align and streamline the design and operation of its financial control environment.

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information called for by this item is incorporated herein by reference to the discussion of the Audit Committee under the caption "Item 1. Election of Directors - Board Committees"; and the material under the captions "Item 1. Election of Directors" and "Stock Ownership and Section 16 Compliance – Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement; and the material under the caption "Executive Officers of the Registrant" in Part I of this Report.

The Company's Code of Business Conduct, which covers all employees (including the Chief Executive Officer, Chief Financial Officer and Controller), meets the requirements of the SEC rules promulgated under Section 406 of the Sarbanes-Oxley Act of 2002. The Code of Business Conduct is available on the Company's website at *www.jnj.com/code-of-business-conduct*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code of Business Conduct or any waiver of the Code granted to the Chief Executive Officer, the Chief Financial Officer or the Controller will be posted on the Company's website at *www.investor.jnj.com/gov.cfm* within five business days (and retained on the website for at least one year).

In addition, the Company has adopted a Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers. The Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers is available on the Company's website at *www.investor.jnj.com/gov/boardconduct.cfm*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code or any waiver of the Code granted to any member of the Board of Directors or any executive officer will be posted

on the Company's website at *www.investor.jnj.com/gov.cfm* within five business days (and retained on the website for at least one year).

Item 11. EXECUTIVE COMPENSATION

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1. Election of Directors – Director Compensation," and "Item 2. Compensation Committee Report," "Compensation Discussion and Analysis" and "Executive Compensation Tables" in the Proxy Statement.

The material incorporated herein by reference to the material under the caption "Compensation Committee Report" in the Proxy Statement shall be deemed furnished, and not filed, in this Report and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, as a result of this furnishing, except to the extent that the Company specifically incorporates it by reference.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information called for by this item is incorporated herein by reference to the material under the caption "Item 1. Stock Ownership and Section 16 Compliance" in the Proxy Statement; and Note 17 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements in Item 8 of this Report.

Equity Compensation Plan Information

The following table provides certain information as of December 30, 2018 concerning the shares of the Company's Common Stock that may be issued under existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights	Weighted Average Exercise Price of Outstanding Options and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans[2][3]
Equity Compensation Plans Approved by Security Holders[1]	130,605,768	$82.52	351,079,202
Equity Compensation Plans Not Approved by Security Holders	-	-	-
Total	130,605,768	$82.52	351,079,202

(1) Included in this category are the following equity compensation plans which have been approved by the Company's shareholders: 2005 Long-Term Incentive Plan and 2012 Long-Term Incentive Plan.

(2) This column excludes shares reflected under the column "Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights."

(3) The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1. Election of Directors - Director Independence" and "Related Person Transactions" in the Proxy Statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information called for by this item is incorporated herein by reference to the material under the caption "Item 3. Ratification of Appointment of Independent Registered Public Accounting Firm" in the Proxy Statement.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this report:

1. *Financial Statements*

   Consolidated Balance Sheets at end of Fiscal Years 2018 and 2017

   Consolidated Statements of Earnings for Fiscal Years 2018, 2017 and 2016

   Consolidated Statements of Comprehensive Income for Fiscal Years 2018, 2017 and 2016

   Consolidated Statements of Equity for Fiscal Years 2018, 2017 and 2016

   Consolidated Statements of Cash Flows for Fiscal Years 2018, 2017 and 2016

   Notes to Consolidated Financial Statements

   Report of Independent Registered Public Accounting Firm

   All schedules are omitted because they are not applicable or the required information is included in the financial statements or notes.

2. *Exhibits* Required *to be Filed by Item 601 of Regulation S-K*

   The information called for by this item is incorporated herein by reference to the Exhibit Index in this Report.

Item 16. FORM 10-K SUMMARY

Registrants may voluntarily include a summary of information required by Form 10-K under this Item 16. The Company has elected not to include such summary information.

SIGNATURES

Pursuant to the requirements of Section 13 of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 20, 2019

JOHNSON & JOHNSON
(Registrant)

By /s/ A. Gorsky
A. Gorsky, Chairman, Board of Directors,
and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ A. Gorsky A. Gorsky	Chairman, Board of Directors Chief Executive Officer (Principal Executive Officer)	February 20, 2019
/s/ J. J. Wolk J. J. Wolk	Chief Financial Officer (Principal Financial Officer)	February 20, 2019
/s/ R. A. Kapusta R. A. Kapusta	Controller and Chief Accounting Officer (Principal Accounting Officer)	February 20, 2019
/s/ M. C. Beckerle M. C. Beckerle	Director	February 20, 2019
/s/ D. S. Davis D. S. Davis	Director	February 20, 2019
/s/ I. E. L. Davis I. E. L. Davis	Director	February 20, 2019
/s/ J. A. Doudna J. A. Doudna	Director	February 20, 2019

Signature	Title	Date
/s/ M. B. McClellan M. B. McClellan	Director	February 20, 2019
/s/ A. M. Mulcahy A. M. Mulcahy	Director	February 20, 2019
/s/ W. D. Perez W. D. Perez	Director	February 20, 2019
/s/ C. Prince C. Prince	Director	February 20, 2019
/s/ A. E. Washington A. E. Washington	Director	February 20, 2019
/s/ R. A. Williams R. A. Williams	Director	February 20, 2019

EXHIBIT INDEX

Reg. S-K Exhibit Table Item No.	Description of Exhibit
3(i)	Restated Certificate of Incorporation effective February 19, 2016 — Incorporated herein by reference to Exhibit 3(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.
3(ii)	By-Laws of the Company, as amended effective January 26, 2016 — Incorporated herein by reference to Exhibit 3.1 the Registrant's Form 8-K Current Report filed January 26, 2016.
4(a)	Upon the request of the Securities and Exchange Commission, the Registrant will furnish a copy of all instruments defining the rights of holders of long-term debt of the Registrant.
10(a)	2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 4 of the Registrant's S-8 Registration Statement filed with the Commission on May 10, 2005 (file no. 333-124785).*
10(b)	Form of Stock Option Certificate under the 2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 8-K Current Report filed January 13, 2012.*
10(c)	2012 Long-Term Incentive Plan — Incorporated herein by reference to Appendix A of the Registrant's Proxy Statement filed with the Commission on March 15, 2017 .*
10(d)	Form of Stock Option Certificate, Restricted Share Unit Certificate and Performance Share Unit Certificate under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.2, 10.3 and 10.4 of the Registrant's Form 10-Q Quarterly Report filed May 7, 2012.*
10(e)	Global NonQualified Stock Option Award Agreement, Global Restricted Share Unit Award Agreement and Global Performance Share Unit Award Agreement under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.1, 10.2 and 10.3 of the Registrant's Form 10-Q Quarterly Report filed May 1, 2018.*
10(f)	Johnson & Johnson Executive Incentive Plan (as amended) — Incorporated herein by reference to Exhibit 10(f) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 31, 2000.*
10(g)	Domestic Deferred Compensation (Certificate of Extra Compensation) Plan — Incorporated herein by reference to Exhibit 10(g) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2003.*
10(h)	Amendments to the Certificate of Extra Compensation Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(i)	2009 Certificates of Long-Term Performance Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 27, 2009.*
10(j)	Amended and Restated Deferred Fee Plan for Directors (Amended as of January 17, 2012) — Incorporated herein by reference to Exhibit 10(k) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 1, 2012.*
10(k)	The Johnson & Johnson Executive Income Deferral Plan (Amended and Restated Effective January 1, 2010) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*
10(l)	Excess Savings Plan (Effective as of January 1, 1996) — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 29, 1996.*
10(m)	Amendments to the Johnson & Johnson Excess Savings Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(p) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2008.*
10(n)**	Excess Benefit Plan (Supplemental Retirement Plan) — Incorporated herein by reference to Exhibit 10(h) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 1993.*
10(o)	Amendments to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(r) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2008.*
10(p)	Amendment to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies, effective as of January 1, 2015 — Incorporated herein by reference to Exhibit 10(q) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2014.*
10(q)**	Executive Life Plan Agreement — Incorporated herein by reference to Exhibit 10(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 1993.*
10(r)	Executive Life Plan Agreement Closure Letter — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended March 29, 2015.*
10(s)	Employment Agreement for Dr. Paulus Stoffels - Incorporated herein by reference to Exhibit 10.2 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*

Reg. S-K Exhibit Table Item No.	Description of Exhibit
10(t)	Summary of Employment Arrangements for Sandra E. Peterson — Incorporated herein by reference to Exhibit 10(t) of the Registrant's Form 10-K Annual Report for the year ended December 30, 2012.*
10(u)	Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies, Amended and Restated as of October 1, 2014 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 28, 2014.*
10(v)	First Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended June 28, 2015.*
10(w)	Second Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10(x) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.*
21	Subsidiaries - Filed with this document.
23	Consent of Independent Registered Public Accounting Firm — Filed with this document.
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
32.1	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
32.2	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
101	XBRL (Extensible Business Reporting Language) The following materials from this Report for the fiscal year ended December 30, 2018, formatted in Extensive Business Reporting Language (XBRL): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Earnings, (iii) Consolidated Statements of Comprehensive Income, (iv) Consolidated Statements of Equity, (v) Consolidated Statements of Cash Flows, and (vi) Notes to the Consolidated Financial Statements.

* Management contract or compensatory plan.

** Paper filing.

A copy of any of the Exhibits listed above will be provided without charge to any shareholder submitting a written request specifying the desired exhibit(s) to the Secretary at the principal executive offices of the Company. Pursuant to Item 601(b)(4)(iii)(A) of Regulation S-K, the Company has not filed as exhibits to this Form 10-K certain long-term debt instruments, including indentures, under which the total amount of securities authorized does not exceed 10% of the total assets of the Company and its subsidiaries on a consolidated basis. The Company hereby agrees to furnish a copy of any such instrument to the SEC upon request.

Exhibit “J17”

This is Exhibit “J17” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OF THE SECURITIES EXCHANGE ACT OF 1934

☑

For the fiscal year ended December 29, 2019

or

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

☐ **for the transition period from to**

Commission file number 1-3215

JOHNSON & JOHNSON

(Exact name of registrant as specified in its charter)

New Jersey	**22-1024240**
(State of incorporation)	(I.R.S. Employer Identification No.)
One Johnson & Johnson Plaza **New Brunswick, New Jersey**	**08933**
(Address of principal executive offices)	(Zip Code)

One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
(Address of principal executive offices)

Registrant's telephone number, including area code: **(732) 524-0400**

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, Par Value $1.00	JNJ	New York Stock Exchange
0.250% Notes Due January 2022	JNJ	New York Stock Exchange
0.650% Notes Due May 2024	JNJ	New York Stock Exchange
5.50% Notes Due November 2024	JNJ	New York Stock Exchange
1.150% Notes Due November 2028	JNJ	New York Stock Exchange
1.650% Notes Due May 2035	JNJ	New York Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $368 billion.

On February 10, 2020, there were 2,634,721,257 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Parts I and III:	Portions of registrant's proxy statement for its 2019 annual meeting of shareholders filed within 120 days after the close of the registrant's fiscal year (the "Proxy Statement"), are incorporated by reference to this report on Form 10-K (this "Report").

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and Johnson & Johnson's other publicly available documents contain "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Management and representatives of Johnson & Johnson and its subsidiaries (the "Company") also may from time to time make forward-looking statements. Forward-looking statements do not relate strictly to historical or current facts and reflect management's assumptions, views, plans, objectives and projections about the future. Forward-looking statements may be identified by the use of words such as "plans," "expects," "will," "anticipates," "estimates" and other words of similar meaning in conjunction with, among other things: discussions of future operations; expected operating results and financial performance; impact of planned acquisitions and dispositions; the Company's strategy for growth; product development; regulatory approvals; market position and expenditures.

Because forward-looking statements are based on current beliefs, expectations and assumptions regarding future events, they are subject to uncertainties, risks and changes that are difficult to predict and many of which are outside of the Company's control. Investors should realize that if underlying assumptions prove inaccurate, or known or unknown risks or uncertainties materialize, the Company's actual results and financial condition could vary materially from expectations and projections expressed or implied in its forward-looking statements. Investors are therefore cautioned not to rely on these forward-looking statements. Risks and uncertainties include, but are not limited to:

Risks Related to Product Development, Market Success and Competition

- Challenges and uncertainties inherent in innovation and development of new and improved products and technologies on which the Company's continued growth and success depend, including uncertainty of clinical outcomes, additional analysis of existing clinical data, obtaining regulatory approvals, health plan coverage and customer access, and initial and continued commercial success;
- Challenges to the Company's ability to obtain and protect adequate patent and other intellectual property rights for new and existing products and technologies in the United States and other important markets;
- The impact of patent expirations, typically followed by the introduction of competing biosimilars and generics and resulting revenue and market share losses;
- Increasingly aggressive and frequent challenges to the Company's patents by competitors and others seeking to launch competing generic, biosimilar or other products and increased receptivity of courts, the United States Patent and Trademark Office and other decision makers to such challenges, potentially resulting in loss of market exclusivity and rapid decline in sales for the relevant product sooner than expected;
- Competition in research and development of new and improved products, processes and technologies, which can result in product and process obsolescence;
- Competition to reach agreement with third parties for collaboration, licensing, development and marketing agreements for products and technologies;
- Competition based on cost-effectiveness, product performance, technological advances and patents attained by competitors; and
- Allegations that the Company's products infringe the patents and other intellectual property rights of third parties, which could adversely affect the Company's ability to sell the products in question and require the payment of money damages and future royalties.

Risks Related to Product Liability, Litigation and Regulatory Activity

- Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the United States Food and Drug Administration (or international counterparts), declining sales, reputational damage, increased litigation expense and share price impact;
- Impact, including declining sales and reputational damage, of significant litigation or government action adverse to the Company, including product liability claims and allegations related to pharmaceutical marketing practices and contracting strategies;
- Impact of an adverse judgment or settlement and the adequacy of reserves related to legal proceedings, including patent litigation, product liability, personal injury claims, securities class actions, government investigations, employment and other legal proceedings;

- Increased scrutiny of the health care industry by government agencies and state attorneys general resulting in investigations and prosecutions, which carry the risk of significant civil and criminal penalties, including, but not limited to, debarment from government business;
- Failure to meet compliance obligations in the McNEIL-PPC, Inc. Consent Decree or any other compliance agreements with governments or government agencies, which could result in significant sanctions;
- Potential changes to applicable laws and regulations affecting United States and international operations, including relating to: approval of new products; licensing and patent rights; sales and promotion of health care products; access to, and reimbursement and pricing for, health care products and services; environmental protection and sourcing of raw materials;
- Compliance with local regulations and laws that may restrict the Company's ability to manufacture or sell its products in relevant markets including, requirements to comply with medical device reporting regulations and other requirements such as the European Union's Medical Devices Regulation;
- Changes in domestic and international tax laws and regulations, including changes related to The Tax Cuts and Jobs Act in the United States, the Federal Act on Tax Reform and AHV Financing in Switzerland, increasing audit scrutiny by tax authorities around the world and exposures to additional tax liabilities potentially in excess of existing reserves; and
- Issuance of new or revised accounting standards by the Financial Accounting Standards Board and regulations by the Securities and Exchange Commission.

Risks Related to the Company's Strategic Initiatives and Healthcare Market Trends

- Pricing pressures resulting from trends toward health care cost containment, including the continued consolidation among health care providers and other market participants, trends toward managed care, the shift toward governments increasingly becoming the primary payers of health care expenses, significant new entrants to the health care markets seeking to reduce costs and government pressure on companies to voluntarily reduce costs and price increases;
- Restricted spending patterns of individual, institutional and governmental purchasers of health care products and services due to economic hardship and budgetary constraints;
- Challenges to the Company's ability to realize its strategy for growth including through externally sourced innovations, such as development collaborations, strategic acquisitions, licensing and marketing agreements, and the potential heightened costs of any such external arrangements due to competitive pressures;
- The potential that the expected strategic benefits and opportunities from any planned or completed acquisition or divestiture by the Company may not be realized or may take longer to realize than expected; and
- The potential that the expected benefits and opportunities related to past and ongoing restructuring actions may not be realized or may take longer to realize than expected.

Risks Related to Economic Conditions, Financial Markets and Operating Internationally

- Impact of inflation and fluctuations in interest rates and currency exchange rates and the potential effect of such fluctuations on revenues, expenses and resulting margins;
- Potential changes in export/import and trade laws, regulations and policies of the United States and other countries, including any increased trade restrictions or tariffs and potential drug reimportation legislation;
- The impact on international operations from financial instability in international economies, sovereign risk, possible imposition of governmental controls and restrictive economic policies, and unstable international governments and legal systems;
- Changes to global climate, extreme weather and natural disasters that could affect demand for the Company's products and services, cause disruptions in manufacturing and distribution networks, alter the availability of goods and services within the supply chain, and affect the overall design and integrity of the Company's products and operations; and
- The impact of armed conflicts and terrorist attacks in the United States and other parts of the world including social and economic disruptions and instability of financial and other markets.

Risks Related to Supply Chain and Operations

- Difficulties and delays in manufacturing, internally through third party providers or otherwise within the supply chain, that may lead to voluntary or involuntary business interruptions or shutdowns, product shortages, withdrawals or suspensions of products from the market, and potential regulatory action;
- Interruptions and breaches of the Company's information technology systems or those of the Company's vendors which, could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action;

- Reliance on global supply chains and production and distribution processes that are complex and subject to increasing regulatory requirements that may adversely affect supply, sourcing and pricing of materials used in the Company's products; and
- The potential that the expected benefits and opportunities related to restructuring actions contemplated for the global supply chain, including the Company's transaction with Jabil, may not be realized or may take longer to realize than expected, including due to any required approvals from applicable regulatory authorities. Disruptions associated with the announced global supply chain actions may adversely affect supply and sourcing of materials used in the Company's products.

Investors also should carefully read the Risk Factors described in Item 1A of this Annual Report on Form 10-K for a description of certain risks that could, among other things, cause the Company's actual results to differ materially from those expressed in its forward-looking statements. Investors should understand that it is not possible to predict or identify all such factors and should not consider the risks described above and in Item 1A to be a complete statement of all potential risks and uncertainties. The Company does not undertake to publicly update any forward-looking statement that may be made from time to time, whether as a result of new information or future events or developments.

PART I

Item 1. BUSINESS

General

Johnson & Johnson and its subsidiaries (the Company) have approximately 132,200 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. Johnson & Johnson is a holding company, with operating companies conducting business in virtually all countries of the world. The Company's primary focus is products related to human health and well-being. Johnson & Johnson was incorporated in the State of New Jersey in 1887.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Company's three business segments: Consumer, Pharmaceutical and Medical Devices. Within the strategic parameters provided by the Committee, senior management groups at U.S. and international operating companies are each responsible for their own strategic plans and the day-to-day operations of those companies. Each subsidiary within the business segments is, with limited exceptions, managed by residents of the country where located.

Segments of Business

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. Additional information required by this item is incorporated herein by reference to the narrative and tabular descriptions of segments and operating results under: "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition" of this Report; and Note 18 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Consumer

The Consumer segment includes a broad range of products focused on personal healthcare used in the beauty, over-the-counter pharmaceutical, baby care, oral care, women's health and wound care markets. Major brands in Beauty include the AVEENO®; CLEAN & CLEAR®; DR. CI:LABO®; NEUTROGENA® and OGX® product lines. Over-the-counter medicines include the broad family of TYLENOL® acetaminophen products; SUDAFED® cold, flu and allergy products; BENADRYL® and ZYRTEC® allergy products; MOTRIN® IB ibuprofen products; NICORETTE® smoking cessation products outside the U.S.; ZARBEE'S NATURALS® and the PEPCID® line of acid reflux products. Baby Care includes the JOHNSON'S® and AVEENO Baby® line of products. Oral Care includes the LISTERINE® product line. Major brands in Women's Health outside of North America are STAYFREE® and CAREFREE® sanitary pads and o.b.® tampon brands. Wound Care brands include the BAND-AID® Brand Adhesive Bandages and NEOSPORIN® First Aid product lines. These products are marketed to the general public and sold online and to retail outlets and distributors throughout the world.

Pharmaceutical

The Pharmaceutical segment is focused on six therapeutic areas: Immunology (e.g., rheumatoid arthritis, inflammatory bowel disease and psoriasis), Infectious Diseases (e.g., HIV/AIDS), Neuroscience (e.g., mood disorders, neurodegenerative disorders and schizophrenia), Oncology (e.g., prostate cancer and hematologic malignancies), Cardiovascular and Metabolism (e.g., thrombosis and diabetes) and Pulmonary Hypertension (e.g., Pulmonary Arterial Hypertension). Medicines in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. Key products in the Pharmaceutical segment include: REMICADE® (infliximab), a treatment for a number of immune-mediated inflammatory diseases; SIMPONI® (golimumab), a subcutaneous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis and moderately active to severely active ulcerative colitis; SIMPONI ARIA® (golimumab), an intravenous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis and active ankylosing spondylitis; STELARA® (ustekinumab), a treatment for adults and children with moderate to severe plaque psoriasis, for adults with active psoriatic arthritis, for adults with moderately to severely active Crohn's disease and treatment of moderately to severely active ulcerative colitis; TREMFYA® (guselkumab), a treatment for adults with moderate to severe plaque psoriasis; EDURANT® (rilpivirine), PREZISTA® (darunavir) and PREZCOBIX®/REZOLSTA® (darunavir/cobicistat), antiretroviral medicines for the treatment of human immunodeficiency virus (HIV-1) in combination with other antiretroviral products and SYMTUZA® (darunavir/cobicistat/emtricitabine/tenofovir alafenamide), a once-daily single tablet regimen for the treatment of HIV; CONCERTA® (methylphenidate HCl) extended-release tablets CII, a treatment for attention deficit hyperactivity disorder; INVEGA SUSTENNA®/XEPLION® (paliperidone palmitate), for the treatment of schizophrenia and schizoaffective disorder in adults; INVEGA TRINZA®/TREVICTA® (paliperidone palmitate), for the treatment of schizophrenia in patients after they have been adequately treated with INVEGA SUSTENNA® for at least four months; RISPERDAL CONSTA® (risperidone long-acting injection), for the treatment of schizophrenia and the

maintenance treatment of Bipolar 1 Disorder in adults; ZYTIGA® (abiraterone acetate), a treatment for metastatic castration-resistant prostate cancer (mCRPC) and metastatic high-risk castration-sensitive prostate cancer; IMBRUVICA® (ibrutinib), a treatment for certain B-cell malignancies, or blood cancers, chronic graft versus host disease and Waldenström's Macroglobulinemia; DARZALEX® (daratumumab), a treatment for relapsed/refractory multiple myeloma; VELCADE® (bortezomib), a treatment for multiple myeloma mantle cell lymphoma; PROCRIT®/EPREX® (epoetin alfa), a treatment for chemotherapy-induced anemia and patients with chronic kidney disease; XARELTO® (rivaroxaban), an oral anticoagulant for the prevention of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery, to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, and for the treatment and reduction of risk of recurrence of DVT and PE; INVOKANA® (canagliflozin), for the treatment of adults with type 2 diabetes; INVOKAMET®/VOKANAMET® (canagliflozin/metformin HCl), a combination therapy of fixed doses of canagliflozin and metformin hydrochloride for the treatment of adults with type 2 diabetes; and INVOKAMET® XR (canagliflozin/metformin hydrochloride extended-release), a once-daily, fixed-dose combination therapy of canagliflozin and metformin hydrochloride extended-release, for the treatment of adults with type 2 diabetes; OPSUMIT® (macitentan) as monotherapy or in combination, indicated for the long-term treatment of pulmonary arterial hypertension (PAH); UPTRAVI® (selexipag), the only approved oral, selective IP receptor agonist targeting a prostacyclin pathway in PAH. Many of these medicines were developed in collaboration with strategic partners or are licensed from other companies and maintain active lifecycle development programs.

Medical Devices

The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, interventional solutions (cardiovascular and neurovascular) and eye health fields. These products are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics. They include orthopaedic products; general surgery, biosurgical, endomechanical and energy products; electrophysiology products to treat cardiovascular disease; and vision products such as disposable contact lenses and ophthalmic products related to cataract and laser refractive surgery.

Geographic Areas

Johnson & Johnson and its subsidiaries (the Company) have approximately 132,200 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The products made and sold in the international business include many of those described above under "– Segments of Business – Consumer," "– Pharmaceutical" and "– Medical Devices." However, the principal markets, products and methods of distribution in the international business vary with the country and the culture. The products sold in international business include those developed in the U.S. and by subsidiaries abroad.

Investments and activities in some countries outside the U.S. are subject to higher risks than comparable U.S. activities because the investment and commercial climate may be influenced by financial instability in international economies, restrictive economic policies and political and legal system uncertainties.

Raw Materials

Raw materials essential to the Company's business are generally readily available from multiple sources. Where there are exceptions, the temporary unavailability of those raw materials would not likely have a material adverse effect on the financial results of the Company.

Patents

The Company's subsidiaries have made a practice of obtaining patent protection on their products and processes where possible. They own, or are licensed under, a significant number of patents in the U.S. and other countries relating to their products, product uses, formulations and manufacturing processes, which in the aggregate are believed to be of material importance to the Company in the operation of its businesses. The Company's subsidiaries face patent challenges from third parties, including challenges seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. Significant legal proceedings and claims involving the Company's patent and other intellectual property are described in Note 21, "Legal Proceedings—Intellectual Property" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Sales of the Company's largest product, STELARA® (ustekinumab), accounted for approximately 7.8% of the Company's total revenues for fiscal 2019. Accordingly, the patents related to this product are believed to be material to the Company.

There is one set of granted patents related specifically to STELARA®. This set of patents is owned by Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson. These patents are in force in the U.S. and many countries outside the U.S. In the U.S., the latest projected expiration date for patents in this set is 2023 due to patent term extension and adjustment. In most of Europe, the latest projected expiration date for patents in this set is 2024 due to a Supplementary Protection Certificate (patent term extension). In most other countries, the latest projected expiration date is 2021.

In addition to competing in the immunology market with STELARA®, the Company is currently marketing SIMPONI® (golimumab) and SIMPONI ARIA® (golimumab), next generation immunology products. Patents related to these products are in force and the latest projected U.S. expiration date is 2024 due to patent term extension and adjustment. The Company also markets REMICADE® (infliximab) in the immunology market which is the Company's 2nd largest product. Patents on this product have expired and the Food and Drug Administration approved the first infliximab biosimilar for sale in the U.S. in 2016, and a number of such products have been launched since then. For a more extensive description of legal matters regarding the patents related to REMICADE®, see Note 21 "Legal Proceedings - Intellectual Property - Pharmaceutical - REMICADE® Related Cases" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Trademarks

The Company's subsidiaries have made a practice of selling their products under trademarks and of obtaining protection for these trademarks by all available means. These trademarks are protected by registration in the U.S. and other countries where such products are marketed. The Company considers these trademarks in the aggregate to be of material importance in the operation of its businesses.

Seasonality

Worldwide sales do not reflect any significant degree of seasonality; however, spending has been heavier in the fourth quarter of each year than in other quarters. This reflects increased spending decisions, principally for advertising and research and development activity.

Competition

In all of their product lines, the Company's subsidiaries compete with companies both locally and globally. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, both internally and externally sourced, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products, as well as protecting the underlying intellectual property of the Company's product portfolio, is important to the Company's success in all areas of its business. The competitive environment requires substantial investments in continuing research. In addition, the development and maintenance of customer demand for the Company's consumer products involve significant expenditures for advertising and promotion.

Environment

The Company is subject to a variety of U.S. and international environmental protection measures. The Company believes that its operations comply in all material respects with applicable environmental laws and regulations. The Company's compliance with these requirements did not change during the past year, and is not expected to have a material effect upon its capital expenditures, cash flows, earnings or competitive position.

Regulation

The Company's businesses are subject to varying degrees of governmental regulation in the countries in which operations are conducted, and the general trend is toward increasingly stringent regulation and enforcement. We are subject to costly and complex U.S. and foreign laws and governmental regulations and any adverse regulatory action may materially adversely affect our financial condition and business operations. In the U.S., the drug, device and cosmetic industries have long been subject to regulation by various federal and state agencies, primarily as to product safety, efficacy, manufacturing, advertising, labeling and safety reporting. The exercise of broad regulatory powers by the U.S. Food and Drug Administration (the FDA) continues to result in increases in the amounts of testing and documentation required for FDA approval of new drugs and devices and a corresponding increase in the expense of product introduction. Similar trends are also evident in major markets outside of the U.S. The new medical device regulatory framework and the new privacy regulations in Europe and in other countries are examples of such increased regulation.

The regulatory agencies under whose purview the Company operates have administrative powers that may subject it to actions such as product withdrawals, recalls, seizure of products and other civil and criminal sanctions. In some cases, the Company's subsidiaries may deem it advisable to initiate product recalls.

The FDA and regulatory agencies around the globe are also increasing their enforcement activities. If the U.S. FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our drugs or medical devices are ineffective or pose an unreasonable health risk, the U.S. FDA could ban such products, detain or seize adulterated or misbranded products, order a recall, repair, replacement, or refund of such products, refuse to grant pending applications for marketing authorization or require certificates of foreign governments for exports, and/or require us to notify health professionals and others that the products present unreasonable risks of substantial harm to the public health. The U.S. FDA may also assess civil or criminal penalties against us, our officers or employees and impose operating restrictions on a company-wide basis, or enjoin and/or restrain certain conduct resulting in violations of applicable law. The U.S. FDA may also recommend prosecution to the US Department of Justice. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and limit our ability to obtain future clearances or approvals, and could result in a substantial modification to our business practices and operations. Equivalent enforcement mechanisms exist in different countries in which we conduct business.

The costs of human health care have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. In the U.S., attention has been focused by states, regulatory agencies and congress on drug prices and profits and programs that encourage doctors to write prescriptions for particular drugs, or to recommend, use or purchase particular medical devices. There is increased focus on interactions between healthcare companies and health care providers and various transparency laws and regulations require disclosures of financial relationships between companies and health care providers. Payers have become a more potent force in the market place and increased attention is being paid to drug and medical device pricing, appropriate drug and medical device utilization and the quality and costs of health care generally.

U.S. government agencies continue efforts to repeal and modify provisions of the Patient Protection and Affordable Care Act (the ACA) which passed in 2010. For example, federal legislation repealed the ACA's individual mandate tax penalty as well as the tax on generous employer-sponsored healthcare plans; CMS began permitting states to impose work requirements on persons covered by Medicaid expansion plans; certain federal subsidies to insurers have ended; and certain short-term insurance plans not offering the full array of ACA benefits have been allowed to extend in duration. Some of these changes are being challenged in U.S. courts and so their long-term impact remains uncertain. The U.S. government also continues to propose and implement changes to the Medicare Part D benefit including the size of manufacturer discounts in the coverage gap and catastrophic phases of the benefit. This changing federal landscape has both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of federal law, and potential modification or repeal of these laws, will ultimately affect the industry.

In addition, business practices in the health care industry have come under increased scrutiny, particularly in the U.S., by government agencies and state attorneys general, and resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Further, the Company relies on global supply chains, and production and distribution processes, that are complex, are subject to increasing regulatory requirements, and may be faced with unexpected changes such as those resulting from Brexit, that may affect sourcing, supply and pricing of materials used in the Company's products. These processes also are subject to complex and lengthy regulatory approvals.

Available Information

The Company's main corporate website address is *www.jnj.com.* All of the Company's SEC filings are also available on the Company's website at *www.investor.jnj.com/sec.cfm*, as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*.

Investors and the public should note that the Company also announces information at *www.factsaboutourprescriptionopioids.com* and *www.factsabouttalc.com.* We use these websites to communicate with investors and the public about our products, litigation and other matters. It is possible that the information we post to these websites could be deemed to be material information. Therefore, we encourage investors and others interested in the Company to review the information posted to these websites in conjunction with *www.jnj.com,* the Company's SEC filings, press releases, public conference calls and webcasts.

In addition, the Restated Certificate of Incorporation, By-Laws, the written charters of the Audit Committee, the Compensation & Benefits Committee, the Nominating & Corporate Governance Committee, the Regulatory Compliance Committee and the Science, Technology & Sustainability Committee of the Board of Directors and the Company's Principles of Corporate Governance, Code of Business Conduct (for employees), Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers, and other corporate governance materials, are available at *www.investor.jnj.com/gov.cfm* on the Company's website and will be provided without charge to any shareholder submitting a written request, as

provided above. The information on *www.jnj.com*, *www.factsaboutourprescriptionopioids.com* and *www.factsabouttalc.com* is not, and will not be deemed, a part of this Report or incorporated into any other filings the Company makes with the SEC.

Item 1A. RISK FACTORS

The Company faces a number of uncertainties and risks that are difficult to predict and many of which are outside of the Company's control. In addition to the other information in this report and the Company's other filings with the SEC, investors should consider carefully the factors set forth below. Investors should be aware that it is not possible to predict or identify all such factors and that the following is not meant to be a complete discussion of all potential risks or uncertainties. If known or unknown risks or uncertainties materialize, the Company's business, results of operations or financial condition could be adversely affected, potentially in a material way.

Global sales in the Company's pharmaceutical and medical devices segments may be negatively impacted by healthcare reforms and increasing pricing pressures.

Sales of the Company's pharmaceutical and medical device products are significantly affected by reimbursements by third-party payers such as government healthcare programs, private insurance plans and managed care organizations. As part of various efforts to contain healthcare costs, these payers are putting downward pressure on prices at which products will be reimbursed. In the U.S., increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, in part due to continued consolidation among health care providers, could result in further pricing pressures. In addition, increased political scrutiny could result in additional pricing pressures. Outside the U.S., numerous major markets, including the EU and Japan, have pervasive government involvement in funding healthcare and, in that regard, directly or indirectly impose price controls, limit access to, or reimbursement for, the Company's products, or reduce the value of its intellectual property protection.

The Company is subject to significant legal proceedings that can result in significant expenses, fines and reputational damage.

In the ordinary course of business, Johnson & Johnson and its subsidiaries are subject to numerous claims and lawsuits involving various issues such as patent disputes, product liability and claims that their product sales, marketing and pricing practices violate various antitrust, unfair trade practices and/or consumer protection laws. The most significant of these proceedings are described in Note 21, "Legal Proceedings" under Notes to the Consolidated Financial Statements included in Item 8 of this Report. Litigation, in general, and securities, derivative action, class action and multi-district litigation, in particular, can be expensive and disruptive. Some of these matters may include thousands of plaintiffs or may be determined to be class actions and may involve parties seeking large and/or indeterminate amounts, including punitive or exemplary damages, and may remain unresolved for several years. For example, the Company is a defendant in numerous lawsuits arising out of the use of body powders containing talc, primarily JOHNSONS® Baby Powder, and the Company's sale, manufacturing and marketing of opioids. While the Company believes it has substantial defenses in these matters, it is not feasible to predict the ultimate outcome of litigation. The Company could in the future be required to pay significant amounts as a result of settlements or judgments in these matters, potentially in excess of accruals, including matters where the Company could be held jointly and severally liable among other defendants. The resolution of, or increase in accruals for, one or more of these matters in any reporting period could have a material adverse effect on the Company's results of operations and cash flows for that period. Furthermore, as a result of cost and availability factors, effective November 1, 2005, the Company ceased purchasing third-party product liability insurance.

Product reliability, safety and effectiveness concerns can have significant negative impacts on sales and results of operations, lead to litigation and cause reputational damage.

Concerns about product safety, whether raised internally or by litigants, regulators or consumer advocates, and whether or not based on scientific evidence, can result in safety alerts, product recalls, governmental investigations, regulatory action on the part of the FDA (or its counterpart in other countries), private claims and lawsuits, payment of fines and settlements, declining sales and reputational damage. These circumstances can also result in damage to brand image, brand equity and consumer trust in the Company's products. Product recalls have in the past, and could in the future, prompt government investigations and inspections, the shutdown of manufacturing facilities, continued product shortages and related sales declines, significant remediation costs, reputational damage, possible civil penalties and criminal prosecution.

Changes in tax laws or exposures to additional tax liabilities could negatively impact the Company's operating results.

Changes in tax laws or regulations around the world could negatively impact the Company's effective tax rate and results of operations. A change in statutory tax rate in any country would result in the revaluation of the Company's deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is enacted. This change would result in an expense or benefit recorded to the Company's Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries where it operates. Changes to the statutory tax rate may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted.

In fiscal year 2019, Switzerland enacted the Federal Act on Tax Reform and AHV Financing (TRAF) which became effective on January 1, 2020. As of December 29, 2019, certain cantons where the Company operates have not yet enacted portions of the tax reform as stipulated in the Swiss Federal law. These enactments and future possible guidance from the applicable taxing authorities may have a material impact on the Company's operating results.

See Note 8 on income taxes for additional information.

The Company conducts business and files tax returns in numerous countries and is addressing tax audits and disputes with many tax authorities. In connection with the Organization for Economic Cooperation and Development Base Erosion and Profit Shifting (BEPS) project, companies are required to disclose more information to tax authorities on operations around the world, which may lead to greater audit scrutiny of profits earned in other countries. The Company regularly assesses the likely outcomes of its tax audits and disputes to determine the appropriateness of its tax reserves. However, any tax authority could take a position on tax treatment that is contrary to the Company's expectations, which could result in tax liabilities in excess of reserves.

The Company may not be able to successfully secure and defend intellectual property rights essential to the Company's businesses.

The Company owns or licenses a significant number of patents and other proprietary rights, determined by patent offices, courts and lawmakers in various countries, relating to its products and manufacturing processes. These rights are essential to the Company's businesses and materially important to the Company's results of operations. Public policy, both within and outside the U.S., has become increasingly unfavorable toward intellectual property rights. The Company cannot be certain that it will obtain adequate patent protection for new products and technologies in the U.S. and other important markets or that such protections, once granted, will last as long as originally anticipated.

Competitors routinely challenge the validity or extent of the Company's owned or licensed patents and proprietary rights through litigation, interferences, oppositions and other proceedings. These proceedings absorb resources and can be protracted as well as unpredictable. In addition, challenges that the Company's products infringe the patents of third parties could result in the need to pay past damages and future royalties and adversely affect the competitive position and sales of the products in question.

The Company has faced increasing patent challenges from third parties seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the U.S., manufacturers of generic versions of innovative human pharmaceutical products may challenge the validity, or claim non-infringement, of innovator products through the Abbreviated New Drug Application, or ANDA, process with the FDA. The Biologics Price Competition and Innovation Act (BPCIA), enacted in 2010, which created a new regulatory pathway for the approval by the FDA of biosimilar alternatives to innovator-developed biological products, also created mechanisms for biosimilar applicants to challenge the patents on the innovator biologics. The inter partes review (IPR) process with the USPTO, created under the 2011 America Invents Act, is also being used by competitors to challenge patents held by the Company's subsidiaries.

In the event the Company is not successful in defending its patents against such challenges, or upon the "at-risk" launch (despite pending patent infringement litigation) by the generic or biosimilar firm of its product, the Company can lose a major portion of revenues for the referenced product in a very short period of time. Current legal proceedings involving the Company's patents and other intellectual property rights are described in Note 21, "Legal Proceedings—Intellectual Property" of the Notes to the Consolidated Financial Statements included in Item 8 of this Report.

The Company's businesses operate in highly competitive product markets and competitive pressures could adversely affect the Company's earnings.

The Company faces substantial competition in all three operating segments and in all geographic markets. The Company's businesses compete with companies of all sizes on the basis of cost-effectiveness, technological innovations, intellectual property rights, product performance, real or perceived product advantages, pricing and availability and rate of reimbursement. The Company also competes with other market participants in securing rights to acquisitions, collaborations and licensing agreements with third parties. Competition for rights to product candidates and technologies may result in significant investment and acquisition costs and onerous agreement terms for the Company. Competitors' development of more effective or less costly products, and/or their ability to secure patent and other intellectual property rights and successfully market products ahead of the Company, could negatively impact sales of the Company's existing products as well as its ability to bring new products to market despite significant prior investment in the related product development.

For the Company's pharmaceutical businesses, loss of patent exclusivity for a product often is followed by a substantial reduction in sales as competitors gain regulatory approval for generic and other competing products and enter the market. Similar competition can be triggered by the loss of exclusivity for a biological product. For the Company's medical device businesses, technological innovation, product quality, reputation and customer service are especially important to competitiveness. Development by other companies of new or improved products, processes and technologies could threaten to make the Company's products or technologies less desirable, less economical or obsolete. The Company's consumer businesses face intense competition from other branded products and retailers' private-label brands. If the Company fails to sufficiently differentiate and market its brand name consumer products, this could adversely affect revenues and profitability of those products.

Significant challenges or delays in the Company's innovation and development of new products, technologies and indications could have an adverse impact on the Company's long-term success.

The Company's continued growth and success depends on its ability to innovate and develop new and differentiated products and services that address the evolving health care needs of patients, providers and consumers. Development of successful products and technologies is also necessary to offset revenue losses when the Company's existing products lose market share due to various factors such as competition and loss of patent exclusivity. New products introduced within the past five years accounted for approximately 25% of 2019 sales. The Company cannot be certain when or whether it will be able to develop, license or otherwise acquire companies, products and technologies, whether particular product candidates will be granted regulatory approval, and, if approved, whether the products will be commercially successful.

The Company pursues product development through internal research and development as well as through collaborations, acquisitions, joint ventures and licensing or other arrangements with third parties. In all of these contexts, developing new products, particularly pharmaceutical and biotechnology products and medical devices, requires significant investment of resources over many years. Only a very few biopharmaceutical research and development programs result in commercially viable products. The process depends on many factors including the ability to discern patients' and health care providers' future needs; develop promising new compounds, strategies and technologies; achieve successful clinical trial results; secure effective intellectual property protection; obtain regulatory approvals on a timely basis; and, if and when they reach the market, successfully differentiate the Company's products from competing products and approaches to treatment. New products or enhancements to existing products may not be accepted quickly or significantly in the marketplace due to product and price competition, changes in customer preferences or healthcare purchasing patterns, resistance by healthcare providers or uncertainty over third-party reimbursement. Even following initial regulatory approval, the success of a product can be adversely impacted by safety and efficacy findings in larger real world patient populations, as well as market entry of competitive products.

The Company faces increasing regulatory scrutiny which imposes significant compliance costs and exposes the Company to government investigations, legal actions and penalties.

Like other companies in the healthcare industry, the Company is subject to extensive regulation, investigations and legal action, by national, state and local government agencies in the U.S. and other countries in which they operate. Regulatory issues regarding compliance with Good Manufacturing Practices (cGMP) (and comparable quality regulations in foreign countries) by manufacturers of drugs, devices and consumer products can lead to fines and penalties, product recalls, product shortages, interruptions in production, delays in new product approvals and litigation. In addition, the marketing, pricing and sale of the Company's products are subject to regulation, investigations and legal actions including under the Federal Food, Drug, and Cosmetic Act, the Medicaid Rebate Program, federal and state false claims acts, state unfair trade practices acts and consumer protection laws. Increased scrutiny of health care industry business practices in recent years by government agencies and state attorneys general in the U.S., and any resulting investigations and prosecutions, carry risk of significant civil and criminal penalties including, but not limited to, debarment from participation in government healthcare programs. Any such debarment could have a material adverse effect on the Company's business and results of operations. The most significant current investigations and litigation brought by government agencies are described in Note 21, "Legal Proceedings-Government Proceedings" under Notes to the Consolidated Financial Statements included in Item 8 of this Report.

The Company faces a variety of risks associated with conducting business internationally.

The Company's extensive operations and business activity outside the U.S. are accompanied by certain financial, economic and political risks, including those listed below.

Foreign Currency Exchange: In fiscal 2019, approximately 49% of the Company's sales occurred outside of the U.S., with approximately 23% in Europe, 7% in the Western Hemisphere, excluding the U.S., and 19% in the Asia-Pacific and Africa region. Changes in non-U.S. currencies relative to the U.S. dollar impact the Company's revenues and expenses. While the Company uses financial instruments to mitigate the impact of fluctuations in currency exchange rates on its cash flows,

unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the U.S. dollar may result in significant favorable or unfavorable translation effects when the operating results of the Company's non-U.S. business activity are translated into U.S. dollars. 1013

Inflation and Currency Devaluation Risks: The Company faces challenges in maintaining profitability of operations in economies experiencing high inflation rates. The Company has accounted for operations in Argentina (beginning in the fiscal third quarter of 2018) and Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. While the Company strives to maintain profit margins in these areas through cost reduction programs, productivity improvements and periodic price increases, it might experience operating losses as a result of continued inflation. In addition, the impact of currency devaluations in countries experiencing high inflation rates or significant currency exchange fluctuations could negatively impact the Company's operating results.

Illegal Importation of Pharmaceutical Products: The illegal importation of pharmaceutical products from countries where government price controls or other market dynamics result in lower prices may adversely affect the Company's sales and profitability in the U.S. and other countries in which the Company operates. With the exception of limited quantities of prescription drugs for personal use, foreign imports of pharmaceutical products are illegal under current U.S. law. However, the volume of illegal imports continues to rise as the ability of patients and other customers to obtain the lower-priced imports has grown significantly.

Anti-Bribery and Other Regulations: The Company is subject to various federal and foreign laws that govern its international business practices with respect to payments to government officials. Those laws include the U.S. Foreign Corrupt Practices Act (FCPA), which prohibits U.S. publicly traded companies from promising, offering, or giving anything of value to foreign officials with the corrupt intent of influencing the foreign official for the purpose of helping the Company obtain or retain business or gain any improper advantage. The Company's business is heavily regulated and therefore involves significant interaction with foreign officials. Also, in many countries outside the U.S., the health care providers who prescribe human pharmaceuticals are employed by the government and the purchasers of human pharmaceuticals are government entities; therefore, the Company's interactions with these prescribers and purchasers are subject to regulation under the FCPA. In addition to the U.S. application and enforcement of the FCPA, various jurisdictions in which the Company operates have laws and regulations, including the U.K Bribery Act 2010, aimed at preventing and penalizing corrupt and anticompetitive behavior. Enforcement activities under these laws could subject the Company to additional administrative and legal proceedings and actions, which could include claims for civil penalties, criminal sanctions, and administrative remedies, including exclusion from health care programs.

Other Legal, Social and Political Risks. Other risks inherent in conducting business globally include:

- protective economic policies taken by governments such as trade protection measures and import/export licensing requirements;
- compliance with local regulations and laws including, in some countries, regulatory requirements restricting the Company's ability to manufacture or sell its products in the relevant market;
- diminished protection of intellectual property and contractual rights in certain jurisdictions;
- potential nationalization or expropriation of the Company's foreign assets; and
- disruptions to markets due to war, armed conflict, terrorism, social upheavals or pandemics.

Interruptions and delays in manufacturing operations could adversely affect the Company's business, sales and reputation.

The Company's manufacture of products requires the timely delivery of sufficient amounts of complex, high-quality components and materials. The Company's subsidiaries operate 97 manufacturing facilities as well as sourcing from hundreds of suppliers around the world. The Company has in the past, and may in the future, face unanticipated interruptions and delays in manufacturing through its internal or external supply chain. Manufacturing disruptions can occur for many reasons including regulatory action, production quality deviations or safety issues, labor disputes, site-specific incidents (such as fires), natural disasters such as hurricanes and other severe weather events, raw material shortages, political unrest and terrorist attacks. Such delays and difficulties in manufacturing can result in product shortages, declines in sales and reputational impact as well as significant remediation and related costs associated with addressing the shortage.

The Company relies on third parties to manufacture certain of our products. Any failure by or loss of a third party manufacturer could result in delays and increased costs, which may adversely affect our business.

The Company relies on third parties to manufacture certain of our products. We depend on these third party manufacturers to allocate to us a portion of their manufacturing capacity sufficient to meet our needs, to produce products of acceptable quality

and at acceptable manufacturing yields and to deliver those products to us on a timely basis and at acceptable prices. However, we cannot guarantee that these third party manufacturers will be able to meet our near-term or long-term manufacturing requirements, which could result in lost sales and have an adverse effect on our business.

Other risks associated with our reliance on third parties to manufacture these products include, reliance on the third party for regulatory compliance and quality assurance, misappropriation of the Company's intellectual property, limited ability to manage our inventory, possible breach of the manufacturing agreement by the third party and the possible termination or nonrenewal of the manufacturing agreement by the third party at a time that is costly or inconvenient for us. Moreover, if any of our third party manufacturers suffer any damage to facilities, lose benefits under material agreements, experience power outages, encounter financial difficulties, are unable to secure necessary raw materials from their suppliers or suffer any other reduction in efficiency, the Company may experience significant business disruption. In the event of any such disruption, the Company would need to seek and source other qualified third party manufacturers, likely resulting in further delays and increased costs which could affect our business adversely.

Counterfeit versions of our products could harm our patients and have a negative impact on our revenues, earnings, reputation and business.

Our industry continues to be challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Third parties may illegally distribute and sell counterfeit versions of our products, which do not meet our rigorous manufacturing and testing standards. To distributors and patients, counterfeit products may be visually indistinguishable from the authentic version. Counterfeit medicines pose a risk to patient health and safety because of the conditions under which they are manufactured-often in unregulated, unlicensed, uninspected and unsanitary sites-as well as the lack of regulation of their contents.

The industry's failure to mitigate the threat of counterfeit medicines could adversely impact our business and reputation by impacting patient confidence in our authentic products, potentially resulting in lost sales, product recalls, and an increased threat of litigation. In addition, diversion of our products from their authorized market into other channels may result in reduced revenues and negatively affect our profitability.

An information security incident, including a cybersecurity breach, could have a negative impact to the Company's business or reputation

To meet business objectives, the Company relies on both internal information technology (IT) systems and networks, and those of third parties and their vendors, to process and store sensitive data, including confidential research, business plans, financial information, intellectual property, and personal data that may be subject to legal protection. The extensive information security and cybersecurity threats, which affect companies globally, pose a risk to the security and availability of these IT systems and networks, and the confidentiality, integrity, and availability of the Company's sensitive data. The Company continually assesses these threats and makes investments to increase internal protection, detection, and response capabilities, as well as ensure the Company's third party providers have required capabilities and controls, to address this risk. To date, the Company has not experienced any material impact to the business or operations resulting from information or cybersecurity attacks; however, because of the frequently changing attack techniques, along with the increased volume and sophistication of the attacks, there is the potential for the Company to be adversely impacted. This impact could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action. The Company maintains cybersecurity insurance in the event of an information security or cyber incident, however, the coverage may not be sufficient to cover all financial losses.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

The Company's subsidiaries operate 97 manufacturing facilities occupying approximately 15.2 million square feet of floor space. The manufacturing facilities are used by the industry segments of the Company's business approximately as follows:

Segment	Square Feet (in thousands)
Consumer	4,832
Pharmaceutical	5,496
Medical Devices	4,825
Worldwide Total	15,153

Within the U.S., five facilities are used by the Consumer segment, five by the Pharmaceutical segment and 22 by the Medical Devices segment. Outside of the U.S., 25 facilities are used by the Consumer segment, 14 by the Pharmaceutical segment and 26 by the Medical Devices segment.

The locations of the manufacturing facilities by major geographic areas of the world are as follows:

Geographic Area	Number of Facilities	Square Feet (in thousands)
United States	32	4,480
Europe	27	5,939
Western Hemisphere, excluding U.S.	11	1,833
Africa, Asia and Pacific	27	2,901
Worldwide Total	97	15,153

In addition to the manufacturing facilities discussed above, the Company maintains numerous office and warehouse facilities throughout the world. Research facilities are also discussed in Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition of this Report.

The Company's subsidiaries generally seek to own, rather than lease, their manufacturing facilities, although some, principally in non-U.S. locations, are leased. Office and warehouse facilities are often leased. The Company also engages contract manufacturers.

The Company is committed to maintaining all of its properties in good operating condition.

McNEIL-PPC, Inc. (now Johnson & Johnson Consumer Inc.) (McNEIL-PPC) continues to operate under a consent decree, signed in 2011 with the FDA, which governs certain McNeil Consumer Healthcare manufacturing operations, and requires McNEIL-PPC to remediate the facilities it operates in Lancaster, Pennsylvania, Fort Washington, Pennsylvania, and Las Piedras, Puerto Rico (the "Consent Decree"). Following FDA inspections McNEIL-PPC received notifications from the FDA that all three manufacturing facilities are in conformity with applicable laws and regulations, and commercial production has restarted in 2015.

Under the Consent Decree, after receiving notice from the FDA of being in compliance with applicable laws and regulations, each of the three facilities is subject to a five-year audit period by a third-party cGMP expert. Thus, a third-party expert will continue to reassess the sites at various times until at least 2020.

For information regarding lease obligations, see Note 16 "Lease Commitments" of the Notes to Consolidated Financial Statements included in Item 8 of this Report. Segment information on additions to property, plant and equipment is contained in Note 18 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 3. LEGAL PROCEEDINGS

The information called for by this item is incorporated herein by reference to the information set forth in Note 21 "Legal Proceedings" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

In addition, Johnson & Johnson and its subsidiaries are also parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the cost of past and/or future remediation.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

EXECUTIVE OFFICERS OF THE REGISTRANT

Listed below are the executive officers of the Company. There are no family relationships between any of the executive officers, and there is no arrangement or understanding between any executive officer and any other person pursuant to which the executive officer was selected. At the annual meeting of the Board of Directors, the executive officers are elected by the Board to hold office for one year and until their respective successors are elected and qualified, or until earlier resignation or removal.

Information with regard to the directors of the Company, including information for Alex Gorsky, who is also an executive officer, is incorporated herein by reference to the material captioned "Item 1. Election of Directors" in the Proxy Statement.

Name	Age	Position
Joaquin Duato	57	Vice Chairman, Executive Committee[a]
Peter M. Fasolo, Ph.D.	57	Member, Executive Committee; Executive Vice President, Chief Human Resources Officer[b]
Alex Gorsky	59	Chairman, Board of Directors; Chairman, Executive Committee; Chief Executive Officer
Ashley McEvoy	49	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Medical Devices[c]
Thibaut Mongon	50	Member, Executive Committee, Executive Vice President, Worldwide Chairman, Consumer[d]
Michael E. Sneed	60	Member, Executive Committee; Executive Vice President, Global Corporate Affairs and Chief Communication Officer[e]
Paulus Stoffels, M.D.	57	Vice Chairman, Executive Committee; Chief Scientific Officer[f]
Jennifer L. Taubert	56	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Pharmaceuticals[g]
Michael H. Ullmann	61	Member, Executive Committee; Executive Vice President, General Counsel[h]
Kathryn E. Wengel	54	Member, Executive Committee; Executive Vice President, Chief Global Supply Chain Officer[i]
Joseph J. Wolk	53	Member, Executive Committee; Executive Vice President, Chief Financial Officer[j]

(a) Mr. J. Duato joined the Company in 1989 with Janssen-Farmaceutica S.A. (Spain), a subsidiary of the Company, and held executive positions of increasing responsibility in the Pharmaceutical sector. In 2009, he was named Company Group Chairman, Pharmaceuticals, and in 2011, he was named Worldwide Chairman, Pharmaceuticals. In 2016, Mr. Duato became a member of the Executive Committee and was named Executive Vice President, Worldwide Chairman, Pharmaceuticals. In July 2018, Mr. Duato was promoted to Vice Chairman of the Executive Committee, with responsibility for the company's Pharmaceutical and Consumer sectors, supply chain, information technology, global services and the Health & Wellness groups.

(b) Dr. P. M. Fasolo joined the Company in 2004 as Vice President, Worldwide Human Resources for Cordis Corporation, a subsidiary of the Company, and was subsequently named Vice President, Global Talent Management for the Company. He left Johnson & Johnson in 2007 to join Kohlberg Kravis Roberts & Co. as Chief Talent Officer. Dr. Fasolo returned to the Company in 2010 as the Vice President, Global Human Resources, and in 2011, he became a member of the Executive Committee. In April 2016, he was named Executive Vice President, Chief Human Resources Officer. Dr. Fasolo has responsibility for global talent, recruiting, diversity, compensation, benefits, employee relations and all aspects of the human resources agenda for the Company.

(c) Ms. A. McEvoy joined the Company in 1996 as Assistant Brand Manager of McNeil Consumer Health, a subsidiary of the Company, advancing through positions of increasing responsibilities until she was appointed Company Group Chairman, Vision Care in 2012, followed by Company Group Chairman, Consumer Medical Devices in 2014. In July 2018, Ms. McEvoy was promoted to Executive Vice President, Worldwide Chairman, Medical Devices, and became a member of the Executive Committee. Ms. McEvoy has responsibility for the surgery, orthopaedics, interventional solutions and eye health businesses across Ethicon, DePuy Synthes, Biosense Webster and Johnson & Johnson Vision.

(d) Mr. T. Mongon joined the Company in 2000 as Director of Marketing for the Vision Care group in France and subsequently held general management positions as Country Manager France, Belgium and North Africa, Managing Director Latin America, and President Asia-Pacific. Mr. Mongon transitioned to the Pharmaceutical sector in 2012 as the Global Commercial Strategy Leader for the Neuroscience therapeutic area, before joining the consumer sector as Company Group Chairman Asia-Pacific. In 2019, he was promoted to Executive Vice President and Worldwide Chairman, Consumer, and became a member of the Executive Committee. Mr. Mongon has responsibility for the global development of Johnson & Johnson's health and wellness products and solutions in beauty, OTC, oral care, baby care, women's health, and wound care.

(e) Mr. M. E. Sneed joined the Company in 1983 as Marketing Assistant for Personal Products Company, a subsidiary of the Company, and gained increased responsibilities in executive positions across the global enterprise. In 2004, Mr. Sneed was appointed Company Group Chairman, Consumer North America, followed by Company Group Chairman, Vision Care Franchise in 2007. In 2012, he became the Vice President, Global Corporate Affairs and Chief Communications Officer. Mr. Sneed was appointed Executive Vice President, Global Corporate Affairs and Chief Communications Officer in January 2018, and became a member of the Executive Committee in July 2018, leading the Company's global marketing, communication, design and philanthropy functions.

(f) Dr. P. Stoffels rejoined the Company in 2002 with the acquisition of Tibotec Virco NV, where he was Chief Executive Officer of Virco NV and Chairman of Tibotec NV. In 2005, he was appointed Company Group Chairman, Global Virology. In 2006, he assumed the role of Company Group Chairman, Pharmaceuticals. Dr. Stoffels was appointed Global Head, Research & Development, Pharmaceuticals in 2009, and in 2011, became Worldwide Chairman, Pharmaceuticals. In 2012, Dr. Stoffels was appointed Chief Scientific Officer, and became a member of the Executive Committee. In 2016, Dr. Stoffels was named Executive Vice President, Chief Scientific Officer. In 2018, Dr. Stoffels was promoted to Vice Chairman of the Executive Committee, Chief Scientific Officer. He is responsible for the Company's innovation agenda across the Pharmaceutical, Medical Devices and Consumer sectors, product safety strategy, and the Company's global public health strategy.

(g) Ms. J. L. Taubert joined the Company in 2005 as Worldwide Vice President at Johnson & Johnson Pharmaceutical Services, a subsidiary of the Company. She held several executive positions of increasing responsibility in the Pharmaceutical sector until 2012 when she was appointed Company Group Chairman, North America Pharmaceuticals, and in 2015 became Company Group Chairman, The Americas, Pharmaceuticals. In July 2018, Ms. Taubert was promoted to Executive Vice President, Worldwide Chairman, Pharmaceuticals, and became a member of the Executive Committee. Ms. Taubert has responsibility for the Immunology, Infectious Diseases, Neuroscience, Oncology, Cardiovascular and Metabolism, and Pulmonary Hypertension businesses throughout Janssen.

(h) Mr. M. H. Ullmann joined the Company in 1989 as a corporate attorney in the Law Department. He was appointed Corporate Secretary in 1999 and served in that role until 2006. During that time, he also held various management positions in the Law Department. In 2006, he was named General Counsel, Medical Devices and Diagnostics and was appointed Vice President, General Counsel and became a member of the Executive Committee in 2012. In April 2016, Mr. Ullmann was named Executive Vice President, General Counsel. Mr. Ullmann has worldwide responsibility for legal, government affairs & policy, global security, aviation and health care compliance & privacy.

(i) Ms. K. E. Wengel joined the Company in 1988 as Project Engineer and Engineering Supervisor at Janssen, a subsidiary of the Company. During her tenure with the Company, she has held a variety of strategic leadership and executive positions across the global enterprise, in roles within operations, quality, engineering, new products, information technology, and other technical and business functions. In 2010, Ms. Wengel became the first Chief Quality Officer of the Company. In 2014, she was promoted to Vice President, Johnson & Johnson Supply Chain. In July 2018, she was promoted to Executive Vice President, Chief Global Supply Chain Officer, and became a member of the Executive Committee.

(j) Mr. J. J. Wolk joined the Company in 1998 as Finance Manager, Business Development for Ortho-McNeil, a subsidiary of the Company, and through the years held a variety of senior leadership roles in several segments and functions across the Company's subsidiaries, in Pharmaceuticals, Medical Devices and Supply Chain. From 2014 to 2016, he served as Vice President, Finance and Chief Financial Officer of the Janssen Pharmaceutical Companies of Johnson & Johnson. In 2016, Mr. Wolk became the Vice President, Investor Relations. In July 2018, he was appointed Executive Vice President, Chief Financial Officer and became a member of the Executive Committee. Mr. Wolk plays a strategic role in the overall management of the Company, and leads the development and execution of the Company's global long-term financial strategy.

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

As of February 12, 2020, there were 135,953 record holders of common stock of the Company. Additional information called for by this item is incorporated herein by reference to the following sections of this Report: Note 17 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements included in Item 8; and Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters – Equity Compensation Plan Information".

Issuer Purchases of Equity Securities

On December 17, 2018, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's Common Stock. Share repurchases take place from time to time on the open market or through privately negotiated transactions. The repurchase program was completed in the fiscal third quarter of 2019.

The following table provides information with respect to common stock purchases by the Company during the fiscal fourth quarter of 2019. Common stock purchases on the open market are made as part of a systematic plan to meet the needs of the Company's compensation programs. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal fourth quarter.

Fiscal Period	Total Number of Shares Purchased[1]	Avg. Price Paid Per Share	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs[2]	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
September 30, 2019 through October 27, 2019	—	$ —	-	-
October 28, 2019 through November 24, 2019	734,409	130.60	-	-
November 25, 2019 through December 29, 2019	2,327,205	141.91	-	-
Total	3,061,614			

(1) During the fiscal fourth quarter of 2019, the Company repurchased an aggregate of 3,061,614 shares of Johnson & Johnson Common Stock in open-market transactions, of which 3,061,614 shares were purchased in open-market transactions as part of a systematic plan to meet the needs of the Company's compensation programs.

(2) As of September 29, 2019, the share repurchase program was completed with an aggregate of 37,181,268 shares purchased for a total of $5.0 billion since the inception of the repurchase program announced on December 17, 2018.

Item 6. SELECTED FINANCIAL DATA

Summary of Operations and Statistical Data 2009-2019

(Dollars in Millions Except Per Share Amounts)	2019	2018	2017	2016	2015	2014	2013	2012	2011	2010	2009
Sales to customers — U.S.	$42,097	41,884	39,863	37,811	35,687	34,782	31,910	29,830	28,908	29,450	30,889
Sales to customers — International	39,962	39,697	36,587	34,079	34,387	39,549	39,402	37,394	36,122	32,137	31,008
Total sales	82,059	81,581	76,450	71,890	70,074	74,331	71,312	67,224	65,030	61,587	61,897
Cost of products sold	27,556	27,091	25,439	21,789	21,426	22,684	22,181	21,515	20,219	18,688	18,380
Selling, marketing and administrative expenses	22,178	22,540	21,520	20,067	21,079	21,887	21,650	20,697	20,800	19,296	19,712
Research and development expense	11,355	10,775	10,594	9,143	8,999	8,471	8,119	7,602	7,486	6,796	6,949
In-process research and development	890	1,126	408	29	224	178	580	1,163	—	—	—
Interest income	(357)	(611)	(385)	(368)	(128)	(67)	(74)	(64)	(91)	(107)	(90)
Interest expense, net of portion capitalized	318	1,005	934	726	552	533	482	532	571	455	451
Other (income) expense, net	2,525	1,405	(42)	210	(1,783)	82	2,903	2,004	3,115	(488)	(333)
Restructuring	266	251	309	491	509	—	—	—	569	—	1,073
	64,731	63,582	58,777	52,087	50,878	53,768	55,841	53,449	52,669	44,640	46,142
Earnings before provision for taxes on income	$17,328	17,999	17,673	19,803	19,196	20,563	15,471	13,775	12,361	16,947	15,755
Provision for taxes on income	2,209	2,702	16,373	3,263	3,787	4,240	1,640	3,261	2,689	3,613	3,489
Net earnings	15,119	15,297	1,300	16,540	15,409	16,323	13,831	10,514	9,672	13,334	12,266
Add: Net loss attributable to noncontrolling interest	—	—	—	—	—	—	—	339	—	—	—
Net earnings attributable to Johnson & Johnson	15,119	15,297	1,300	16,540	15,409	16,323	13,831	10,853	9,672	13,334	12,266
Percent of sales to customers	18.4%	18.8	1.7	23.0	22.0	22.0	19.4	16.1	14.9	21.7	19.8
Diluted net earnings per share of common stock [1]	$5.63	5.61	0.47	5.93	5.48	5.70	4.81	3.86	3.49	4.78	4.40
Percent return on average shareholders' equity	25.4%	25.5	2.0	23.4	21.9	22.7	19.9	17.8	17.0	24.9	26.4
Percent increase (decrease) over previous year:											
Sales to customers	0.6%	6.7	6.3	2.6	(5.7)	4.2	6.1	3.4	5.6	(0.5)	(2.9)
Diluted net earnings per share	0.4%	N/M	(92.1)	8.2	(3.9)	18.5	24.6	10.6	(27.0)	8.6	(3.7)
Supplementary balance sheet data:											
Property, plant and equipment, net	17,658	17,035	17,005	15,912	15,905	16,126	16,710	16,097	14,739	14,553	14,759
Additions to property, plant and equipment	3,498	3,670	3,279	3,226	3,463	3,714	3,595	2,934	2,893	2,384	2,365
Total assets	157,728	152,954	157,303	141,208	133,411	130,358	131,754	121,347	113,644	102,908	94,682
Long-term debt	26,494	27,684	30,675	22,442	12,857	15,122	13,328	11,489	12,969	9,156	8,223
Operating cash flow	23,416	22,201	21,056	18,767	19,569	18,710	17,414	15,396	14,298	16,385	16,571
Common stock information											
Dividends paid per share	3.75	3.54	3.32	3.15	2.95	2.76	2.59	2.40	2.25	2.11	1.93
Shareholders' equity per share	22.59	22.44	22.43	26.02	25.82	25.06	26.25	23.33	20.95	20.66	18.37
Market price per share (year-end close)	$145.75	127.27	139.72	115.21	102.72	105.06	92.35	69.48	65.58	61.85	64.41
Average shares outstanding (millions)											
— basic	2,645.1	2,681.5	2,692.0	2,737.3	2,771.8	2,815.2	2,809.2	2,753.3	2,736.0	2,751.4	2,759.5
— diluted	2,684.3	2,728.7	2,745.3	2,788.9	2,812.9	2,863.9	2,877.0	2,812.6	2,775.3	2,788.8	2,789.1
Employees (thousands)	132.2	135.1	134.0	126.4	127.1	126.5	128.1	127.6	117.9	114.0	115.5

[1] Attributable to Johnson & Johnson
N/M = Not Meaningful

Organization and Business Segments

Description of the Company and Business Segments

Johnson & Johnson and its subsidiaries (the Company) have approximately 132,200 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. The Consumer segment includes a broad range of products used in the baby care, oral care, beauty, over-the-counter pharmaceutical, women's health and wound care markets. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on six therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, pulmonary hypertension, and cardiovascular and metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, interventional solutions (cardiovascular and neurovascular) and eye health fields. These products are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Consumer, Pharmaceutical and Medical Devices business segments.

In all of its product lines, the Company competes with other companies both locally and globally, throughout the world. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products, as well as protecting the underlying intellectual property of the Company's product portfolio, is important to the Company's success in all areas of its business. The competitive environment requires substantial investments in continuing research. In addition, the development and maintenance of customer demand for the Company's consumer products involves significant expenditures for advertising and promotion.

Management's Objectives

With "Our Credo" as the foundation, the Company's purpose is to blend heart, science and ingenuity to profoundly change the trajectory of health for humanity. The Company is committed to bringing its full breadth and depth to ensure health for people today and for future generations. United around this common ambition, the Company is poised to fulfill its purpose and successfully meet the demands of the rapidly evolving markets in which it competes.

The Company is broadly based in human healthcare, and is committed to creating value by developing accessible, high quality, innovative products and services. New products introduced within the past five years accounted for approximately 25% of 2019 sales. In 2019, $11.4 billion was invested in research and development and $5.8 billion spent on acquisitions, reflecting management's commitment to create life-enhancing innovations and to create value through partnerships that will profoundly change the trajectory of health for humanity.

A critical driver of the Company's success is the 132,200 diverse employees worldwide. Employees are empowered and inspired to lead with the Company's Our Credo and purpose as guides. This allows every employee to use the Company's reach and size to advance the Company's purpose, and to also lead with agility and urgency. Leveraging the extensive resources across the enterprise, enables the Company to innovate and execute with excellence. This ensures the Company can remain focused on addressing the unmet needs of society every day and invest for an enduring impact, ultimately delivering value to its patients, consumers and healthcare professionals, employees, communities and shareholders.

Results of Operations

Analysis of Consolidated Sales

For discussion on results of operations and financial condition pertaining to the fiscal years 2018 and 2017 see the Company's Annual Report on Form 10-K for the fiscal year ended December 30, 2018, Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition.

In 2019, worldwide sales increased 0.6% to $82.1 billion as compared to an increase of 6.7% in 2018. These sales changes consisted of the following:

Sales increase/(decrease) due to:	2019	2018
Volume	3.7 %	8.5 %
Price	(0.9)	(2.2)
Currency	(2.2)	0.4
Total	**0.6 %**	**6.7 %**

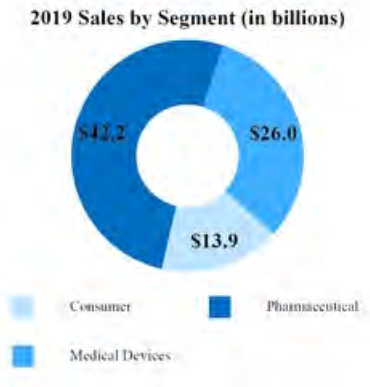
The net impact of acquisitions and divestitures on the worldwide sales growth was a negative impact of 1.7% in 2019 and a positive impact of 0.8% in 2018.

Sales by U.S. companies were $42.1 billion in 2019 and $41.9 billion in 2018. This represents increases of 0.5% in 2019 and 5.1% in 2018. Sales by international companies were $40.0 billion in 2019 and $39.7 billion in 2018. This represents an increase of 0.7% in 2019 and 8.5% in 2018.

The five-year compound annual growth rates for worldwide, U.S. and international sales were 2.0%, 3.9% and 0.2%, respectively. The ten-year compound annual growth rates for worldwide, U.S. and international sales were 2.9%, 3.1% and 2.6%, respectively.

In 2019, sales by companies in Europe experienced a sales decline of 1.5% as compared to the prior year, which included operational growth of 3.8% offset by a negative currency impact of 5.3%. Sales by companies in the Western Hemisphere (excluding the U.S.) experienced a sales decline of 2.8% as compared to the prior year, which included operational growth of 5.7% offset by a negative currency impact of 8.5%. Sales by companies in the Asia-Pacific, Africa region achieved growth of 4.9% as compared to the prior year, including operational growth of 6.9% partially offset by a negative currency impact of 2.0%.

In 2019, the Company utilized three wholesalers distributing products for all three segments that represented approximately 15.0%, 12.0% and 11.0% of the total consolidated revenues. In 2018, the Company had three wholesalers distributing products for all three segments that represented approximately 14.0%, 11.0% and 11.0% of the total consolidated revenues.



Analysis of Sales by Business Segments

Consumer Segment

Consumer segment sales in 2019 were $13.9 billion, an increase of 0.3% from 2018, which included 3.0% operational growth and a negative currency impact of 2.7%. U.S. Consumer segment sales were $5.8 billion, an increase of 1.4%. International sales were $8.1 billion, a decrease of 0.4%, which included 4.2% operational growth and a negative currency impact of 4.6%. In 2019, acquisitions and divestitures had a net positive impact of 1.6% on the operational sales growth of the worldwide Consumer segment.

Major Consumer Franchise Sales:

(Dollars in Millions)	2019	2018	% Change '19 vs. '18
Beauty	$ 4,593	4,382	4.8 %
OTC	4,444	4,334	2.5
Baby Care	1,675	1,858	(9.9)
Oral Care	1,528	1,555	(1.7)
Women's Health	986	1,049	(6.0)
Wound Care/Other	671	675	(0.6)
Total Consumer Sales	**$ 13,898**	**13,853**	**0.3 %**

The Beauty franchise sales of $4.6 billion increased 4.8% as compared to the prior year. Growth was primarily driven by incremental sales from the acquisition of Ci:z Holdings Co., Ltd., (DR.CI:LABO) in Japan as well as market growth and share gains of NEUTROGENA® and AVEENO® products. Growth was partially offset by the divestitures of RoC® and NIZORAL® in the fiscal year 2018.

The Over-the-Counter (OTC) franchise sales of $4.4 billion increased 2.5% as compared to the prior year. Growth was primarily driven by incremental sales from the acquisition of ZARBEES®. Additional contributors to the growth were TYLENOL®, Children's MOTRIN®, digestive health products and anti-smoking aids.

The Baby Care franchise sales were $1.7 billion in 2019, a decrease of 9.9% compared to the prior year, primarily due to JOHNSON's® competitive pressures coupled with comparisons to prior year relaunch activities and the Baby Center divestiture.

The Oral Care franchise sales of $1.5 billion decreased 1.7% as compared to the prior year. Growth in LISTERINE® Mouthwash and Ready Tabs outside the U.S. was offset by share declines and retailer destocking in the U.S. and the negative impact of currency.

The Women's Health franchise sales were $1.0 billion in 2019, a decrease of 6.0% as compared to the prior year. The decline was primarily driven by the negative impact of currency and weakness in liners partially offset by strength in napkins in Asia Pacific and Latin America.

The Wound Care/Other franchise sales were $0.7 billion in 2019, a decrease of 0.6% as compared to the prior year. The decline was primarily driven by the divestiture of COMPEED® outside the U.S. and the negative impact of currency.

Pharmaceutical Segment

Pharmaceutical segment sales in 2019 were $42.2 billion, an increase of 3.6% from 2018, which included operational growth of 5.8% and a negative currency impact of 2.2%. U.S. sales were $23.9 billion, an increase of 2.5%. International sales were $18.3 billion, an increase of 5.0%, which included 10.1% operational growth and a negative currency impact of 5.1%. In 2019, the net impact of acquisitions and divestitures on the Pharmaceutical segment operational sales growth was negligible. Adjustments to previous reserve estimates, as compared to the prior year, positively impacted the Pharmaceutical segment operational growth by approximately 1.3%, primarily in the Immunology and Cardiovascular/Metabolism/Other therapeutic areas.

Major Pharmaceutical Therapeutic Area Sales:

(Dollars in Millions)	2019	2018	% Change '19 vs. '18
Total Immunology	**$ 13,950**	**13,120**	**6.3 %**
REMICADE®	4,380	5,326	(17.8)
SIMPONI®/SIMPONI ARIA®	2,188	2,084	5.0
STELARA®	6,361	5,156	23.4
TREMFYA®	1,012	544	85.9
Other Immunology	10	10	4.5
Total Infectious Diseases	**3,413**	**3,304**	**3.3**
EDURANT®/rilpivirine	861	816	5.6
PREZISTA®/ PREZCOBIX®/REZOLSTA®/SYMTUZA®	2,110	1,955	8.0
Other Infectious Diseases	441	533	(17.3)
Total Neuroscience	**6,328**	**6,077**	**4.1**
CONCERTA®/methylphenidate	696	663	4.9
INVEGA SUSTENNA®/XEPLION®/INVEGA TRINZA®/TREVICTA®	3,330	2,928	13.7
RISPERDAL CONSTA®	688	737	(6.7)
Other Neuroscience	1,614	1,749	(7.7)
Total Oncology	**10,692**	**9,844**	**8.6**
DARZALEX®	2,998	2,025	48.0
IMBRUVICA®	3,411	2,615	30.4
VELCADE®	751	1,116	(32.7)
ZYTIGA® /abiraterone acetate	2,795	3,498	(20.1)
Other Oncology	739	590	25.0
Total Pulmonary Hypertension	**2,623**	**2,573**	**1.9**
OPSUMIT®	1,327	1,215	9.2
TRACLEER®/bosentan	341	546	(37.5)
UPTRAVI®	819	663	23.5
Other Pulmonary Hypertension	135	149	(9.4)
Total Cardiovascular / Metabolism / Other	**5,192**	**5,816**	**(10.7)**
XARELTO®	2,313	2,477	(6.6)
INVOKANA®/ INVOKAMET®	735	881	(16.5)
PROCRIT®/EPREX®	790	988	(20.0)
Other	1,353	1,470	(8.0)
Total Pharmaceutical Sales	**$ 42,198**	**40,734**	**3.6 %**

Immunology products sales were $14.0 billion in 2019, representing an increase of 6.3% as compared to the prior year. Growth was driven by strong uptake of STELARA® (ustekinumab) in Crohn's disease, and TREMFYA® (guselkumab) in Psoriasis, expanded indications of SIMPONI®/SIMPONI ARIA® (golimumab), and the U.S. immunology market growth. Immunology was negatively impacted by lower sales of REMICADE® (infliximab) due to increased discounts/rebates and biosimilar competition.

The patents for REMICADE® (infliximab) in certain countries in Europe expired in February 2015. Biosimilar versions of REMICADE® have been introduced in certain markets outside the U.S., resulting in a reduction in sales of REMICADE® in those markets. Additional biosimilar competition will likely result in a further reduction in REMICADE® sales in markets outside the United States. In the U.S., a biosimilar version of REMICADE® was introduced in 2016, and additional competitors continue to enter the market. Continued infliximab biosimilar competition in the U.S. market will result in a further reduction in U.S. sales of REMICADE®. See Note 21 to the Consolidated Financial Statements for a description of legal matters regarding the REMICADE® patents.

Infectious disease products sales were $3.4 billion in 2019, representing an increase of 3.3% as compared to the prior year. Strong sales of SYMTUZA® and the launch of JULUCA® (dolutegravir/rilpivirine) were partially offset by lower sales of PREZISTA® and PREZCOBIX®/REZOLSTA® (darunavir/cobicistat) due to increased competition and loss of exclusivity of PREZISTA® in certain countries outside the U.S.

Neuroscience products sales were $6.3 billion, representing an increase of 4.1% as compared to the prior year. Strong sales of long-acting injectables INVEGA TRINZA®/TREVICTA® (paliperidone palmitate) and INVEGA SUSTENNA®/XEPLION® were partially offset by cannibalization of RISPERDAL CONSTA® (risperidone).

Oncology products achieved sales of $10.7 billion in 2019, representing an increase of 8.6% as compared to the prior year. Contributors to the growth were strong sales of DARZALEX® (daratumumab) with continued market growth and share gain, IMBRUVICA® (ibrutinib) due to increased patient uptake globally. Additionally, sales from the launch of ERLEADA™ (apalutamide) contributed to the growth. Growth was negatively impacted from a decline in U.S. sales of ZYTIGA® (abiraterone acetate) driven by generic competition partially offset by increased sales outside the U.S. Lower sales of VELCADE® (bortezomib) were also due to generic competition.

Pulmonary Hypertension products achieved sales of $2.6 billion, representing an increase of 1.9% as compared to the prior year. Sales of OPSUMIT® (macitentan) and UPTRAVI® (selexipag) were due to continued market growth and increased share gains while sales of TRACLEER® (bosentan) were negatively impacted by generics and cannibalization from OPSUMIT®.

Cardiovascular/Metabolism/Other products sales were $5.2 billion, a decline of 10.7% as compared to the prior year. XARELTO® (rivaroxaban) sales volume growth was offset by higher discounts and rebates. Lower sales of INVOKANA®/INVOKAMET® (canagliflozin) were due to share loss from competitive pressure and a safety label update in the U.S. and lower sales of PROCRIT®/ EPREX® (epoetin alfa) were due to biosimilar competition.

During 2019, the Company advanced its pipeline with several regulatory submissions and approvals for new drugs and additional indications for existing drugs as follows:

Product Name (Chemical Name)	Indication	US Approval	EU Approval	US Filing	EU Filing
BALVERSA™ (erdafitinib)	Treatment of locally advanced or metastatic urothelial cancer	☐			
DARZALEX® (daratumumab)	Combination Regimen for Newly Diagnosed, Transplant-eligible Patients with Multiple Myeloma	☐			☐
	Newly diagnosed patients with Multiple Myeloma in combination with Lenalidomide and Dexamethasone	☐			
	Split-dosing regimen	☐			
	Combination therapy for transplant ineligible Multiple Myeloma patients		☐	☐	
	Subcutaneous Formulation in Multiple Myeloma			☐	☐
ERLEADA™ (apalutamide)	Treatment of Metastatic Castration-Sensitive Prostate Cancer	☐			
	Treatment of Metastatic Hormone-Sensitive Prostate Cancer				☐
IMBRUVICA® (ibrutinib)	Expanded Use in Combination with Obinutuzumab in Adult Patients with Previously Untreated Chronic Lymphocytic Leukemia and in Combination with Rituximab in Waldenström's Macroglobulinemia		☐		
	Treatment for Chronic Lymphocytic Leukemia in combination with obinutuzumab	☐			
INVOKANA® (canagliflozin)	Treatment of Diabetic Kidney Disease	☐			
rilpivirine and cabotegravir	For Monthly, Injectable, Two Drug Regimen for Treatment of HIV			☐	☐
SPRAVATO® (esketamine)	Treatment-resistant depression	☐	☐		
	Rapid Reduction of Depressive Symptoms in Adults with Major Depressive Disorder who have Active Suicidal Ideation with Intent			☐	
STELARA® (ustekinumab)	Extended Use for the Treatment of Moderately to Severely Active Ulcerative Colitis	☐	☐		
	Treatment of Pediatric Patients with Moderate to Severe Plaque Psoriasis			☐	
TREMFYA® (guselkumab)	One-press patient-controlled injector	☐			
	Treatment of Adults with Active Psoriatic Arthritis			☐	☐
XARELTO® (rivaroxaban)	For the prevention of Blood Clots in Acutely Ill Medical Patients	☐			

Medical Devices Segment

The Medical Devices segment sales in 2019 were $26.0 billion, a decrease of 3.8% from 2018, which included an operational decrease of 1.7% and a negative currency impact of 2.1%. U.S. sales were $12.4 billion, a decrease of 3.5% as compared to the prior year. International sales were $13.6 billion, a decrease of 4.1% as compared to the prior year, with an operational decrease of 0.1% and a negative currency impact of 4.0%. In 2019, the net impact of acquisitions and divestitures on the Medical Devices segment worldwide operational sales growth was a negative 5.6% of which, the divestitures of LifeScan and Advanced Sterilization Products (ASP) had an impact of approximately 3.8% and 1.6%, respectively.

Major Medical Devices Franchise Sales:

(Dollars in Millions)	2019	2018	% Change '19 vs. '18
Surgery	**$ 9,501**	**9,901**	**(4.0)%**
Advanced	4,095	4,002	2.3
General	4,480	4,557	(1.7)
Specialty	926	1,342	(31.0)
Orthopaedics	**8,839**	**8,885**	**(0.5)**
Hips	1,438	1,418	1.4
Knees	1,480	1,502	(1.4)
Trauma	2,720	2,699	0.8
Spine & Other	3,201	3,266	(2.0)
Vision	**4,624**	**4,553**	**1.6**
Contact Lenses/Other	3,392	3,302	2.7
Surgical	1,232	1,251	(1.6)
Interventional Solutions	**2,997**	**2,646**	**13.3**
Diabetes Care[1]	**—**	**1,009**	*
Total Medical Devices Sales	**$ 25,963**	**26,994**	**(3.8)%**

[1]LifeScan was divested in the fiscal fourth quarter of 2018.
*Percentage greater than 100% or not meaningful

The Surgery franchise sales were $9.5 billion in 2019, a decrease of 4.0% from 2018. Growth in Advanced Surgery was primarily driven by endocutter, biosurgery and energy products. The decline in General Surgery was primarily driven by the negative impact of currency partially offset by growth of wound closure products. The decline in Specialty Surgery was primarily driven by the divestiture of the sterilization business (ASP) partially offset by growth of aesthetic products.

The Orthopaedics franchise sales were $8.8 billion in 2019, a decrease of 0.5%, including operational growth of 1.2% offset by a negative currency impact of 1.7% as compared to the prior year. The growth in hips was driven by leadership position in the anterior approach, strong market demand for the ACTIS® stem and the KINCISE™ surgical automated system. Knees grew outside the U.S. from new products coupled with continued global uptake of ATTUNE® Revision, offset by a negative currency impact. Growth in trauma was due to strong market growth coupled with continued uptake of new products. The decline in Spine & Other was primarily driven by base business declines in Spine partially offset by growth in Sports which was led by new products, MONOVISC® in the U.S. and growth in Asia Pacific.

The Vision franchise achieved sales of $4.6 billion in 2019, an increase of 1.6% from 2018. Growth was primarily driven by the strength of daily disposable lenses in the ACUVUE® OASYS contact lenses category. The Surgical operational growth was primarily driven by the strength of cataracts outside the U.S. partially offset by competitive pressures in the U.S.

The Interventional Solutions franchise achieved sales of $3.0 billion in 2019, an increase of 13.3% from 2018. Strong growth in the electrophysiology business was driven by Atrial Fibrillation procedure growth and with strong THERMOCOOL SMARTTOUCH® SF Contact Force Sensing Catheter and diagnostic catheter sales.

Analysis of Consolidated Earnings Before Provision for Taxes on Income

Consolidated earnings before provision for taxes on income was $17.3 billion and $18.0 billion for the fiscal years ended 2019 and 2018, respectively. As a percent to sales, consolidated earnings before provision for taxes on income was 21.1% and 22.1%, in 2019 and 2018, respectively.

Cost of Products Sold and Selling, Marketing and Administrative Expenses: Cost of products sold and selling, marketing and administrative expenses as a percent to sales were as follows:

% of Sales	2019	2018
Cost of products sold	33.6%	33.2
Percent point increase/(decrease) over the prior year	0.4	(0.1)
Selling, marketing and administrative expenses	27.0%	27.6
Percent point increase/(decrease) over the prior year	(0.6)	(0.5)

In 2019, cost of products sold as a percent to sales increased to 33.6% from 33.2% as compared to the same period a year ago primarily driven by the negative impact of currency in the Pharmaceutical business as well as increased intangible asset amortization expense. Intangible asset amortization expense of $4.5 billion was included in cost of products sold for 2019 as compared to $4.4 billion in 2018. There was a decrease in the percent to sales of selling, marketing and administrative expenses in 2019 as compared to the prior year, primarily due to favorable segment mix with a higher percentage of sales coming from the Pharmaceutical business, planned prioritization and reduced brand marketing expense in the Consumer business partially offset by increased selling and marketing investments in the Medical Devices business.

Research and Development Expense: Research and development expense by segment of business was as follows:

	2019		2018	
(Dollars in Millions)	Amount	% of Sales*	Amount	% of Sales*
Consumer	$ 493	3.5%	565	4.1
Pharmaceutical	8,834	20.9	8,446	20.7
Medical Devices	2,028	7.8	1,764	6.5
Total research and development expense	$ 11,355	13.8%	10,775	13.2
Percent increase/(decrease) over the prior year	5.4%		1.7	

*As a percent to segment sales

Research and development activities represent a significant part of the Company's business. These expenditures relate to the processes of discovering, testing and developing new products, upfront payments and developmental milestones, improving existing products, as well as ensuring product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products. In 2019, worldwide costs of research and development activities increased by 5.4% compared to 2018 primarily driven by increased investment in the Medical Devices business related to robotics and digital surgery platforms along with higher upfront and developmental milestone payments, primarily from the argenx collaboration in the Pharmaceutical business.

Research facilities are located in the U.S., Belgium, Brazil, China, France, Germany, India, Israel, the Netherlands, Poland, Singapore, Sweden, Switzerland and the United Kingdom with additional R&D support in over 30 other countries.

In-Process Research and Development (IPR&D): In the fiscal first quarter of 2019, the Company recorded an IPR&D charge of $0.9 billion for the remaining intangible asset value related to the development program of AL-8176, an investigational drug for the treatment of Respiratory Syncytial Virus (RSV) and human metapneumovirus (hMPV) acquired with the 2014 acquisition of Alios Biopharma Inc. The impairment charge was based on additional information, including clinical data, which became available and led to the Company's decision to abandon the development of AL-8176. In the fiscal third quarter of 2018, the Company recorded an impairment charge of $1.1 billion which included a partial impairment charge of $0.8 billion related to the development program of AL-8176 and an impairment charge of $0.3 billion for the discontinuation of the development project for an anti-thrombin antibody associated with the 2015 acquisition of XO1 Limited.

Other (Income) Expense, Net: Other (income) expense, net is the account where the Company records gains and losses related to the sale and write-down of certain investments in equity securities held by Johnson & Johnson Innovation - JJDC, Inc. (JJDC), unrealized gains and losses on investments, gains and losses on divestitures, certain transactional currency gains and losses, acquisition-related costs, litigation accruals and settlements, as well as royalty income.

The change in other (income) expense, net for the fiscal year 2019 was additional net expense of $1.1 billion primarily attributable to litigation expense of $5.1 billion in 2019, primarily related to the agreement in principle to settle opioid litigation of $4.0 billion, as compared to litigation expense of $2.0 billion in 2018. This was partially offset by divestiture gains in 2019 of $2.2 billion of which $2.0 billion related to the divestiture of the ASP business. In addition, the fiscal year 2019 included higher unrealized gains on securities of $0.7 billion, an equity step-up gain of $0.3 billion related to the Company's previously held equity investment in DR. CI:LABO, and lower restructuring related expense of $0.2 billion as compared to the same period a year ago. Divestiture gains were approximately $1.2 billion in 2018 and included the LifeScan business, NIZORAL®, RoC® and certain non-strategic Pharmaceutical products. Additionally, 2018 included a reversal of a contingent liability of $0.2 billion.

Interest (Income) Expense: The fiscal year 2019 included net interest income as compared to an expense in the fiscal year 2018. This was primarily due to the positive effect of net investment hedging arrangements and certain cross currency swaps, and a lower average debt balance. Cash, cash equivalents and marketable securities totaled $19.3 billion at the end of 2019, and averaged $19.5 billion as compared to the cash, cash equivalents and marketable securities total of $19.7 billion and $19.0 billion average cash balance in 2018. The total debt balance at the end of 2019 was $27.7 billion with an average debt balance of $29.1 billion as compared to $30.5 billion at the end of 2018 and an average debt balance of $32.5 billion. The decrease in debt was due to the retirement of long-term debt.

Income Before Tax by Segment

Income before tax by segment of business were as follows:

	Income Before Tax		Segment Sales		Percent of Segment Sales	
(Dollars in Millions)	**2019**	**2018**	**2019**	**2018**	**2019**	**2018**
Consumer	$ 2,061	2,320	13,898	13,853	14.8%	16.7
Pharmaceutical	8,816	12,568	42,198	40,734	20.9	30.9
Medical Devices	7,286	4,397	25,963	26,994	28.1	16.3
Total [1]	18,163	19,285	82,059	81,581	22.1	23.6
Less: Net expense not allocated to segments [2]	835	1,286				
Earnings before provision for taxes on income	$ 17,328	17,999	82,059	81,581	21.1%	22.1

(1) See Note 18 to the Consolidated Financial Statements for more details.

(2) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.

Consumer Segment: In 2019, the Consumer segment income before tax as a percent to sales was 14.8%, versus 16.7% in 2018. The decrease in the income before tax as a percent of sales in 2019 as compared to 2018 was primarily attributable to higher expenses for litigation of $0.1 billion, intangible asset amortization of $0.1 billion and restructuring of $0.1 billion in the fiscal year 2019 as compared to the fiscal year 2018. This was partially offset by planned prioritization and brand marketing expense reductions. The fiscal year 2019 included a gain of $0.3 billion related to the Company's previously held equity investment in DR. CI:LABO. Divestiture gains for the fiscal year of 2018 included a gain of $0.3 billion from the divestiture of NIZORAL®.

Pharmaceutical Segment: In 2019, the Pharmaceutical segment income before tax as a percent to sales was 20.9% versus 30.9% in 2018. The decrease in the income before tax as a percent of sales was primarily due to higher litigation expense of $4.3 billion, primarily due to the agreement in principle to settle opioid litigation of $4.0 billion, increased spending in research and development, including a $0.3 billion upfront payment to argenx. This was partially offset by $0.8 billion of higher unrealized gains on securities, a lower in-process research and development charge of $0.2 billion, and lower Actelion acquisition and integration related costs as compared to the fiscal year 2018. In addition, the fiscal year 2018 included a contingent liability reversal of $0.2 billion and higher divestiture gains of $0.2 billion.

Medical Devices Segment: In 2019, the Medical Devices segment income before tax as a percent to sales was 28.1% versus 16.3% in 2018. The increase in the income before tax as a percent to sales was primarily attributable to higher divestiture gains in 2019. Divestiture gains in the fiscal 2019 included a gain of $2.0 billion related to the ASP business. Divestiture gains for the fiscal year of 2018 included a gain of $0.5 billion related to LifeScan. Additionally, the fiscal year 2019 included lower litigation expense of $1.3 billion, lower restructuring charges of $0.2 billion and lower intangible asset amortization expense of $0.1 billion as compared to the fiscal year 2018. This was partially offset by increased investment in robotics and digital solutions.

Restructuring: In the fiscal second quarter of 2018, the Company announced plans to implement actions across its global supply chain that are intended to enable the Company to focus resources and increase investments in critical capabilities, technologies and solutions necessary to manufacture and supply its product portfolio of the future, enhance agility and drive growth. The Company expects these supply chain actions will include expanding its use of strategic collaborations, and bolstering its initiatives to reduce complexity, improving cost-competitiveness, enhancing capabilities and optimizing its network. Discussions regarding specific future actions are ongoing and are subject to all relevant consultation requirements before they are finalized. In total, the Company expects these actions to generate approximately $0.6 to $0.8 billion in annual pre-tax cost savings that will be substantially delivered by 2022. The Company expects to record pre-tax restructuring charges of approximately $1.9 to $2.3 billion. The Company estimates that approximately 70% of the cumulative pre-tax costs will result in cash outlays. In 2019, the Company recorded a pre-tax charge of $0.6 billion, which is included on the following lines of the Consolidated Statement of Earnings, $0.3 billion in restructuring, $0.2 billion in other (income) expense and $0.1 billion in cost of products sold. Total project costs of approximately $0.8 billion have been recorded since the restructuring was announced.

See Note 22 to the Consolidated Financial Statements for additional details related to the restructuring programs.

Provision for Taxes on Income: The worldwide effective income tax rate was 12.7% in 2019 and 15.0% in 2018.

For discussion related to the fiscal 2019 provision for taxes refer to Note 8 to the Consolidated Financial Statements.

On September 28, 2018 the Swiss Parliament approved the Federal Act on Tax Reform and AHV Financing (TRAF). On May 19, 2019 a public referendum was held in Switzerland that approved the federal reform proposals. In the fiscal third quarter of 2019, the Swiss Federal Council enacted TRAF which became effective on January 1, 2020. On February 9, 2020 a public referendum on the legislative change was held in the last remaining canton where the Company has significant operations. The legislation was approved by the voters and formal enactment is expected in the fiscal first half of 2020. The Company has not yet elected the transitional provision in this canton. However, the net financial benefit is estimated to be between $0.2 billion and $0.5 billion in the fiscal first half of 2020. The Company does not believe that TRAF will have a material impact to the Company’s ongoing consolidated effective tax rate beginning in fiscal year 2020.

Liquidity and Capital Resources

Liquidity & Cash Flows

Cash and cash equivalents were $17.3 billion at the end of 2019 as compared to $18.1 billion at the end of 2018. The primary sources and uses of cash that contributed to the $0.8 billion decrease were approximately $23.4 billion of cash generated from operating activities. This was offset by $6.2 billion net cash used by investing activities and $18.0 billion net cash used by financing activities. In addition, the Company had $2.0 billion in marketable securities at the end of 2019 and $1.6 billion at the end of 2018. See Note 1 to the Consolidated Financial Statements for additional details on cash, cash equivalents and marketable securities.

Cash flow from operations of $23.4 billion was the result of $15.1 billion of net earnings and $9.1 billion of non-cash expenses and other adjustments for depreciation and amortization, stock-based compensation, assets write-downs (primarily related to the Alios IPR&D asset), and favorable increases in accounts payable, accrued liabilities and other liabilities of $5.5 billion. This was reduced by $1.6 billion related to an increase in accounts receivable, inventories, other current and non-current assets. as well as non-cash expenses and other adjustments of $2.5 billion for the increase in the deferred tax provision and a net gain on sale of assets/businesses of $2.2 billion (primarily related to the ASP divestiture).

Investing activities use of $6.2 billion of cash was primarily used for acquisitions of $5.8 billion primarily related to the acquisitions of Auris Health, Inc. and DR. CI:LABO, additions to property, plant and equipment of $3.5 billion and $0.5 billion from the net purchases of investments. Investing activities also included a source of $3.3 billion of proceeds from the disposal of assets/businesses, primarily the ASP divestiture, and proceeds from credit support agreements of $0.3 billion.

Financing activities use of $18.0 billion of cash was primarily used for dividends to shareholders of $9.9 billion, the repurchase of common stock of $6.7 billion and the net retirement of short and long term debt of $2.9 billion. Financing activities also included sources of $1.5 billion from proceeds of stock options exercised/employee withholding tax on stock awards, and other financing activities.

On December 17, 2018, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's shares of common stock. Shares acquired are available for general corporate purposes. The Company financed the share repurchase program through available cash. As of September 29, 2019, $5.0 billion was repurchased under the program and the program was completed.

As of December 29, 2019, the Company's notes payable and long-term debt was in excess of cash, cash equivalents and marketable securities. As of December 29, 2019, the net debt position was $8.4 billion as compared to the prior year of $10.8 billion. There was a decrease in the net debt position due to retirement of debt. The debt balance at the end of 2019 was $27.7 billion as compared to $30.5 billion in 2018. In 2019, the Company continued to have access to liquidity through the commercial paper market. Additionally, as a result of the TCJA, the Company has access to its cash outside the U.S. at a significantly reduced cost. The Company anticipates that operating cash flows, the ability to raise funds from external sources, borrowing capacity from existing committed credit facilities and access to the commercial paper markets will continue to provide sufficient resources to fund operating needs, including the agreement in principle to settle opioid litigation to be potentially paid over the next two to three years. As discussed in Note 8 to the Consolidated Financial Statements, the Internal Revenue Service (IRS) has completed its audit for the tax years through 2009 and is currently auditing the tax years 2010-2012. The Company currently expects completion of this audit and settlement of the related tax liabilities in the fiscal year 2020. As of December 29, 2019, the Company has classified unrecognized tax benefits and related interest of approximately $0.9 billion as a current liability in the “Accrued taxes on Income” line in the Consolidated Balance Sheet. This is the amount expected to be paid over the next 12 months with respect to the IRS audit. Subsequent to December 29, 2019, the Company made a payment for approximately $0.6 billion to the U.S. Treasury related to the estimated 2010-2012 tax audit liability in anticipation of the final settlement later in fiscal 2020. The completion of this tax audit may result in additional adjustments to the Company’s unrecognized tax benefit liability that may have a material impact on the Company’s future operating results or cash flows in the period that the audit is substantially completed.

The Company monitors the global capital markets on an ongoing basis and from time to time may raise capital when market conditions are favorable. The Company filed a shelf registration on February 27, 2017, which will enable it to issue debt securities on a timely basis and will be updated as required. For additional details on borrowings, see Note 7 to the Consolidated Financial Statements.

Financing and Market Risk

The Company uses financial instruments to manage the impact of foreign exchange rate changes on cash flows. Accordingly, the Company enters into forward foreign exchange contracts to protect the value of certain foreign currency assets and liabilities and to hedge future foreign currency transactions primarily related to product costs. Gains or losses on these contracts are offset by the gains or losses on the underlying transactions. A 10% appreciation of the U.S. Dollar from the December 29, 2019 market rates would increase the unrealized value of the Company’s forward contracts by $271 million. Conversely, a

10% depreciation of the U.S. Dollar from the December 29, 2019 market rates would decrease the unrealized value of the Company's forward contracts by $331 million. In either scenario, the gain or loss on the forward contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated earnings and cash flows.

The Company hedges the exposure to fluctuations in currency exchange rates, and the effect on certain assets and liabilities in foreign currency, by entering into currency swap contracts. A 1% change in the spread between U.S. and foreign interest rates on the Company's interest rate sensitive financial instruments would either increase or decrease the unrealized value of the Company's swap contracts by approximately $1,043 million. In either scenario, at maturity, the gain or loss on the swap contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated cash flows.

The Company does not enter into financial instruments for trading or speculative purposes. Further, the Company has a policy of only entering into contracts with parties that have at least an investment grade credit rating. The counter-parties to these contracts are major financial institutions and there is no significant concentration of exposure with any one counter-party. Management believes the risk of loss is remote. During the fiscal second quarter of 2017, the Company entered into credit support agreements (CSA) with certain derivative counterparties establishing collateral thresholds based on respective credit ratings and netting agreements. See Note 6 to the Consolidated Financial Statements for additional details on credit support agreements.

The Company invests in both fixed rate and floating rate interest earning securities which carry a degree of interest rate risk. The fair market value of fixed rate securities may be adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than predicted if interest rates fall. A 1% (100 basis points) change in spread on the Company's interest rate sensitive investments would either increase or decrease the unrealized value of cash equivalents and current marketable securities by approximately $7 million.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2019, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 10, 2020. Interest charged on borrowings under the credit line agreement is based on either bids provided by banks, the prime rate, London Interbank Offered Rates (LIBOR), or other applicable market rate as allowed under the terms of the agreement, plus applicable margins. Commitment fees under the agreement are not material.

Total borrowings at the end of 2019 and 2018 were $27.7 billion and $30.5 billion, respectively. The decrease in borrowings was due to the retirement of debt in 2019. In 2019, net debt (cash and current marketable securities, net of debt) was $8.4 billion compared to net debt of $10.8 billion in 2018. Total debt represented 31.8% of total capital (shareholders' equity and total debt) in 2019 and 33.8% of total capital in 2018. Shareholders' equity per share at the end of 2019 was $22.59 compared to $22.44 at year-end 2018.

A summary of borrowings can be found in Note 7 to the Consolidated Financial Statements.

Contractual Obligations and Commitments

The Company's contractual obligations are primarily for the recently enacted tax legislation, leases, debt and unfunded retirement plans. There are no other significant obligations. To satisfy these obligations, the Company will use cash from operations. The following table summarizes the Company's contractual obligations and their aggregate maturities as of December 29, 2019 (see Notes 7, 8, 10 and 16 to the Consolidated Financial Statements for further details):

(Dollars in Millions)	Tax Legislation (TCJA)	Debt Obligations	Interest on Debt Obligations	Unfunded Retirement Plans	Leases	Total
2020	$ 528	1,100	886	103	215	2,832
2021	812	1,797	841	107	254	3,811
2022	812	2,106	796	113	197	4,024
2023	1,522	1,552	764	118	141	4,097
2024	2,029	1,474	729	127	86	4,445
After 2024	2,536	19,565	8,121	749	201	31,172
Total	**$ 8,239**	**27,594**	**12,137**	**1,317**	**1,094**	**50,381**

For tax matters, see Note 8 to the Consolidated Financial Statements. For other retirement plan and post-employment medical benefit information, see Note 10 to the Consolidated Financial Statements. The table does not include activity related to business combinations.

Dividends
The Company increased its dividend in 2019 for the 57th consecutive year. Cash dividends paid were $3.75 per share in 2019 and $3.54 per share in 2018.

Other Information
Critical Accounting Policies and Estimates
Management's discussion and analysis of results of operations and financial condition are based on the Company's consolidated financial statements that have been prepared in accordance with accounting principles generally accepted in the U.S. (GAAP). The preparation of these financial statements requires that management make estimates and assumptions that affect the amounts reported for revenues, expenses, assets, liabilities and other related disclosures. Actual results may or may not differ from these estimates. The Company believes that the understanding of certain key accounting policies and estimates are essential in achieving more insight into the Company's operating results and financial condition. These key accounting policies include revenue recognition, income taxes, legal and self-insurance contingencies, valuation of long-lived assets, assumptions used to determine the amounts recorded for pensions and other employee benefit plans and accounting for stock based awards.

Revenue Recognition: The Company recognizes revenue from product sales when obligations under the terms of a contract with the customer are satisfied; generally, this occurs with the transfer of control of the goods to customers. The Company's global payment terms are typically between 30 to 90 days. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns and discounts to customers are accounted for as variable consideration and recorded as a reduction in sales. See Note 1 to the Consolidated Financial Statements for the Accounting Standards Update related to revenue which was adopted in 2018.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including consideration of competitor pricing. Rebates are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns are estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales return accruals.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The sales returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual net trade sales during the fiscal reporting years 2019 and 2018.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the same period as related sales. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue. The Company also earns profit-share payments through collaborative arrangements of certain products, which are included in sales to customers. For all years presented, profit-share payments were approximately 2.0% of the total revenues and are included in sales to customers.

In addition, the Company enters into collaboration arrangements that contain multiple revenue generating activities. Amounts due from collaborative partners for these arrangements are recognized as each activity is performed or delivered, based on the relative selling price. Upfront fees received as part of these arrangements are deferred and recognized over the performance period. See Note 1 to the Consolidated Financial Statements for additional disclosures on collaborations.

Reasonably likely changes to assumptions used to calculate the accruals for rebates, returns and promotions are not anticipated to have a material effect on the financial statements. The Company currently discloses the impact of changes to assumptions in the quarterly or annual filing in which there is a material financial statement impact.

Below are tables that show the progression of accrued rebates, returns, promotions, reserve for doubtful accounts and reserve for cash discounts by segment of business for the fiscal years ended December 29, 2019 and December 30, 2018.

Consumer Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits	Balance at End of Period
2019				
Accrued rebates [1]	$ 271	841	(828)	284
Accrued returns	57	128	(122)	63
Accrued promotions	497	2,119	(2,129)	487
Subtotal	$ 825	3,088	(3,079)	834
Reserve for doubtful accounts	32	21	(18)	35
Reserve for cash discounts	23	198	(204)	17
Total	$ 880	3,307	(3,301)	886
2018				
Accrued rebates[1]	$ 186	836	(751)	271
Accrued returns	68	98	(109)	57
Accrued promotions	481	2,233	(2,217)	497
Subtotal	$ 735	3,167	(3,077)	825
Reserve for doubtful accounts	31	10	(9)	32
Reserve for cash discounts	23	204	(204)	23
Total	$ 789	3,381	(3,290)	880

(1) Includes reserve for customer rebates of $54 million at December 29, 2019 and $57 million at December 30, 2018, recorded as a contra asset.

Pharmaceutical Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits[2]	Balance at End of Period
2019				
Accrued rebates [1]	$ 7,510	26,868	(25,365)	9,013
Accrued returns	436	354	(290)	500
Accrued promotions	13	17	(25)	5
Subtotal	$ 7,959	27,239	(25,680)	9,518
Reserve for doubtful accounts	47	2	(13)	36
Reserve for cash discounts	53	936	(924)	65
Total	$ 8,059	28,177	(26,617)	9,619
2018				
Accrued rebates [1]	$ 4,862	22,644	(19,996)	7,510
Accrued returns	362	385	(311)	436
Accrued promotions	35	46	(68)	13
Subtotal	$ 5,259	23,075	(20,375)	7,959
Reserve for doubtful accounts	77	37	(67)	47
Reserve for cash discounts	55	860	(862)	53
Total	$ 5,391	23,972	(21,304)	8,059

(1) Includes reserve for customer rebates of $93 million at December 29, 2019 and $89 million at December 30, 2018, recorded as a contra asset.

(2) Includes adjustments

Medical Devices Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits	Balance at End of Period
2019				
Accrued rebates[1]	$ 1,218	5,487	(5,692)	1,013
Accrued returns	114	673	(669)	118
Accrued promotions	42	106	(102)	46
Subtotal	$ 1,374	6,266	(6,463)	1,177
Reserve for doubtful accounts	169	30	(44)	155
Reserve for cash discounts	—	106	(96)	10
Total	$ 1,543	6,402	(6,603)	1,342
2018[2]				
Accrued rebates[1]	$ 1,620	6,344	(6,746)	1,218
Accrued returns	152	750	(788)	114
Accrued promotions	83	116	(157)	42
Subtotal	$ 1,855	7,210	(7,691)	1,374
Reserve for doubtful accounts	183	29	(43)	169
Reserve for cash discounts	15	140	(155)	—
Total	$ 2,053	7,379	(7,889)	1,543

(1) Includes reserve for customer rebates of $499 million at December 29, 2019 and $632 million at December 30, 2018, recorded as a contra asset.

(2) Certain prior period amounts have been reclassified to conform to current year presentation.

Income Taxes: Income taxes are recorded based on amounts refundable or payable for the current year and include the results of any difference between U.S. GAAP accounting and tax reporting, recorded as deferred tax assets or liabilities. The Company estimates deferred tax assets and liabilities based on enacted tax regulations and rates. Future changes in tax laws and rates may affect recorded deferred tax assets and liabilities.

The Company has unrecognized tax benefits for uncertain tax positions. The Company follows U.S. GAAP, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Management believes that changes in these estimates would not have a material effect on the Company's results of operations, cash flows or financial position.

The Company has recorded deferred tax liabilities on all undistributed earnings prior to December 31, 2017 from its international subsidiaries. The Company has not provided deferred taxes on the undistributed earnings subsequent to January 1, 2018 from certain international subsidiaries where the earnings are considered to be indefinitely reinvested. The Company intends to continue to reinvest these earnings in those international operations. If the Company decides at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company estimates that the total tax effect of this repatriation would be approximately $0.8 billion under current enacted tax laws and regulations and at current currency exchange rates.

See Note 8 to the Consolidated Financial Statements for further information regarding income taxes.

Legal and Self Insurance Contingencies: The Company records accruals for various contingencies, including legal proceedings and product liability claims as these arise in the normal course of business. The accruals are based on management's judgment as to the probability of losses and, where applicable, actuarially determined estimates. The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated.

The Company follows the provisions of U.S. GAAP when recording litigation related contingencies. A liability is recorded when a loss is probable and can be reasonably estimated. The best estimate of a loss within a range is accrued; however, if no estimate in the range is better than any other, the minimum amount is accrued.

See Notes 1 and 21 to the Consolidated Financial Statements for further information regarding product liability and legal proceedings.

Long-Lived and Intangible Assets: The Company assesses changes in economic conditions and makes assumptions regarding estimated future cash flows in evaluating the value of the Company's property, plant and equipment, goodwill and intangible assets. As these assumptions and estimates may change over time, it may or may not be necessary for the Company to record impairment charges.

Employee Benefit Plans: The Company sponsors various retirement and pension plans, including defined benefit, defined contribution and termination indemnity plans, which cover most employees worldwide. These plans are based on assumptions for the discount rate, expected return on plan assets, mortality rates, expected salary increases, health care cost trend rates and attrition rates. See Note 10 to the Consolidated Financial Statements for further details on these rates and the effect a rate change to the health care cost trend would have on the Company's results of operations.

Stock Based Compensation: The Company recognizes compensation expense associated with the issuance of equity instruments to employees for their services. Based on the type of equity instrument, the fair value is estimated on the date of grant using either the Black-Scholes option valuation model or a combination of both the Black-Scholes option valuation model and Monte Carlo valuation model, and is expensed in the financial statements over the service period. The input assumptions used in determining fair value are the expected life, expected volatility, risk-free rate and expected dividend yield. For performance share units the fair market value is calculated for each of the three component goals at the date of grant. The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award, discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. See Note 17 to the Consolidated Financial Statements for additional information.

New Accounting Pronouncements

Refer to Note 1 to the Consolidated Financial Statements for recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of December 29, 2019.

Economic and Market Factors

The Company is aware that its products are used in an environment where, for more than a decade, policymakers, consumers and businesses have expressed concerns about the rising cost of health care. In response to these concerns, the Company has a long-standing policy of pricing products responsibly. For the period 2009 - 2019, in the U.S., the weighted average compound annual growth rate of the Company's net price increases for health care products (prescription and over-the-counter drugs, hospital and professional products) was below the U.S. Consumer Price Index (CPI).

The Company operates in certain countries where the economic conditions continue to present significant challenges. The Company continues to monitor these situations and take appropriate actions. Inflation rates continue to have an effect on worldwide economies and, consequently, on the way companies operate. The Company has accounted for operations in Argentina (beginning in the fiscal third quarter of 2018) and Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. This did not have a material impact to the Company's results in the period. In the face of increasing costs, the Company strives to maintain its profit margins through cost reduction programs, productivity improvements and periodic price increases.

In June 2016, the United Kingdom (U.K.) held a referendum in which voters approved an exit from the European Union (E.U.), commonly referred to as "Brexit" and on January 31, 2020, the U.K. formally exited the E.U. Given the lack of comparable precedent, it is unclear what the ultimate financial, trade, regulatory and legal implications the withdrawal of the U.K. from the E.U. will have. Brexit creates global political and economic uncertainty, which may cause, among other consequences, volatility in exchange rates and interest rates, additional cost containment by third-party payors and changes in regulations. However, the Company currently does not believe that these and other related effects will have a material impact on the Company's consolidated financial position or operating results. As of December 29, 2019, the business of the Company's U.K. subsidiaries represented less than 3% of both the Company's consolidated assets and fiscal twelve months revenues, respectively.

The Company is exposed to fluctuations in currency exchange rates. A 1% change in the value of the U.S. Dollar as compared to all foreign currencies in which the Company had sales, income or expense in 2019 would have increased or decreased the translation of foreign sales by approximately $390 million and net income by approximately $120 million.

Governments around the world consider various proposals to make changes to tax laws, which may include increasing or decreasing existing statutory tax rates. A change in statutory tax rate in any country would result in the revaluation of the Company's deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is enacted. This change would result in an expense or benefit recorded to the Company's Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries where it operates. Changes to the statutory tax rate

may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted. For discussion on Federal Act on Tax Reform and AHV Financing (Swiss Tax Reform) see Provision for Taxes on Income in Management's Discussion and Analysis of Financial Condition and Results of Operations.

The Company faces various worldwide health care changes that may continue to result in pricing pressures that include health care cost containment and government legislation relating to sales, promotions and reimbursement of health care products.

Changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing health care insurance coverage, as a result of the current global economic downturn, may continue to impact the Company's businesses.

The Company also operates in an environment increasingly hostile to intellectual property rights. Firms have filed Abbreviated New Drug Applications or Biosimilar Biological Product Applications with the FDA or otherwise challenged the coverage and/or validity of the Company's patents, seeking to market generic or biosimilar forms of many of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the event the Company is not successful in defending the patent claims challenged in the resulting lawsuits, generic or biosimilar versions of the products at issue will be introduced to the market, resulting in the potential for substantial market share and revenue losses for those products, and which may result in a non-cash impairment charge in any associated intangible asset. There is also a risk that one or more competitors could launch a generic or biosimilar version of the product at issue following regulatory approval even though one or more valid patents are in place. For further information, see the discussion on "REMICADE® Related Cases" and "Litigation Against Filers of Abbreviated New Drug Applications" in Note 21 to the Consolidated Financial Statements.

Legal Proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability, intellectual property, commercial and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of business.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of December 29, 2019, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; or there are numerous parties involved. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution of, or increase in accruals for, one or more of these matters in any reporting period may have a material adverse effect on the Company's results of operations and cash flows for that period.

See Note 21 to the Consolidated Financial Statements for further information regarding legal proceedings.

Common Stock

The Company's Common Stock is listed on the New York Stock Exchange under the symbol JNJ. As of February 12, 2020, there were 135,953 record holders of Common Stock of the Company.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The information called for by this item is incorporated herein by reference to "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition - Liquidity and Capital Resources - Financing and Market Risk" of this Report; and Note 1 "Summary of Significant Accounting Policies - Financial Instruments" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Audited Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
At December 29, 2019 and December 30, 2018
(Dollars in Millions Except Share and Per Share Amounts) (Note 1)

		2019	2018
Assets			
Current assets			
Cash and cash equivalents (Notes 1 and 2)	$	17,305	18,107
Marketable securities (Notes 1 and 2)		1,982	1,580
Accounts receivable trade, less allowances for doubtful accounts $226 (2018, $248)		14,481	14,098
Inventories (Notes 1 and 3)		9,020	8,599
Prepaid expenses and other receivables		2,392	2,699
Assets held for sale (Note 20)		94	950
Total current assets		**45,274**	**46,033**
Property, plant and equipment, net (Notes 1 and 4)		17,658	17,035
Intangible assets, net (Notes 1 and 5)		47,643	47,611
Goodwill (Notes 1 and 5)		33,639	30,453
Deferred taxes on income (Note 8)		7,819	7,640
Other assets		5,695	4,182
Total assets	**$**	**157,728**	**152,954**
Liabilities and Shareholders' Equity			
Current liabilities			
Loans and notes payable (Note 7)	$	1,202	2,796
Accounts payable		8,544	7,537
Accrued liabilities		9,715	7,601
Accrued rebates, returns and promotions		10,883	9,380
Accrued compensation and employee related obligations		3,354	3,098
Accrued taxes on income (Note 8)		2,266	818
Total current liabilities		**35,964**	**31,230**
Long-term debt (Note 7)		26,494	27,684
Deferred taxes on income (Note 8)		5,958	7,506
Employee related obligations (Notes 9 and 10)		10,663	9,951
Long-term taxes payable (Note 8)		7,444	8,242
Other liabilities		11,734	8,589
Total liabilities		**98,257**	**93,202**
Commitments and Contingencies (Note 21)			
Shareholders' equity			
Preferred stock — without par value (authorized and unissued 2,000,000 shares)		—	—
Common stock — par value $1.00 per share (Note 12) (authorized 4,320,000,000 shares; issued 3,119,843,000 shares)		3,120	3,120
Accumulated other comprehensive income (loss) (Note 13)		(15,891)	(15,222)
Retained earnings		110,659	106,216
		97,888	94,114
Less: common stock held in treasury, at cost (Note 12) (487,336,000 shares and 457,519,000 shares)		38,417	34,362
Total shareholders' equity		**59,471**	**59,752**
Total liabilities and shareholders' equity	**$**	**157,728**	**152,954**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EARNINGS
(Dollars and Shares in Millions Except Per Share Amounts) (Note 1)

		2019	2018	2017
Sales to customers	$	82,059	81,581	76,450
Cost of products sold		27,556	27,091	25,439
Gross profit		54,503	54,490	51,011
Selling, marketing and administrative expenses		22,178	22,540	21,520
Research and development expense		11,355	10,775	10,594
In-process research and development (Note 5)		890	1,126	408
Interest income		(357)	(611)	(385)
Interest expense, net of portion capitalized (Note 4)		318	1,005	934
Other (income) expense, net		2,525	1,405	(42)
Restructuring (Note 22)		266	251	309
Earnings before provision for taxes on income		17,328	17,999	17,673
Provision for taxes on income (Note 8)		2,209	2,702	16,373
Net earnings	**$**	**15,119**	**15,297**	**1,300**
Net earnings per share (Notes 1 and 15)				
Basic	**$**	**5.72**	**5.70**	**0.48**
Diluted	**$**	**5.63**	**5.61**	**0.47**
Average shares outstanding (Notes 1 and 15)				
Basic		**2,645.1**	**2,681.5**	**2,692.0**
Diluted		**2,684.3**	**2,728.7**	**2,745.3**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Dollars in Millions) (Note 1)

	2019	2018	2017
Net earnings	$ 15,119	15,297	1,300
Other comprehensive income (loss), net of tax			
Foreign currency translation	164	(1,518)	1,696
Securities:			
Unrealized holding gain (loss) arising during period	—	(1)	159
Reclassifications to earnings	—	1	(338)
Net change	—	—	(179)
Employee benefit plans:			
Prior service credit (cost), net of amortization	(18)	(44)	2
Gain (loss), net of amortization	(714)	(56)	29
Effect of exchange rates	(1)	92	(201)
Net change	(733)	(8)	(170)
Derivatives & hedges:			
Unrealized gain (loss) arising during period	(107)	(73)	(4)
Reclassifications to earnings	7	(192)	359
Net change	(100)	(265)	355
Other comprehensive income (loss)	(669)	(1,791)	1,702
Comprehensive income	$ 14,450	13,506	3,002

The tax effects in other comprehensive income for the fiscal years ended 2019, 2018 and 2017 respectively: Foreign Currency Translation; $19 million in 2019 and $236 million in 2018; Securities: $96 million in 2017, Employee Benefit Plans: $222 million, $4 million and $83 million, Derivatives & Hedges: $27 million, $70 million and $191 million.

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY
(Dollars in Millions) (Note 1)

	Total	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Common Stock Issued Amount	Treasury Stock Amount
Balance, January 1, 2017	**$ 70,418**	**110,551**	**(14,901)**	**3,120**	**(28,352)**
Net earnings	1,300	1,300			
Cash dividends paid ($3.32 per share)	(8,943)	(8,943)			
Employee compensation and stock option plans	2,077	(1,079)			3,156
Repurchase of common stock	(6,358)				(6,358)
Other	(36)	(36)			
Other comprehensive income (loss), net of tax	1,702		1,702		
Balance, December 31, 2017	**60,160**	**101,793**	**(13,199)**	**3,120**	**(31,554)**
Cumulative adjustment	(486)	(254) [1]	(232)		
Net earnings	15,297	15,297			
Cash dividends paid ($3.54 per share)	(9,494)	(9,494)			
Employee compensation and stock option plans	1,949	(1,111)			3,060
Repurchase of common stock	(5,868)				(5,868)
Other	(15)	(15)			
Other comprehensive income (loss), net of tax	(1,791)		(1,791)		
Balance, December 30, 2018	**59,752**	**106,216**	**(15,222)**	**3,120**	**(34,362)**
Net earnings	15,119	15,119			
Cash dividends paid ($3.75 per share)	(9,917)	(9,917)			
Employee compensation and stock option plans	1,933	(758)			2,691
Repurchase of common stock	(6,746)				(6,746)
Other	(1)	(1)			
Other comprehensive income (loss), net of tax	(669)		(669)		
Balance, December 29, 2019	**$ 59,471**	**110,659**	**(15,891)**	**3,120**	**(38,417)**

(1) See Note 1 to Consolidated Financial Statements for additional details on the effect of cumulative adjustments to retained earnings.

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Dollars in Millions) (Note 1)

		2019	2018	2017
Cash flows from operating activities				
Net earnings	$	15,119	15,297	1,300
Adjustments to reconcile net earnings to cash flows from operating activities:				
Depreciation and amortization of property and intangibles		7,009	6,929	5,642
Stock based compensation		977	978	962
Asset write-downs		1,096	1,258	795
Gain on sale of assets/businesses		(2,154)	(1,217)	(1,307)
Deferred tax provision		(2,476)	(1,016)	2,406
Accounts receivable allowances		(20)	(31)	17
Changes in assets and liabilities, net of effects from acquisitions and divestitures:				
Increase in accounts receivable		(289)	(1,185)	(633)
(Increase)/Decrease in inventories		(277)	(644)	581
Increase in accounts payable and accrued liabilities		4,060	3,951	2,725
Increase in other current and non-current assets		(1,054)	(275)	(411)
Increase/(Decrease) in other current and non-current liabilities		1,425	(1,844)	8,979
Net cash flows from operating activities		**23,416**	**22,201**	**21,056**
Cash flows from investing activities				
Additions to property, plant and equipment		(3,498)	(3,670)	(3,279)
Proceeds from the disposal of assets/businesses, net		3,265	3,203	1,832
Acquisitions, net of cash acquired (Note 20)		(5,810)	(899)	(35,151)
Purchases of investments		(3,920)	(5,626)	(6,153)
Sales of investments		3,387	4,289	28,117
Proceeds from credit support agreements		338	—	—
Other		44	(464)	(234)
Net cash used by investing activities		**(6,194)**	**(3,167)**	**(14,868)**
Cash flows from financing activities				
Dividends to shareholders		(9,917)	(9,494)	(8,943)
Repurchase of common stock		(6,746)	(5,868)	(6,358)
Proceeds from short-term debt		39	80	869
Repayment of short-term debt		(100)	(2,479)	(1,330)
Proceeds from long-term debt, net of issuance costs		3	5	8,992
Repayment of long-term debt		(2,823)	(1,555)	(1,777)
Proceeds from the exercise of stock options/employee withholding tax on stock awards, net		954	949	1,062
Other		575	(148)	(188)
Net cash used by financing activities		**(18,015)**	**(18,510)**	**(7,673)**
Effect of exchange rate changes on cash and cash equivalents		(9)	(241)	337
(Decrease)/Increase in cash and cash equivalents		(802)	283	(1,148)
Cash and cash equivalents, beginning of year (Note 1)		18,107	17,824	18,972
Cash and cash equivalents, end of year (Note 1)	**$**	**17,305**	**18,107**	**17,824**

Supplemental cash flow data				
Cash paid during the year for:				
Interest	$	995	1,049	960
Interest, net of amount capitalized		925	963	866
Income taxes		4,191	4,570	3,312

Supplemental schedule of non-cash investing and financing activities				
Treasury stock issued for employee compensation and stock option plans, net of cash proceeds/ employee withholding tax on stock awards	$	1,736	2,095	2,062
Conversion of debt		1	6	16
Acquisitions				
Fair value of assets acquired	$	7,228	1,047	36,937
Fair value of liabilities assumed and noncontrolling interests		(1,418)	(148)	(1,786)
Net cash paid for acquisitions (Note 20)	**$**	**5,810**	**899**	**35,151**

See Notes to Consolidated Financial Statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Johnson & Johnson and its subsidiaries (the Company). Intercompany accounts and transactions are eliminated. Columns and rows within tables may not add due to rounding. Percentages have been calculated using actual, non-rounded figures.

Description of the Company and Business Segments

The Company has approximately 132,200 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world and its primary focus is on products related to human health and well-being.

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. The Consumer segment includes a broad range of products used in the baby care, oral care, beauty, over-the-counter pharmaceutical, women's health and wound care markets. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on six therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, pulmonary hypertension, and cardiovascular and metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, interventional solutions (cardiovascular and neurovascular) and eye health fields, which are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

New Accounting Standards

Recently Adopted Accounting Standards

ASU 2016-02: Leases

The Company adopted this standard as of the beginning of fiscal year 2019, on a prospective basis. This update requires the recognition of lease assets and lease liabilities on the balance sheet for all lease obligations and disclosing key information about leasing arrangements. This update requires the recognition of lease assets and lease liabilities by lessees for arrangements that are classified as operating leases. The Company's operating leases resulted in the recognition of additional assets and the corresponding liabilities on its Consolidated Balance Sheet, however it did not have a material impact on the consolidated financial statements.

The Company determines whether an arrangement is a lease at contract inception by establishing if the contract conveys the right to control the use of identified property, plant, or equipment for a period of time in exchange for consideration.

Right of Use (ROU) Assets and Lease Liabilities for operating leases are included in Other assets, Accrued liabilities, and Other liabilities on the consolidated balance sheet. The ROU Assets represent the right to use an underlying asset for the lease term and lease liabilities represent an obligation to make lease payments arising from the lease. Commitments under finance leases are not significant, and are included in Property, plant and equipment, Loans and notes payable, and Long-term debt on the consolidated balance sheet.

ROU Assets and Lease Liabilities are recognized at the lease commencement date based on the present value of all minimum lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments, when the implicit rate is not readily determinable. Lease terms may include options to extend or terminate the lease. These options are included in the lease term when it is reasonably certain that the Company will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term.

The Company has elected the following policy elections on adoption: use of portfolio approach on leases of assets under master service agreements, exclusion of short term leases on the balance sheet, and not separating lease and non-lease components.

For additional disclosures see Note 16 to the Consolidated Financial Statements.

ASU 2018-02: Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income

This update allows a Company to elect to reclassify stranded tax effects resulting from the Tax Cuts and Job Act enacted in December 2017 from accumulated other comprehensive income to retained earnings. The Company has elected not to reclassify the income tax effects of this standard and therefore this standard will not impact the Company's consolidated financial statements.

ASU 2018-16: Derivatives and Hedging (Topic ASC 815)
This update adds the Overnight Index Swap (OIS) rate based on the Secured Overnight Financing Rate (SOFR) as an eligible benchmark interest rate permitted in the application of hedge accounting. The guidance was effective for the Company as of the fiscal fourth quarter of 2018, due to the previous adoption of ASU 2017-12. The impact of the adoption of this guidance did not have a material impact on the Company's consolidated financial statements and related disclosures. The standard may have an impact in the future as the market for SOFR derivatives develops over time and if SOFR is used to hedge the Company's financial instruments.

Accounting Standards adopted in the fiscal 2018 with a cumulative effect to the 2018 opening balance of Retained Earnings
The following table summarizes the cumulative effect adjustments made to the 2018 opening balance of retained earnings upon adoption of the new accounting standards mentioned below:

(Dollars in Millions)	Cumulative Effect Adjustment Increase (Decrease) to Retained Earnings
ASU 2014-09 - Revenue from Contracts with Customers	$ (47)
ASU 2016-01 - Financial Instruments	232
ASU 2016-16 - Income Taxes: Intra-Entity Transfers	(439)
Total	$ (254)

Recently Issued Accounting Standards
Not Adopted as of December 29, 2019
ASU 2018-18: Collaborative Arrangements
This update clarifies the interaction between ASC 808, Collaborative Arrangements and ASC 606, Revenue from Contracts with Customers. The update clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer. In addition, the update precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue if the counterparty is not a customer for that transaction. This update will be effective for the Company for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. ASU 2018-18 should be applied retrospectively to the date of initial application of ASC 606 and early adoption is permitted. The adoption of this standard will not have a material impact on the Company's consolidated financial statements.

ASU 2016-13: Financial Instruments - Credit Losses
This update introduces the current expected credit loss (CECL) model, which will require an entity to measure credit losses for certain financial instruments and financial assets, including trade receivables. Under this update, on initial recognition and at each reporting period, an entity will be required to recognize an allowance that reflects the entity's current estimate of credit losses expected to be incurred over the life of the financial instrument. This update will be effective for the Company for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. Early adoption is permitted. The adoption of this standard will not have a material impact on the Company's consolidated financial statements.

Cash Equivalents
The Company classifies all highly liquid investments with stated maturities of three months or less from date of purchase as cash equivalents and all highly liquid investments with stated maturities of greater than three months from the date of purchase as current marketable securities. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating. The Company invests its cash primarily in government securities and obligations, corporate debt securities, money market funds and reverse repurchase agreements (RRAs).

RRAs are collateralized by deposits in the form of Government Securities and Obligations for an amount not less than 102% of their value. The Company does not record an asset or liability as the Company is not permitted to sell or repledge the associated collateral. The Company has a policy that the collateral has at least an A (or equivalent) credit rating. The Company utilizes a third party custodian to manage the exchange of funds and ensure that collateral received is maintained at 102% of the value of the RRAs on a daily basis. RRAs with stated maturities of greater than three months from the date of purchase are classified as marketable securities.

Investments

Investments classified as held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings. Investments classified as available-for-sale debt securities are carried at estimated fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income. Available-for-sale securities available for current operations are classified as current assets otherwise, they are classified as long term. Management determines the appropriate classification of its investment in debt and equity securities at the time of purchase and re-evaluates such determination at each balance sheet date. The Company reviews its investments for impairment and adjusts these investments to fair value through earnings, as required.

Property, Plant and Equipment and Depreciation

Property, plant and equipment are stated at cost. The Company utilizes the straight-line method of depreciation over the estimated useful lives of the assets:

Building and building equipment	20 - 30 years
Land and leasehold improvements	10 - 20 years
Machinery and equipment	2 - 13 years

The Company capitalizes certain computer software and development costs, included in machinery and equipment, when incurred in connection with developing or obtaining computer software for internal use. Capitalized software costs are amortized over the estimated useful lives of the software, which generally range from 3 to 8 years.

The Company reviews long-lived assets to assess recoverability using undiscounted cash flows. When certain events or changes in operating or economic conditions occur, an impairment assessment may be performed on the recoverability of the carrying value of these assets. If the asset is determined to be impaired, the loss is measured based on the difference between the asset’s fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows.

Revenue Recognition

The Company recognizes revenue from product sales when obligations under the terms of a contract with the customer are satisfied; generally, this occurs with the transfer of control of the goods to customers. The Company's global payment terms are typically between 30 to 90 days. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns and discounts to customers are accounted for as variable consideration and recorded as a reduction in sales. The liability is recognized within Accrued Rebates, Returns, and Promotions on the consolidated balance sheet.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including consideration of competitor pricing. Rebates are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. A significant portion of the liability related to rebates is from the sale of the Company's pharmaceutical products within the U.S., primarily the Managed Care, Medicare and Medicaid programs, which amounted to $7.0 billion and $5.8 billion as of December 29, 2019 and December 30, 2018, respectively. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns are estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales return accruals.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The sales returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company’s accounting policies, the Company generally issues credit to customers for returned goods. The Company’s sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual net trade sales during the fiscal reporting years 2019, 2018 and 2017.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the same period as related sales. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue. The Company also earns profit-share payments through collaborative arrangements for certain products, which are included in

sales to customers. For all years presented, profit-share payments were approximately 2.0% of the total revenues and are included in sales to customers.

See Note 18 to the Consolidated Financial Statements for further disaggregation of revenue.

Shipping and Handling
Shipping and handling costs incurred were $1.0 billion, $1.1 billion and $1.0 billion in 2019, 2018 and 2017, respectively, and are included in selling, marketing and administrative expense. The amount of revenue received for shipping and handling is less than 0.5% of sales to customers for all periods presented.

Inventories
Inventories are stated at the lower of cost or net realizable value determined by the first-in, first-out method.

Intangible Assets and Goodwill
The authoritative literature on U.S. GAAP requires that goodwill and intangible assets with indefinite lives be assessed annually for impairment. The Company completed its annual impairment test for 2019 in the fiscal fourth quarter. Future impairment tests will be performed annually in the fiscal fourth quarter, or sooner if warranted. Purchased in-process research and development is accounted for as an indefinite lived intangible asset until the underlying project is completed, at which point the intangible asset will be accounted for as a definite lived intangible asset, or abandoned, at which point the intangible asset will be written off or partially impaired.

Intangible assets that have finite useful lives continue to be amortized over their useful lives, and are reviewed for impairment when warranted by economic conditions. See Note 5 for further details on Intangible Assets and Goodwill.

Financial Instruments
As required by U.S. GAAP, all derivative instruments are recorded on the balance sheet at fair value. Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value, with Level 1 having the highest priority and Level 3 having the lowest. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The Company documents all relationships between hedged items and derivatives. The overall risk management strategy includes reasons for undertaking hedge transactions and entering into derivatives. The objectives of this strategy are: (1) minimize foreign currency exposure's impact on the Company's financial performance; (2) protect the Company's cash flow from adverse movements in foreign exchange rates; (3) ensure the appropriateness of financial instruments; and (4) manage the enterprise risk associated with financial institutions. See Note 6 for additional information on Financial Instruments.

Product Liability
Accruals for product liability claims are recorded, on an undiscounted basis, when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated based on existing information and actuarially determined estimates where applicable. The accruals are adjusted periodically as additional information becomes available. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated.

Research and Development
Research and development expenses are expensed as incurred in accordance with ASC 730, Research and Development. Upfront and milestone payments made to third parties in connection with research and development collaborations are expensed as incurred up to the point of regulatory approval. Payments made to third parties subsequent to regulatory approval are capitalized and amortized over the remaining useful life of the related product. Amounts capitalized for such payments are included in other intangibles, net of accumulated amortization.

The Company enters into collaborative arrangements, typically with other pharmaceutical or biotechnology companies, to develop and commercialize drug candidates or intellectual property. These arrangements typically involve two (or more) parties who are active participants in the collaboration and are exposed to significant risks and rewards dependent on the commercial success of the activities. These collaborations usually involve various activities by one or more parties, including research and development, marketing and selling and distribution. Often, these collaborations require upfront, milestone and royalty or profit

share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development. Amounts due from collaborative partners related to development activities are generally reflected as a reduction of research and development expense because the performance of contract development services is not central to the Company's operations. In general, the income statement presentation for these collaborations is as follows:

Nature/Type of Collaboration	Statement of Earnings Presentation
Third-party sale of product & profit share payments received	Sales to customers
Royalties/milestones paid to collaborative partner (post-regulatory approval)*	Cost of products sold
Royalties received from collaborative partner	Other income (expense), net
Upfront payments & milestones paid to collaborative partner (pre-regulatory approval)	Research and development expense
Research and development payments to collaborative partner	Research and development expense
Research and development payments received from collaborative partner	Reduction of Research and development expense

* Milestones are capitalized as intangible assets and amortized to cost of products sold over the useful life.

For all years presented, there was no individual project that represented greater than 5% of the total annual consolidated research and development expense.

The Company has a number of products and compounds developed in collaboration with strategic partners including XARELTO®, co-developed with Bayer HealthCare AG and IMBRUVICA®, developed in collaboration and co-marketed with Pharmacyclics LLC, an AbbVie company.

Separately, the Company has a number of licensing arrangements for products and compounds including DARZALEX®, licensed from Genmab A/S.

Advertising

Costs associated with advertising are expensed in the year incurred and are included in selling, marketing and administrative expenses. Advertising expenses worldwide, which comprised television, radio, print media and Internet advertising, were $2.2 billion, $2.6 billion and $2.5 billion in 2019, 2018 and 2017, respectively.

Income Taxes

Income taxes are recorded based on amounts refundable or payable for the current year and include the results of any difference between U.S. GAAP accounting and tax reporting, recorded as deferred tax assets or liabilities. The Company estimates deferred tax assets and liabilities based on enacted tax regulations and rates. Future changes in tax laws and rates may affect recorded deferred tax assets and liabilities in the future.

The Company has unrecognized tax benefits for uncertain tax positions. The Company follows U.S. GAAP which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Management believes that changes in these estimates would not have a material effect on the Company's results of operations, cash flows or financial position.

In January 2018, the FASB issued guidance that allows companies to elect as an accounting policy whether to record the tax effects of the global intangible low-taxed income (GILTI) in the period the tax liability is generated (i.e., "period cost") or provide for deferred tax assets and liabilities related to basis differences that exist and are expected to effect the amount of GILTI inclusion in future years upon reversal (i.e., "deferred method"). In fiscal 2018, the Company elected to account for GILTI under the deferred method. The deferred tax amounts recorded are based on the evaluation of temporary differences that are expected to reverse as GILTI is incurred in future periods.

The Company has recorded deferred tax liabilities on all undistributed earnings prior to December 31, 2017 from its international subsidiaries. The Company has not provided deferred taxes on the undistributed earnings subsequent to January 1, 2018 from certain international subsidiaries where the earnings are considered to be indefinitely reinvested. The Company intends to continue to reinvest these earnings in those international operations. If the Company decides at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company estimates that the total tax effect of this repatriation would be approximately $0.8 billion under current enacted tax laws and regulations and at current currency exchange rates.

See Note 8 to the Consolidated Financial Statements for further information regarding income taxes.

Net Earnings Per Share
Basic earnings per share is computed by dividing net earnings available to common shareholders by the weighted average number of common shares outstanding for the period. Diluted earnings per share reflects the potential dilution that could occur if securities were exercised or converted into common stock using the treasury stock method.

Use of Estimates
The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the amounts reported. Estimates are used when accounting for sales discounts, rebates, allowances and incentives, product liabilities, income taxes, withholding taxes, depreciation, amortization, employee benefits, contingencies and intangible asset and liability valuations. Actual results may or may not differ from those estimates.

The Company follows the provisions of U.S. GAAP when recording litigation related contingencies. A liability is recorded when a loss is probable and can be reasonably estimated. The best estimate of a loss within a range is accrued; however, if no estimate in the range is better than any other, the minimum amount is accrued.

Annual Closing Date
The Company follows the concept of a fiscal year, which ends on the Sunday nearest to the end of the month of December. Normally each fiscal year consists of 52 weeks, but every five or six years the fiscal year consists of 53 weeks, and therefore includes additional shipping days, as was the case in 2015, and will be the case again in 2020.

Reclassification
Certain prior period amounts have been reclassified to conform to current year presentation.

2. Cash, Cash Equivalents and Current Marketable Securities
At the end of the fiscal year 2019 and 2018, cash, cash equivalents and current marketable securities were comprised of:

(Dollars in Millions)	2019		
	Carrying Amount	Cash & Cash Equivalents	Current Marketable Securities
Cash	$ 2,637	2,637	—
Non-U.S. Sovereign Securities[1]	439	149	290
U.S. Reverse repurchase agreements	6,375	6,375	—
Other Reverse repurchase agreements	375	375	—
Corporate debt securities[1]	1,323	889	434
Money market funds	2,864	2,864	—
Time deposits[1]	906	906	—
Subtotal	$ 14,919	14,195	724
U.S. Gov't Securities	$ 4,102	3,095	1,007
Corporate debt securities	266	15	251
Subtotal available for sale[2]	$ 4,368	3,110	1,258
Total cash, cash equivalents and current marketable securities		**$ 17,305**	**1,982**

(Dollars in Millions)	2018		
	Carrying Amount	Cash & Cash Equivalents	Current Marketable Securities
Cash	$ 2,619	2,619	—
U.S. Reverse repurchase agreements	3,009	3,009	—
Other Reverse repurchase agreements	443	443	—
Money market funds	3,397	3,397	—
Time deposits[1]	485	485	—
Subtotal	$ 9,953	9,953	—
Gov't Securities	$ 9,474	8,144	1,330
Corporate debt securities	260	10	250
Subtotal available for sale[2]	$ 9,734	8,154	1,580
Total cash, cash equivalents and current marketable securities		**$ 18,107**	**1,580**

[1] Held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings.
[2] Available for sale debt securities are reported at fair value with unrealized gains and losses reported net of taxes in other comprehensive income.

Fair value of government securities and obligations and corporate debt securities were estimated using quoted broker prices and significant other observable inputs.
In 2019 and 2018, the carrying amount was the same as the estimated fair value.

The contractual maturities of the available for sale debt securities at December 29, 2019 are as follows:

(Dollars in Millions)	Cost Basis	Fair Value
Due within one year	$ 4,322	4,322
Due after one year through five years	46	46
Due after five years through ten years	—	—
Total debt securities	$ 4,368	4,368

The Company invests its excess cash in both deposits with major banks throughout the world and other high-quality money market instruments. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating.

3. Inventories

At the end of 2019 and 2018, inventories were comprised of:

(Dollars in Millions)	2019	2018
Raw materials and supplies	$ 1,117	1,114
Goods in process	1,832	2,109
Finished goods	6,071	5,376
Total inventories [1]	**$ 9,020**	**8,599**

[1] See Note 20 to the Consolidated Financial Statements for details on assets held for sale and the related divestitures.

4. Property, Plant and Equipment

At the end of 2019 and 2018, property, plant and equipment at cost and accumulated depreciation were:

(Dollars in Millions)	2019	2018
Land and land improvements	$ 854	807
Buildings and building equipment	11,877	11,176
Machinery and equipment	26,964	25,992
Construction in progress	3,637	3,876
Total property, plant and equipment, gross	$ 43,332	41,851
Less accumulated depreciation	25,674	24,816
Total property, plant and equipment, net[1]	**$ 17,658**	**17,035**

[1] See Note 20 to the Consolidated Financial Statements for details on assets held for sale and the related divestitures.

The Company capitalizes interest expense as part of the cost of construction of facilities and equipment. Interest expense capitalized in 2019, 2018 and 2017 was $70 million, $86 million and $94 million, respectively.

Depreciation expense, including the amortization of capitalized interest in 2019, 2018 and 2017 was $2.5 billion, $2.6 billion and $2.6 billion, respectively.

Upon retirement or other disposal of property, plant and equipment, the costs and related amounts of accumulated depreciation or amortization are eliminated from the asset and accumulated depreciation accounts, respectively. The difference, if any, between the net asset value and the proceeds are recorded in earnings.

5. Intangible Assets and Goodwill

At the end of 2019 and 2018, the gross and net amounts of intangible assets were:

(Dollars in Millions)	2019	2018
Intangible assets with definite lives:		
Patents and trademarks — gross	$ 36,634	35,194
Less accumulated amortization	13,154	9,784
Patents and trademarks — net	**$ 23,480**	**25,410**
Customer relationships and other intangibles — gross	$ 22,056	21,334
Less accumulated amortization	9,462	8,323
Customer relationships and other intangibles — net*	**$ 12,594**	**13,011**
Intangible assets with indefinite lives:		
Trademarks	$ 6,922	6,937
Purchased in-process research and development[1]	4,647	2,253
Total intangible assets with indefinite lives	**$ 11,569**	**9,190**
Total intangible assets — net	**$ 47,643**	**47,611**

*The majority is comprised of customer relationships

[1] In the fiscal year 2019, the Company completed the acquisition of Auris Health, Inc. and recorded an in-process research and development intangible asset of $2.9 billion. Additionally, in the fiscal first quarter of 2019, the Company recorded an IPR&D impairment charge of $0.9 billion for the remaining intangible asset value related to the development program of AL-8176, an investigational drug for the treatment of Respiratory Syncytial Virus (RSV) and human metapneumovirus (hMPV) acquired with the 2014 acquisition of Alios Biopharma Inc. The impairment charge was based on additional information, including clinical data, which became available and led to the Company's decision to abandon the development of AL-8176. A partial impairment charge of $0.8 billion was previously recorded in the fiscal third quarter 2018 related to the development program of AL-8176.

Goodwill as of December 29, 2019 and December 30, 2018, as allocated by segment of business, was as follows:

(Dollars in Millions)	Consumer	Pharmaceutical	Medical Devices	Total
Goodwill at December 31, 2017	$ 8,875	9,109	13,922	31,906
Goodwill, related to acquisitions	168	51	184	403
Goodwill, related to divestitures	—	—	(1,348) [1]	(1,348)
Currency translation/other	(373)	(97)	(38)	(508)
Goodwill at December 30, 2018	$ 8,670	9,063	12,720	30,453
Goodwill, related to acquisitions	1,188	75	2,018	3,281
Currency translation/other	(122)	31	(4)	(95)
Goodwill at December 29, 2019	**$ 9,736**	**9,169**	**14,734**	**33,639**

[1] Goodwill of $1.0 billion is related to the divestiture of the LifeScan business. Goodwill of $0.3 billion is related to the divestiture of the Advanced Sterilization Products business which closed in 2019, and was pending and classified as assets held for sale on the Consolidated Balance Sheet as of December 30, 2018.

The weighted average amortization period for patents and trademarks is 12 years. The weighted average amortization period for customer relationships and other intangible assets is 21 years. The amortization expense of amortizable assets included in cost of products sold was $4.5 billion, $4.4 billion and $3.0 billion before tax, for the fiscal years ended December 29, 2019, December 30, 2018 and December 31, 2017, respectively. Intangible asset write-downs are included in Other (income) expense, net.

The estimated amortization expense for approved products, before tax, for the five succeeding years is approximately:

(Dollars in Millions)				
2020	**2021**	**2022**	**2023**	**2024**
$4,500	4,300	4,100	4,100	4,000

See Note 20 to the Consolidated Financial Statements for additional details related to acquisitions and divestitures.

6. Fair Value Measurements

The Company uses forward foreign exchange contracts to manage its exposure to the variability of cash flows, primarily related to the foreign exchange rate changes of future intercompany products and third-party purchases of materials denominated in a foreign currency. The Company uses cross currency interest rate swaps to manage currency risk primarily related to borrowings. Both types of derivatives are designated as cash flow hedges.

Additionally, the Company uses interest rate swaps as an instrument to manage interest rate risk related to fixed rate borrowings. These derivatives are designated as fair value hedges. The Company uses cross currency interest rate swaps and forward foreign exchange contracts designated as net investment hedges. Additionally, the Company uses forward foreign exchange contracts to offset its exposure to certain foreign currency assets and liabilities. These forward foreign exchange contracts are not designated as hedges and therefore, changes in the fair values of these derivatives are recognized in earnings, thereby offsetting the current earnings effect of the related foreign currency assets and liabilities.

The Company does not enter into derivative financial instruments for trading or speculative purposes, or that contain credit risk related contingent features. The Company maintains credit support agreements (CSA) with certain derivative counterparties establishing collateral thresholds based on respective credit ratings and netting agreements. As of December 29, 2019, the total amount of cash collateral held by the Company under the credit support agreements (CSA) amounted to $255 million net, primarily related to net investment hedges. On an ongoing basis, the Company monitors counter-party credit ratings. The Company considers credit non-performance risk to be low, because the Company primarily enters into agreements with commercial institutions that have at least an investment grade credit rating. Refer to the table on significant financial assets and liabilities measured at fair value contained in this footnote for receivables and payables with these commercial institutions. As of December 29, 2019, the Company had notional amounts outstanding for forward foreign exchange contracts, and cross currency interest rate swaps of $45.3 billion, and $20.1 billion respectively. As of December 30, 2018, the Company

had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of $41.1 billion, $7.5 billion, and $0.5 billion respectively.

All derivative instruments are recorded on the balance sheet at fair value. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The designation as a cash flow hedge is made at the entrance date of the derivative contract. At inception, all derivatives are expected to be highly effective. Foreign exchange contracts designated as cash flow hedges are accounted for under the forward method and all gains/losses associated with these contracts will be recognized in the income statement when the hedged item impacts earnings. Changes in the fair value of these derivatives are recorded in accumulated other comprehensive income until the underlying transaction affects earnings, and are then reclassified to earnings in the same account as the hedged transaction.

Gains and losses associated with interest rate swaps and changes in fair value of hedged debt attributable to changes in interest rates are recorded to interest expense in the period in which they occur. The effect of which are immaterial for the fiscal years ended December 29, 2019 and December 30, 2018. Gains and losses on net investment hedge are accounted through the currency translation account within accumulated other comprehensive income. The portion excluded from effectiveness testing is recorded through interest (income) expense using the spot method. On an ongoing basis, the Company assesses whether each derivative continues to be highly effective in offsetting changes of hedged items. If and when a derivative is no longer expected to be highly effective, hedge accounting is discontinued.

The Company designated its Euro denominated notes issued in May 2016 with due dates ranging from 2022 to 2035 as a net investment hedge of the Company's investments in certain of its international subsidiaries that use the Euro as their functional currency in order to reduce the volatility caused by changes in exchange rates.

As of December 29, 2019, the balance of deferred net loss on derivatives included in accumulated other comprehensive income was $295 million after-tax. For additional information, see the Consolidated Statements of Comprehensive Income and Note 13. The Company expects that substantially all of the amounts related to forward foreign exchange contracts will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months, excluding interest rate contracts, net investment hedges. The amount ultimately realized in earnings may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity of the derivative.

The following table is a summary of the activity related to derivatives and hedges for the fiscal years ended December 29, 2019 and December 30, 2018, net of tax:

	December 29, 2019					December 30, 2018				
(Dollars in Millions)	Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense	Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense
The effects of fair value, net investment and cash flow hedging:										
Gain (Loss) on net investment hedging relationship:										
Cross currency interest rate swaps contracts:										
Amount of gain or (loss) recognized in income on derivative amount excluded from effectiveness testing	—	—	—	159	—	—	—	—	56	—
Amount of gain or (loss) recognized in AOCI	—	—	—	159	—	—	—	—	56	—
Gain (Loss) on cash flow hedging relationship:										
Forward foreign exchange contracts:										
Amount of gain or (loss) reclassified from AOCI into income	(54)	(321)	(105)	—	22	47	200	(220)	—	(24)
Amount of gain or (loss) recognized in AOCI	(20)	(606)	(94)	—	39	(32)	(17)	(193)	—	(4)
Cross currency interest rate swaps contracts:										
Amount of gain or (loss) reclassified from AOCI into income	—	—	—	292	—	—	—	—	133	—
Amount of gain or (loss) recognized in AOCI	$ —	—	—	415	—	—	—	—	117	—

For the fiscal years ended December 29, 2019 and December 30, 2018, the following amounts were recorded on the Consolidated Balance Sheet

Line item in the Consolidated Balance Sheet in which the hedged item is included	**Carrying Amount of the Hedged Liability**		**Cumulative Amount of Fair Value Hedging Adjustment Included in the Carrying Amount of the Hedged Liability**	
(Dollars in Millions)	December 29, 2019	December 30, 2018	December 29, 2019	December 30, 2018
Current Portion of Long-term Debt	$ —	494	—	5

The following table is the effect of derivatives not designated as hedging instrument for the fiscal years ended December 29, 2019 and December 30, 2018:

(Dollars in Millions)	Location of Gain /(Loss) Recognized in Income on Derivative	Gain/(Loss) Recognized In Income on Derivative	
Derivatives Not Designated as Hedging Instruments		December 29, 2019	December 30, 2018
Foreign Exchange Contracts	Other (income) expense	(144)	(68)

The following table is the effect of net investment hedges for the fiscal years ended December 29, 2019 and December 30, 2018:

	Gain/(Loss) Recognized In Accumulated OCI		Location of Gain or (Loss) Reclassified from Accumulated Other Comprehensive Income Into Income	Gain/(Loss) Reclassified From Accumulated OCI Into Income	
(Dollars in Millions)	December 29, 2019	December 30, 2018		December 29, 2019	December 30, 2018
Debt	$ 121	218	Interest (income) expense	—	—
Cross Currency interest rate swaps	$ 488	150	Interest (income) expense	—	—

The Company holds equity investments with readily determinable fair values and equity investments without readily determinable fair values. The Company measures equity investments that do not have readily determinable fair values at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer.

The following table is a summary of the activity related to equity investments for the fiscal years ended December 29, 2019 and December 30, 2018:

	December 30, 2018			December 29, 2019	
(Dollars in Millions)	Carrying Value	Changes in Fair Value Reflected in Net Income [1]	Sales/ Purchases/Other[2]	Carrying Value	Non Current Other Assets
Equity Investments with readily determinable value	$ 511	533	104	1,148	1,148
Equity Investments without readily determinable value	$ 681	(38)	69	712	712

	December 31, 2017			December 30, 2018	
(Dollars in Millions)	Carrying Value	Changes in Fair Value Reflected in Net Income [1]	Sales/ Purchases/Other[2]	Carrying Value	Non Current Other Assets
Equity Investments with readily determinable value	$ 751	(247)	7	511	511
Equity Investments without readily determinable value	$ 510	13	158	681	681

[1] Recorded in Other Income/Expense
[2] Other includes impact of currency

For the fiscal years ended December 29, 2019 and December 30, 2018 for equity investments without readily determinable market values, $57 million and $54 million respectively, of the changes in fair value reflected in net income were the result of impairments. There were $19 million and $67 million respectively, of changes in fair value reflected in net income due to changes in observable prices.

Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. In accordance with ASC 820, a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described below with Level 1 having the highest priority and Level 3 having the lowest.

The fair value of a derivative financial instrument (i.e., forward foreign exchange contracts, interest rate contracts) is the aggregation by currency of all future cash flows discounted to its present value at the prevailing market interest rates and subsequently converted to the U.S. Dollar at the current spot foreign exchange rate. The Company does not believe that fair values of these derivative instruments materially differ from the amounts that could be realized upon settlement or maturity, or that the changes in fair value will have a material effect on the Company's results of operations, cash flows or financial position. The Company also holds equity investments which are classified as Level 1 and debt securities which are classified as Level 2. The Company holds acquisition related contingent liabilities based upon certain regulatory and commercial events, which are classified as Level 3, whose values are determined using discounted cash flow methodologies or similar techniques for which the determination of fair value requires significant judgment or estimations.

The following three levels of inputs are used to measure fair value:

Level 1 — Quoted prices in active markets for identical assets and liabilities.

Level 2 — Significant other observable inputs.

Level 3 — Significant unobservable inputs.

The Company's significant financial assets and liabilities measured at fair value as of the fiscal year ended December 29, 2019 and December 30, 2018 were as follows:

	2019				2018
(Dollars in Millions)	**Level 1**	**Level 2**	**Level 3**	**Total**	**Total [1]**
Derivatives designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	$ —	209	—	209	501
Interest rate contracts [2][4]	—	693	—	693	161
Total	—	**902**	—	**902**	**662**
Liabilities:					
Forward foreign exchange contracts	—	426	—	426	548
Interest rate contracts [3][4]	—	193	—	193	292
Total	—	**619**	—	**619**	**840**
Derivatives not designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	—	23	—	23	32
Liabilities:					
Forward foreign exchange contracts	—	33	—	33	32
Available For Sale Other Investments:					
Equity investments[5]	1,148	—	—	1,148	511
Debt securities[6]	$ —	4,368	—	4,368	9,734
Other Liabilities					
Contingent Consideration[7]			1,715	1,715	397

Gross to Net Derivative Reconciliation		2019	2018
(Dollars in Millions)			
Total Gross Assets	$	925	694
Credit Support Agreement (CSA)		(841)	(423)
Total Net Asset		84	271
Total Gross Liabilities		652	872
Credit Support Agreement (CSA)		(586)	(605)
Total Net Liabilities	$	66	267

Summarized information about changes in liabilities for contingent consideration is as follows:

	2019	2018	2017
(Dollars in Millions)			
Beginning Balance	397	600	378
Changes in estimated fair value [8]	151	(156)	87
Additions	1,246	125	160
Payments	(79)	(172)	(25)
Ending Balance	1,715	397	600

(1) 2018 assets and liabilities are all classified as Level 2 with the exception of equity investments of $511 million, which are classified as Level 1 and contingent consideration of $397 million, classified as Level 3.
(2) Includes $1 million and $6 million of non-current assets for the fiscal years ending December 29, 2019 and December 30, 2018, respectively.
(3) Includes $3 million of non-current liabilities for the fiscal years ending December 30, 2018.
(4) Includes cross currency interest rate swaps and interest rate swaps.
(5) Classified as non-current other assets.
(6) Classified as cash equivalents and current marketable securities.
(7) Includes $1,631 million (primarily related to Auris Health), $397 million and $600 million, classified as non-current other liabilities as of December 29, 2019, December 30, 2018 and December 31, 2017 respectively. Includes $84 million classified as current liabilities as of December 29, 2019.
(8) Amounts are recorded primarily in Research and Development expense.

See Notes 2 and 7 for financial assets and liabilities held at carrying amount on the Consolidated Balance Sheet.

7. Borrowings

The components of long-term debt are as follows:

(Dollars in Millions)	2019	Effective Rate %	2018	Effective Rate %
4.75% Notes due 2019 (1B Euro 1.1096)[2]/(1B Euro 1.14)[3]	$ —	—	1,139 [2]	5.83
1.875% Notes due 2019	—	—	494	1.93
0.89% Notes due 2019	—	—	300	1.32
1.125% Notes due 2019	—	—	699	1.13
3% Zero Coupon Convertible Subordinated Debentures due 2020	51	3.00	51	3.00
2.95% Debentures due 2020	549	3.15	548	3.15
1.950% Notes due 2020	500	1.99	499	1.99
3.55% Notes due 2021	449	3.67	449	3.67
2.45% Notes due 2021	349	2.48	349	2.48
1.65% Notes due 2021	999	1.65	998	1.65
0.250% Notes due 2022 (1B Euro 1.1096)[2]/(1B Euro 1.14)[3]	1,108 [2]	0.26	1,137 [3]	0.26
2.25% Notes due 2022	998	2.31	996	2.31
6.73% Debentures due 2023	250	6.73	250	6.73
3.375% Notes due 2023	804	3.17	805	3.17
2.05% Notes due 2023	498	2.09	498	2.09
0.650% Notes due 2024 (750MM Euro 1.1096)[2]/(750MM Euro 1.14)[3]	829 [2]	0.68	851 [3]	0.68
5.50% Notes due 2024 (500MM GBP 1.2987)[2]/(500MM GBP 1.2636)[3]	645 [2]	6.75	627 [3]	6.75
2.625% Notes due 2025	748	2.63	748	2.63
2.45% Notes due 2026	1,993	2.47	1,992	2.47
2.95% Notes due 2027	996	2.96	996	2.96
1.150% Notes due 2028 (750MM Euro 1.1096)[2]/(750MM Euro 1.14)[3]	825 [2]	1.21	847 [3]	1.21
2.900% Notes due 2028	1,494	2.91	1,493	2.91
6.95% Notes due 2029	297	7.14	297	7.14
4.95% Debentures due 2033	498	4.95	498	4.95
4.375% Notes due 2033	855	4.24	856	4.24
1.650% Notes due 2035 (1.5B Euro 1.1096)[2]/(1.5B Euro 1.14)[3]	1,649 [2]	1.68	1,693 [3]	1.68
3.55% Notes due 2036	989	3.59	988	3.59
5.95% Notes due 2037	992	5.99	991	5.99
3.625% Notes due 2037	1,487	3.64	1,486	3.64
5.85% Debentures due 2038	696	5.85	696	5.85
3.400% Notes due 2038	991	3.42	990	3.42
4.50% Debentures due 2040	539	4.63	538	4.63
4.85% Notes due 2041	297	4.89	297	4.89
4.50% Notes due 2043	495	4.52	495	4.52
3.70% Notes due 2046	1,973	3.74	1,972	3.74
3.75% Notes due 2047	991	3.76	991	3.76
3.500% Notes due 2048	742	3.52	742	3.52
Other	18	—	24	—

Subtotal	**27,594** [4]	**3.19%** [1]	**30,320** [4]	**3.19** [1]
Less current portion	1,100		2,636	
Total long-term debt	**$ 26,494**		**27,684**	

(1) Weighted average effective rate.
(2) Translation rate at December 29, 2019.
(3) Translation rate at December 30, 2018.
(4) The excess of the fair value over the carrying value of debt was $3.0 billion in 2019 and $0.3 billion in 2018.

Fair value of the long-term debt was estimated using market prices, which were corroborated by quoted broker prices and significant other observable inputs.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2019, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 10, 2020. Interest charged on borrowings under the credit line agreements is based on either bids provided by banks, the prime rate, London Interbank Offered Rates (LIBOR) or other applicable market rate as allowed under the terms of the agreement, plus applicable margins. Commitment fees under the agreements are not material.

Throughout 2019, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $1.2 billion at the end of 2019, of which $1.1 billion is the current portion of the long-term debt, and the remainder principally represents local borrowing by international subsidiaries.

Throughout 2018, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $2.8 billion at the end of 2018, of which $2.6 billion is the current portion of the long term debt, and the remainder principally represents local borrowing by international subsidiaries.

Aggregate maturities of long-term debt obligations commencing in 2020 are:

(Dollars in Millions)

2020	2021	2022	2023	2024	After 2024
$1,100	1,797	2,106	1,552	1,474	19,565

8. Income Taxes

The provision for taxes on income consists of:

(Dollars in Millions)	2019	2018	2017
Currently payable:			
U.S. taxes	$ 1,941	1,284	12,095
International taxes	2,744	2,434	1,872
Total currently payable	4,685	3,718	13,967
Deferred:			
U.S. taxes	(814)	1,210 [1]	(1,956)
International taxes	(1,662)	(2,226)	4,362
Total deferred	(2,476)	(1,016)	2,406
Provision for taxes on income	**$ 2,209**	**2,702**	**16,373**

(1) Includes $1.4 billion of deferred tax expense for the adoption of the deferred method to account for GILTI.

A comparison of income tax expense at the U.S. statutory rate of 21% in 2019 and 2018 and 35% in 2017, to the Company's effective tax rate is as follows:

(Dollars in Millions)	2019	2018	2017
U.S.	$ 3,543	5,575	4,865
International	13,785	12,424	12,808
Earnings before taxes on income:	$ 17,328	17,999	17,673
Tax rates:			
U.S. statutory rate	21.0 %	21.0	35.0
International operations (1)	(5.9)	(3.7)	(12.8)
U.S. taxes on international income (2)	1.8	1.4	0.7
Tax benefits on share-based compensation	(0.5)	(1.5)	(2.1)
All other	0.2	(0.3)	(1.5)
TCJA and related impacts	(3.9) (3)	(1.9) (3)	73.3 (4)
Effective Rate	12.7 %	15.0	92.6

(1) For all periods presented the Company has subsidiaries operating in Puerto Rico under various tax incentives. International operations reflects the impacts of operations in jurisdictions with statutory tax rates different than the U.S., particularly Ireland, Switzerland and Puerto Rico, which is a favorable impact on the effective tax rate as compared with the U.S. statutory rate. The 2017 amount also includes tax cost related to the revaluation of deferred tax balances related to the change in the Belgian statutory tax rate increasing the tax provision by approximately 3.4%.
(2) Includes the impact of the GILTI tax, the Foreign-Derived Intangible Income deduction and other foreign income that is taxable under the U.S. tax code.
(3) Represents impact of adjustments to balances originally recorded as part of the 2017 TCJA provisional tax charge. Further information provided below.
(4) Includes U.S. state and local taxes provisionally recorded as part TCJA provisional charge which was approximately 0.6% of the total effective tax rate.

The 2019 tax rate decreased by 2.3% compared to the fiscal year 2018 tax rate. In addition to the impact of Swiss tax reform discussed in more detail below, the primary drivers of the net decrease were as follows:

- The Company reorganized the ownership structure of certain wholly-owned international subsidiaries in the fiscal fourth quarter of 2019, which resulted in a reduction of certain withholding and local taxes that it had previously recognized as part of the provisional Tax Cuts and Jobs Act (TCJA) tax charge in the fiscal year 2017 and finalized in the fiscal year 2018. Following the completion of this restructuring and approval by the applicable local authorities, the Company reversed a deferred tax liability of $0.6 billion and a related deferred tax asset of $0.2 billion for U.S. foreign tax credits, for a net deferred tax benefit of $0.4 billion decreasing the annual effective tax rate by 2.2%. This benefit has been reflected as "TCJA and related impacts" on the Company's effective tax rate reconciliation.
- The impact of the agreement in principle to settle opioid litigation for $4 billion (see Note 21 to the Consolidated Financial Statements) which reduced the U.S. earnings before taxes at an effective tax rate of 23.5% and decreased the Company's annual effective tax rate by approximately 2.1%.
- In December of fiscal year 2019, the U.S. Treasury issued final foreign tax credit regulations, which resulted in the Company revising the amount of foreign tax credits that were initially recorded in the fiscal year 2017 as part of the provisional TCJA tax charge. As a result, the Company recorded an increased deferred tax asset related to these foreign tax credits of approximately $0.3 billion or 1.7% to the annual effective tax rate. This benefit has been reflected as "TCJA and related impacts" on the Company's effective tax rate reconciliation.
- The Company reassessed its uncertain tax positions related to the current IRS audit and increased its unrecognized tax benefit by $0.3 billion liability which increased the annual effective tax rate by approximately 1.5% (see section on Unrecognized Tax Benefits for additional information). As these positions were related to uncertain tax regarding international transfer pricing, this expense has been classified as "International Operations" on the Company's effective tax rate reconciliation. Subsequent to December 29, 2019, the Company received and agreed to Notices of Proposed Adjustments (NOPAs) from the IRS. The Company believes it is adequately reserved for potential exposures.
- There were several one-time tax impacts that resulted in a cumulative net tax benefit to the 2018 annual effective tax rate of 1.2%. These items included the LifeScan divestiture, the adjustment to the 2017 provisional TCJA tax charge and the acceleration of certain tax deductions as part of the 2017 tax return.
- More income in higher tax jurisdictions relative to lower tax jurisdictions as compared to 2018.

On September 28, 2018 the Swiss Parliament approved the Federal Act on Tax Reform and AHV Financing (TRAF). On May 19, 2019 a public referendum was held in Switzerland that approved the federal reform proposals. In the fiscal third quarter of 2019, the Swiss Federal Council enacted TRAF which became effective on January 1, 2020. The Federal transitional provisions

of TRAF allow companies, under certain conditions, to adjust their tax basis adjustments to fair value (i.e., "step-up") which is used for tax depreciation and amortization purposes resulting in a deduction over the transitional period. The subsequent adjustment to the Company's asset tax basis will require review and approval by the tax authorities.

TRAF also provides for parameters which enable the Swiss cantons to establish localized tax rates and regulations for companies. The new cantonal tax parameters include favorable tax benefits for patents and additional research and development tax deductions. The cantonal transitional provisions of TRAF are also expected to allow companies to elect either 1) tax basis step-up similar to the Federal transition benefit or 2) alternative statutory tax rate for a period not to exceed 5 years. The Company currently has operations located in various Swiss cantons and enactment may not be uniform in both the substantive nature of the legislation and the timing of enactment.

The Company recorded a net tax expense of $0.1 billion which increased the effective tax rate for the fiscal year 2019 by approximately 0.6%. This net tax expense related to federal and certain cantonal enactments in the fiscal year 2019 consisting of the following provisions:

- approximately $0.6 billion tax expense relating to the remeasurement of Swiss deferred tax assets and liabilities for the change in the Federal and cantonal tax rates, where enactment occurred by December 29, 2019; this expense has been reflected as "International Operations" on the Company's effective tax rate reconciliation.
- a $0.9 billion deferred tax asset related to the estimated value of a Federal tax basis step-up of the Company's Swiss subsidiaries' assets; this benefit has been reflected as "International Operations" on the Company's effective tax rate reconciliation.
- approximately $450 million of U.S. deferred tax expense relating to the GILTI deferred tax liability resulting from the remeasurement of the Swiss deferred tax assets and liabilities and the new deferred tax asset for the Federal step-up. this benefit has been reflected as "U.S. tax on international income" on the Company's effective tax rate reconciliation.

In the fiscal fourth quarter of 2019, the Swiss Federal Tax Administration issued authoritative guidance that required the Company to decrease the estimated value of the Federal tax basis step-up by approximately $0.3 billion from the determination made in the fiscal third quarter of 2019. Further authoritative guidance from the relevant Swiss tax authorities may be issued in the future and additional revisions may be required in the fiscal period that they are issued.

The Company is currently assessing and applying for approval for the elective transition provisions in several cantons which includes discussions with local tax authorities on the application of the new law. The Company has recorded an estimated impact of the transitional provisions based on the best available information for cantons where enactment has occurred but the Company has not yet received a final tax ruling.

As of December 29, 2019, the one canton where the Company maintains significant operations has not yet enacted TRAF legislation and the amounts recorded in the fiscal year 2019 do not include estimates for unenacted legislation. On February 9, 2020 a public referendum on the legislative change was held in this canton and the legislation was approved by the voters; formal enactment is expected in the fiscal first half of 2020. The Company has not yet elected the transitional provision in this canton. However, the net financial benefit is estimated to be between $0.2 billion and $0.5 billion in the fiscal first half of 2020.

U.S. Tax Cuts and Jobs Act (TCJA) (2018 and 2017)
In the fiscal year 2017, the United States enacted into law new U.S. tax legislation, the TCJA. This law included provisions for a comprehensive overhaul of the corporate income tax code, including a reduction of the statutory corporate tax rate from 35% to 21%, effective on January 1, 2018. This legislation also eliminated or reduced certain corporate income tax deductions as well as introduced new provisions that taxed certain foreign income not previously taxed by the United States. The TCJA also included a provision for a tax on all previously undistributed earnings of U.S. companies located in foreign jurisdictions. Undistributed earnings in the form of cash and cash equivalents were taxed at a rate of 15.5% and all other earnings were taxed at a rate of 8.0%. This tax is payable over 8 years and will not accrue interest. These payments began in 2018 and will continue through 2025. The remaining balance at the end of the fiscal year 2019 was approximately $8.2 billion, of which $7.7 billion is classified as noncurrent and reflected as "Long-term taxes payable" on the Company's balance sheet. The balance of this account is related to receivables from tax authorities not expected to be received in the next 12 months.

In the fourth quarter of 2017, the Company recorded a provisional tax cost of approximately $13.0 billion which consisted primarily of the following components:

- a $10.1 billion charge on previously undistributed foreign earnings as of December 31, 2017
- a $4.5 billion deferred tax liability for foreign local and withholding taxes, offset by a $1.1 billion deferred tax asset for U.S. foreign tax credits, for repatriation of substantially all those earnings

- a $0.6 billion tax benefit relating to the remeasurement of U.S. deferred tax assets and liabilities and the impact of the TCJA on unrecognized tax benefits
- a $0.1 billion charge for U.S. state and local taxes on the repatriation of these foreign earnings

In the fiscal year 2018, the Company completed its full assessment and finalized the accounting for the impact of the TCJA. The Company recorded net adjustments to the above components of the provisional charge of approximately $0.2 billion. These revisions were based on updated estimates and additional analysis by management as well as applying interpretative guidance issued by the U.S. Department of Treasury to the facts and circumstances that existed as of the TCJA enactment date. This charge was primarily related to additional deferred tax liabilities for foreign local and withholding taxes for the remaining balance of undistributed foreign earnings as of December 31, 2017 that were not provided for in the 2017 provisional charge.

The TCJA also includes provisions for a tax on GILTI. GILTI is described as the excess of a U.S. shareholder's total net foreign income over a deemed return on tangible assets, as provided by the TCJA. In the fiscal year 2018, the Company elected to treat GILTI as a period expense under the deferred method and recorded a deferred tax cost of approximately $1.4 billion in the fiscal year 2018 related to facts and circumstances that existed on the date of TCJA enactment. See Note 1 for further information regarding income taxes accounting policies.

During 2018, the Company reorganized the ownership structure of certain foreign subsidiaries which resulted in a reduction of certain foreign withholding taxes that it had recognized as part of the provisional TCJA tax charge in the fourth quarter of 2017. Following the completion of this restructuring and as a result of clarification by Swiss tax authorities regarding the applicability of withholding tax to repatriation of certain earnings, the Company reversed a deferred tax liability of $2.8 billion and a related deferred tax asset of $0.9 billion for U.S. foreign tax credits, for a net deferred tax benefit of $1.9 billion. This benefit has been reflected as "TCJA and related impacts" on the Company's effective tax rate reconciliation.

The 2018 effective tax rate decreased by 77.6% compared to 2017. The 2017 effective tax rate was primarily driven by the approximately $13 billion provisional tax charge recorded in the fourth quarter of 2017 and the impact of a Belgian statutory tax rate change which increased the 2017 effective rate by 3.4%. Additional drivers of the 2018 annual effective tax were:

- the reduction of the U.S. statutory corporate tax rate including the effects of tax elections which resulted in the acceleration of certain deductions into the 2017 tax return. The impact of these accelerated deductions decreased the annual effective tax rate by approximately 1.7%
- the impact of the adjustments to the 2017 provisional TCJA charge, including both Staff Accounting Bulletin (SAB) 118 adjustments and the internal restructuring, decreased the effective tax rate by approximately 1.9%
- GILTI tax which increased the annual effective tax rate by approximately 1.6%, which excludes the impact of the SAB 118 adjustment for the adoption of the deferred method for GILTI
- tax benefits received from stock-based compensation during fiscal 2018 and 2017, reduced the effective tax rate by 1.5% and 2.0%, respectively
- in the fourth quarter of 2018, the Company completed the divestiture of its LifeScan business (See Note 20 to the Consolidated Financial Statements), which increased the Company's annual effective tax rate by approximately 0.8%
- more income in higher tax jurisdictions relative to lower tax jurisdictions as compared to 2017

Temporary differences and carryforwards for 2019 and 2018 were as follows:

	2019 Deferred Tax		2018 Deferred Tax	
(Dollars in Millions)	**Asset**	**Liability**	**Asset**	**Liability**
Employee related obligations	$ 2,393		2,398	
Stock based compensation	546		639	
Depreciation & amortization	1,122		1,784	
Non-deductible intangibles		(5,752)		(5,967)
International R&D capitalized for tax	1,189		1,282	
Reserves & liabilities	2,384		1,647	
Income reported for tax purposes	1,605		1,104	
Net operating loss carryforward international	838		786	
Undistributed foreign earnings	765	(1,289)	693	(2,240)
Global intangible low-taxed income		(2,965)		(2,971)
Miscellaneous international	696	(81)	603	(93)
Miscellaneous U.S.	410		469	
Total deferred income taxes	**$ 11,948**	**(10,087)**	**11,405**	**(11,271)**

The Company has wholly-owned international subsidiaries that have cumulative net losses. The Company believes that it is more likely than not that these subsidiaries will generate future taxable income sufficient to utilize these deferred tax assets.

The following table summarizes the activity related to unrecognized tax benefits:

(Dollars in Millions)	**2019**	**2018**	**2017**
Beginning of year	$ 3,326	3,151	3,041
Increases related to current year tax positions	249	242	332
Increases related to prior period tax positions	408	145	232
Decreases related to prior period tax positions	(105)	(137)	(416) [(1)]
Settlements	(9)	(40)	(2)
Lapse of statute of limitations	(16)	(35)	(36)
End of year	**$ 3,853**	**3,326**	**3,151**

[(1)] In 2017, $347 million of this decrease is related to the TCJA.

The unrecognized tax benefits of $3.9 billion at December 29, 2019, if recognized, would affect the Company's annual effective tax rate. The Company conducts business and files tax returns in numerous countries and currently has tax audits in progress with a number of tax authorities. With respect to the United States, the Internal Revenue Service (IRS) has completed its audit for the tax years through 2009 and is currently auditing the tax years 2010-2012. The Company currently expects completion of this audit and settlement of the related tax liabilities in the fiscal year 2020. As of the December 29, 2019, the Company has classified unrecognized tax benefits and related interest of approximately $0.9 billion as a current liability on the "Accrued taxes on Income" line of the Consolidated Balance Sheet. This is the amount expected to be paid over the next 12 months with respect to the IRS audit. Subsequent to December 29, 2019, the Company made a payment for approximately $0.6 billion to the U.S. Treasury related to the estimated 2010-2012 tax audit liability in anticipation of the final settlement later in fiscal 2020. The completion of this tax audit may result in additional adjustments to the Company's unrecognized tax benefit liability.
In other major jurisdictions where the Company conducts business, the years that remain open to tax audit go back to the year 2006. The Company believes it is possible that tax audits may be completed over the next twelve months by taxing authorities in some jurisdictions outside of the United States. However, the Company is not able to provide a reasonably reliable estimate of the timing of any other future tax payments relating to uncertain tax positions.

The Company classifies liabilities for unrecognized tax benefits and related interest and penalties as long-term liabilities, except as previously noted on amounts related to the current United States IRS audit. Interest expense and penalties related to

unrecognized tax benefits are classified as income tax expense. The Company recognized after tax interest expense of $50 million, $53 million and $60 million in 2019, 2018 and 2017, respectively. The total amount of accrued interest was $559 million and $503 million in 2019 and 2018, respectively.

9. Employee Related Obligations

At the end of 2019 and 2018, employee related obligations recorded on the Consolidated Balance Sheets were:

(Dollars in Millions)	2019	2018
Pension benefits	$ 5,538	5,327
Postretirement benefits	2,297	2,283
Postemployment benefits	3,004	2,330
Deferred compensation	338	410
Total employee obligations	11,177	10,350
Less current benefits payable	514	399
Employee related obligations — non-current	**$ 10,663**	**9,951**

Prepaid employee related obligations of $551 million and $475 million for 2019 and 2018, respectively, are included in Other assets on the Consolidated Balance Sheets.

10. Pensions and Other Benefit Plans

The Company sponsors various retirement and pension plans, including defined benefit, defined contribution and termination indemnity plans, which cover most employees worldwide. The Company also provides post-retirement benefits, primarily health care, to all eligible U.S. retired employees and their dependents.

Many international employees are covered by government-sponsored programs and the cost to the Company is not significant.

Retirement plan benefits for employees hired before January 1, 2015 are primarily based on the employee's compensation during the last three to five years before retirement and the number of years of service. In 2014, the Company announced that the U.S. Defined Benefit Plan was amended to adopt a new benefit formula, effective for employees hired on or after January 1, 2015. The benefits are calculated using a new formula based on employee compensation over total years of service.

International subsidiaries have plans under which funds are deposited with trustees, annuities are purchased under group contracts, or reserves are provided.

The Company does not typically fund retiree health care benefits in advance, but may do so at its discretion. The Company also has the right to modify these plans in the future.

In 2019 and 2018 the Company used December 31, 2019 and December 31, 2018, respectively, as the measurement date for all U.S. and international retirement and other benefit plans.

Net periodic benefit costs for the Company's defined benefit retirement plans and other benefit plans for 2019, 2018 and 2017 include the following components:

	Retirement Plans			Other Benefit Plans		
(Dollars in Millions)	2019	2018	2017	2019	2018	2017
Service cost	$ 1,163	1,283	1,080	274	269	247
Interest cost	1,096	996	927	185	148	159
Expected return on plan assets	(2,322)	(2,212)	(2,041)	(6)	(7)	(6)
Amortization of prior service cost (credit)	4	3	2	(31)	(31)	(30)
Recognized actuarial losses	579	852	609	129	123	138
Curtailments and settlements	73	1	17	—	—	—
Net periodic benefit cost	**$ 593**	**923**	**594**	**551**	**502**	**508**

Amounts expected to be recognized in net periodic benefit cost in the coming year for the Company's defined benefit retirement plans and other post-retirement plans:

(Dollars in Millions)	
Amortization of net transition obligation	$ —
Amortization of net actuarial losses	1,022
Amortization of prior service credit	29

Unrecognized gains and losses for the U.S. pension plans are amortized over the average remaining future service for each plan. For plans with no active employees, they are amortized over the average life expectancy. The amortization of gains and losses for the other U.S. benefit plans is determined by using a 10% corridor of the greater of the market value of assets or the accumulated postretirement benefit obligation. Total unamortized gains and losses in excess of the corridor are amortized over the average remaining future service.

Prior service costs/benefits for the U.S. pension plans are amortized over the average remaining future service of plan participants at the time of the plan amendment. Prior service cost/benefit for the other U.S. benefit plans is amortized over the average remaining service to full eligibility age of plan participants at the time of the plan amendment.

The following table represents the weighted-average actuarial assumptions:

	Retirement Plans			Other Benefit Plans		
Worldwide Benefit Plans	**2019**	**2018**	**2017**	**2019**	**2018**	**2017**
Net Periodic Benefit Cost						
Service cost discount rate	3.63%	3.20	3.59	4.45	3.85	4.63
Interest cost discount rate	4.13%	3.60	3.98	4.25	3.62	3.94
Rate of increase in compensation levels	3.99%	3.98	4.01	4.29	4.29	4.31
Expected long-term rate of return on plan assets	8.31%	8.46	8.43			
Benefit Obligation						
Discount rate	2.91%	3.76	3.30	3.39	4.40	3.78
Rate of increase in compensation levels	4.01%	3.97	3.99	4.29	4.29	4.30

The Company’s discount rates are determined by considering current yield curves representing high quality, long-term fixed income instruments. The resulting discount rates are consistent with the duration of plan liabilities. The Company's methodology in determining service and interest cost uses duration specific spot rates along that yield curve to the plans' liability cash flows.

The expected rates of return on plan asset assumptions represent the Company's assessment of long-term returns on diversified investment portfolios globally. The assessment is determined using projections from external financial sources, long-term historical averages, actual returns by asset class and the various asset class allocations by market.

The following table displays the assumed health care cost trend rates, for all individuals:

Health Care Plans	**2019**	**2018**
Health care cost trend rate assumed for next year	5.87%	6.12%
Rate to which the cost trend rate is assumed to decline (ultimate trend)	4.50%	4.55%
Year the rate reaches the ultimate trend rate	2040	2038

A one-percentage-point change in assumed health care cost trend rates would have the following effect:

(Dollars in Millions)	One-Percentage-Point Increase	One-Percentage-Point Decrease
Health Care Plans		
Total interest and service cost	$ 21	(17)
Post-retirement benefit obligation	$ 296	(246)

The following table sets forth information related to the benefit obligation and the fair value of plan assets at year-end 2019 and 2018 for the Company's defined benefit retirement plans and other post-retirement plans:

	Retirement Plans		Other Benefit Plans	
(Dollars in Millions)	**2019**	**2018**	**2019**	**2018**
Change in Benefit Obligation				
Projected benefit obligation — beginning of year	$ 31,670	33,221	4,480	4,582
Service cost	1,163	1,283	274	269
Interest cost	1,096	996	185	148
Plan participant contributions	63	66	—	—
Amendments	—	26	—	—
Actuarial (gains) losses	5,178	(2,326)	562	(119)
Divestitures & acquisitions	(278)	(29)	—	—
Curtailments, settlements & restructuring	(172)	(21)	—	—
Benefits paid from plan assets*	(1,555)	(1,018)	(431)	(383)
Effect of exchange rates	23	(528)	6	(17)
Projected benefit obligation — end of year	**$ 37,188**	**31,670**	**5,076**	**4,480**
Change in Plan Assets				
Plan assets at fair value — beginning of year	$ 26,818	28,404	180	281
Actual return on plan assets	6,185	(1,269)	19	—
Company contributions	908	1,140	347	282
Plan participant contributions	63	66	—	—
Settlements	(16)	(13)	—	—
Divestitures & acquisitions	(274)	(17)	—	—
Benefits paid from plan assets*	(1,555)	(1,018)	(431)	(383)
Effect of exchange rates	72	(475)	—	—
Plan assets at fair value — end of year	**$ 32,201**	**26,818**	**115**	**180**
Funded status — end of year	**$ (4,987)**	**(4,852)**	**(4,961)**	**(4,300)**
Amounts Recognized in the Company's Balance Sheet consist of the following:				
Non-current assets	$ 551	475	—	—
Current liabilities	(113)	(98)	(397)	(281)
Non-current liabilities	(5,425)	(5,229)	(4,564)	(4,019)
Total recognized in the consolidated balance sheet — end of year	**$ (4,987)**	**(4,852)**	**(4,961)**	**(4,300)**
Amounts Recognized in Accumulated Other Comprehensive Income consist of the following:				
Net actuarial loss	$ 8,835	8,323	1,685	1,263
Prior service cost (credit)	(8)	2	(75)	(106)
Unrecognized net transition obligation	—	—	—	—
Total before tax effects	**$ 8,827**	**8,325**	**1,610**	**1,157**
Accumulated Benefit Obligations — end of year	**$ 33,416**	**28,533**		

*In 2019, the Company offered a voluntary lump-sum payment option for certain eligible former employees who are vested participants of the U.S. Qualified Defined Benefit Pension Plan. The distribution of the lump-sums was completed by the end of fiscal 2019. The amount distributed in 2019 was approximately $514 million.

(Dollars in Millions)	Retirement Plans 2019	Retirement Plans 2018	Other Benefit Plans 2019	Other Benefit Plans 2018
Amounts Recognized in Net Periodic Benefit Cost and Other Comprehensive Income				
Net periodic benefit cost	**$ 593**	**923**	**551**	**502**
Net actuarial (gain) loss	1,084	1,153	550	(111)
Amortization of net actuarial loss	(579)	(852)	(129)	(123)
Prior service cost (credit)	—	26	—	—
Amortization of prior service (cost) credit	(4)	(3)	31	31
Effect of exchange rates	1	(114)	1	(3)
Total loss/(income) recognized in other comprehensive income, before tax	**$ 502**	**210**	**453**	**(206)**
Total recognized in net periodic benefit cost and other comprehensive income	**$ 1,095**	**1,133**	**1,004**	**296**

The Company plans to continue to fund its U.S. Qualified Plans to comply with the Pension Protection Act of 2006. International Plans are funded in accordance with local regulations. Additional discretionary contributions are made when deemed appropriate to meet the long-term obligations of the plans. For certain plans, funding is not a common practice, as funding provides no economic benefit. Consequently, the Company has several pension plans that are not funded.

In 2019, the Company contributed $489 million and $419 million to its U.S. and international pension plans, respectively.

The following table displays the funded status of the Company's U.S. Qualified & Non-Qualified pension plans and international funded and unfunded pension plans at December 31, 2019 and December 31, 2018, respectively:

	U.S. Plans				International Plans			
	Qualified Plans		Non-Qualified Plans		Funded Plans		Unfunded Plans	
(Dollars in Millions)	2019	2018	2019	2018	2019	2018	2019	2018
Plan Assets	$ 21,398	17,725	—	—	10,803	9,093	—	—
Projected Benefit Obligation	22,034	18,609	2,544	2,176	12,132	10,467	478	418
Accumulated Benefit Obligation	19,831	16,851	2,115	1,793	11,040	9,510	430	379
Over (Under) Funded Status								
Projected Benefit Obligation	$ (636)	(884)	(2,544)	(2,176)	(1,329)	(1,374)	(478)	(418)
Accumulated Benefit Obligation	1,567	874	(2,115)	(1,793)	(237)	(417)	(430)	(379)

Plans with accumulated benefit obligations in excess of plan assets have an accumulated benefit obligation, projected benefit obligation and plan assets of $4.3 billion, $5.2 billion and $0.9 billion, respectively, at the end of 2019, and $7.5 billion, $8.8 billion and $4.3 billion, respectively, at the end of 2018.

The following table displays the projected future benefit payments from the Company's retirement and other benefit plans:

(Dollars in Millions)	2020	2021	2022	2023	2024	2025-2029
Projected future benefit payments						
Retirement plans	$ 1,126	1,172	1,234	1,323	1,359	7,945
Other benefit plans	$ 437	450	466	479	494	2,356

The following table displays the projected future minimum contributions to the unfunded retirement plans. These amounts do not include any discretionary contributions that the Company may elect to make in the future.

(Dollars in Millions)	2020	2021	2022	2023	2024	2025-2029
Projected future contributions	$ 103	107	113	118	127	749

Each pension plan is overseen by a local committee or board that is responsible for the overall administration and investment of the pension plans. In determining investment policies, strategies and goals, each committee or board considers factors including, local pension rules and regulations; local tax regulations; availability of investment vehicles (separate accounts, commingled accounts, insurance funds, etc.); funded status of the plans; ratio of actives to retirees; duration of liabilities; and other relevant factors including: diversification, liquidity of local markets and liquidity of base currency. A majority of the Company's pension funds are open to new entrants and are expected to be on-going plans. Permitted investments are primarily liquid and/or listed, with little reliance on illiquid and non-traditional investments such as hedge funds.

The Company's retirement plan asset allocation at the end of 2019 and 2018 and target allocations for 2020 are as follows:

	Percent of Plan Assets		Target Allocation
	2019	2018	2020
Worldwide Retirement Plans			
Equity securities	74%	71%	69%
Debt securities	26	29	31
Total plan assets	**100%**	**100%**	**100%**

Determination of Fair Value of Plan Assets

The Plan has an established and well-documented process for determining fair values. Fair value is based upon quoted market prices, where available. If listed prices or quotes are not available, fair value is based upon models that primarily use, as inputs, market-based or independently sourced market parameters, including yield curves, interest rates, volatilities, equity or debt prices, foreign exchange rates and credit curves.

While the Plan believes its valuation methods are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

Valuation Hierarchy

The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described in the table below with Level 1 having the highest priority and Level 3 having the lowest.

The Net Asset Value (NAV) is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Following is a description of the valuation methodologies used for the investments measured at fair value.

- *Short-term investment funds* — Cash and quoted short-term instruments are valued at the closing price or the amount held on deposit by the custodian bank. Other investments are through investment vehicles valued using the NAV provided by the administrator of the fund. The NAV is a quoted price in a market that is not active and classified as Level 2.
- *Government and agency securities* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified within Level 1 of the valuation hierarchy. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows. When quoted market prices for a security are not available in an active market, they are classified as Level 2.
- *Debt instruments* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified as Level 1. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows and are classified as Level 2. Level 3 debt instruments are priced based on unobservable inputs.
- *Equity securities* — Equity securities are valued at the closing price reported on the major market on which the individual securities are traded. Substantially all equity securities are classified within Level 1 of the valuation hierarchy.
- *Commingled funds* — These investment vehicles are valued using the NAV provided by the fund administrator. Assets in the Level 2 category have a quoted market price.

- *Insurance contracts* — The instruments are issued by insurance companies. The fair value is based on negotiated value and the underlying investments held in separate account portfolios as well as considering the credit worthiness of the issuer. The underlying investments are government, asset-backed and fixed income securities. In general, insurance contracts are classified as Level 3 as there are no quoted prices nor other observable inputs for pricing.
- *Other assets* — Other assets are represented primarily by limited partnerships. These investment vehicles are valued using the NAV provided by the fund administrator. Other assets that are exchange listed and actively traded are classified as Level 1, while inactively traded assets are classified as Level 2.

The following table sets forth the Retirement Plans' investments measured at fair value as of December 31, 2019 and December 31, 2018:

	Quoted Prices in Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs[a] (Level 3)		Investments Measured at Net Asset Value		Total Assets	
(Dollars in Millions)	**2019**	**2018**	**2019**	**2018**	**2019**	**2018**	**2019**	**2018**	**2019**	**2018**
Short-term investment funds	$ 119	122	405	529	—	—	—	—	524	651
Government and agency securities	—	—	4,140	3,595	—	—	—	—	4,140	3,595
Debt instruments	—	—	3,452	3,105	—	—	—	—	3,452	3,105
Equity securities	12,483	11,298	2	4	—	—	—	—	12,485	11,302
Commingled funds	—	—	3,338	2,304	181	133	7,580	5,201	11,099	7,638
Insurance contracts	—	—	—	—	19	193	—	—	19	193
Other assets	—	—	9	33	—	—	473	301	482	334
Investments at fair value	**$ 12,602**	**11,420**	**11,346**	**9,570**	**200**	**326**	**8,053**	**5,502**	**32,201**	**26,818**

[a] The activity for the Level 3 assets is not significant for all years presented.

The Company's Other Benefit Plans are unfunded except for U.S. commingled funds (Level 2) of $84 million and $72 million and U.S. short-term investment funds (Level 2) of $31 million and $108 million at December 31, 2019 and December 31, 2018, respectively.

The fair value of Johnson & Johnson Common Stock directly held in plan assets was $984 million (3.1% of total worldwide plan assets) at December 31, 2019 and $876 million (3.3% of total worldwide plan assets) at December 31, 2018.

11. Savings Plan

The Company has voluntary 401(k) savings plans designed to enhance the existing retirement programs covering eligible employees. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which he/she is eligible. Total Company matching contributions to the plans were $235 million, $242 million and $214 million in 2019, 2018 and 2017, respectively.

12. Capital and Treasury Stock
Changes in treasury stock were:

(Amounts in Millions Except Treasury Stock Shares in Thousands)	Treasury Stock Shares	Treasury Stock Amount
Balance at January 1, 2017	413,332	$ 28,352
Employee compensation and stock option plans	(25,508)	(3,156)
Repurchase of common stock	49,494	6,358
Balance at December 31, 2017	437,318	31,554
Employee compensation and stock option plans	(22,082)	(3,060)
Repurchase of common stock	42,283	5,868
Balance at December 30, 2018	457,519	34,362
Employee compensation and stock option plans	(20,053)	(2,691)
Repurchase of common stock	49,870	6,746
Balance at December 29, 2019	487,336	$ 38,417

Aggregate shares of common stock issued were approximately 3,119,843,000 shares at the end of 2019, 2018 and 2017.

Cash dividends paid were $3.75 per share in 2019, compared with dividends of $3.54 per share in 2018, and $3.32 per share in 2017.

On December 17, 2018, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's shares of common stock. This share repurchase program was completed as of September 29, 2019.

On October 13, 2015, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $10.0 billion of the Company's shares of common stock. This share repurchase program was completed as of July 2, 2017.

13. Accumulated Other Comprehensive Income (Loss)
Components of other comprehensive income (loss) consist of the following:

(Dollars in Millions)	Foreign Currency Translation	Gain/(Loss) On Securities	Employee Benefit Plans	Gain/ (Loss) On Derivatives & Hedges	Total Accumulated Other Comprehensive Income (Loss)
January 1, 2017	$ (9,047)	411	(5,980)	(285)	(14,901)
Net 2017 changes	1,696	(179)	(170)	355	1,702
December 31, 2017	(7,351)	232	(6,150)	70	(13,199)
Cumulative adjustment to retained earnings	—	(232) [1]			(232)
Net 2018 changes	(1,518)	—	(8)	(265)	(1,791)
December 30, 2018	(8,869)	—	(6,158)	(195)	(15,222)
Net 2019 changes	164	—	(733)	(100)	(669)
December 29, 2019	$ (8,705)	—	(6,891)	(295)	(15,891)

[1] Per the adoption of ASU 2016-01- Financial Instruments

Amounts in accumulated other comprehensive income are presented net of the related tax impact. Foreign currency translation is not adjusted for income taxes where it relates to permanent investments in international subsidiaries. For additional details on comprehensive income see the Consolidated Statements of Comprehensive Income.

Details on reclassifications out of Accumulated Other Comprehensive Income:
Gain/(Loss) On Securities - reclassifications released to Other (income) expense, net.
Employee Benefit Plans - reclassifications are included in net periodic benefit cost. See Note 10 for additional details.
Gain/(Loss) On Derivatives & Hedges - reclassifications to earnings are recorded in the same account as the hedged transaction. See Note 6 for additional details.

14. International Currency Translation

For translation of its subsidiaries operating in non-U.S. Dollar currencies, the Company has determined that the local currencies of its international subsidiaries are the functional currencies except those in highly inflationary economies, which are defined as those which have had compound cumulative rates of inflation of 100% or more during the past three years, or where a substantial portion of its cash flows are not in the local currency. For the majority of the Company's subsidiaries the local currency is the functional currency.

In consolidating international subsidiaries, balance sheet currency effects are recorded as a component of accumulated other comprehensive income. This equity account includes the results of translating certain balance sheet assets and liabilities at current exchange rates and some accounts at historical rates, except for those located in highly inflationary economies, (Argentina and Venezuela). The translation of balance sheet accounts for highly inflationary economies are reflected in the operating results.

A rollforward of the changes during 2019, 2018 and 2017 for foreign currency translation adjustments is included in Note 13.

Net currency transaction gains and losses included in Other (income) expense were losses of $267 million, $265 million and $216 million in 2019, 2018 and 2017, respectively.

15. Earnings Per Share

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal years ended December 29, 2019, December 30, 2018 and December 31, 2017:

(In Millions Except Per Share Amounts)	2019	2018	2017
Basic net earnings per share	$ 5.72	5.70	0.48
Average shares outstanding — basic	2,645.1	2,681.5	2,692.0
Potential shares exercisable under stock option plans	136.3	139.0	139.7
Less: shares repurchased under treasury stock method	(97.8)	(92.5)	(87.3)
Convertible debt shares	0.7	0.7	0.9
Adjusted average shares outstanding — diluted	2,684.3	2,728.7	2,745.3
Diluted net earnings per share	$ 5.63	5.61	0.47

The diluted net earnings per share calculation included the dilutive effect of convertible debt that is offset by the related reduction in interest expense of $1 million after-tax for 2019, 2018 and 2017.

The diluted net earnings per share calculation for 2019 excluded an insignificant number of shares related to stock options, as the exercise price of these options was greater than the average market value of the Company’s stock. The diluted net earnings per share calculation for 2018 and 2017 included all shares related to stock options, as the exercise price of all options was less than the average market value of the Company's stock.

16. Lease Commitments

The Company primarily has operating leases for space, vehicles, manufacturing equipment and data processing equipment. Leases have remaining lease terms ranging from 1 year to 55 years, some of which could include options to extend the leases when they are reasonably certain.

The operating lease costs were approximately $307 million, $332 million and $372 million in 2019, 2018 and 2017, respectively. Cash paid for amounts included in the measurement of lease liabilities in 2019 were $308 million. Commitments under finance leases are not significant. Other supplemental information related to these leases are as follows:

The Weighted Average Remaining Lease Term and discount rate:

Operating leases 5.8 years

Weighted Average Discount Rate 3%

Maturity of Lease Liabilities related to Operating Lease

The approximate minimum rental payments required under operating leases that have initial or remaining non-cancelable lease terms in excess of one year at December 29, 2019 are:

(Dollars in Millions)	Operating Leases
2020	$ 215
2021	254
2022	197
2023	141
2024	86
After 2024	201
Total lease payments	1,094
Less: Interest	109
Present Value of lease liabilities	$ 985

Supplemental information for comparative periods:

As of December 30, 2018, prior to the adoption of ASU 2016-02, the approximate future minimum rental payments required under operating leases that have initial or remaining non-cancelable lease terms in excess of one year were:

(Dollars in Millions)

2019	2020	2021	2022	2023	After 2023	Total
$223	188	154	116	76	139	896

Supplemental balance sheet information related to leases as of December 29, 2019 were as follows:

(Dollars in Millions)		
Non-current operating lease right-of-use assets	$	957
Current operating lease liabilities		269
Non-current Operating lease liabilities		716
Total operating lease liabilities	$	985

17. Common Stock, Stock Option Plans and Stock Compensation Agreements

At December 29, 2019, the Company had 2 stock-based compensation plans. The shares outstanding are for contracts under the Company's 2005 Long-Term Incentive Plan and the 2012 Long-Term Incentive Plan. The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan. Under the 2012 Long-Term Incentive Plan, the Company may issue up to 650 million shares of common stock, plus any shares canceled, expired, forfeited, or not issued from the 2005 Long-Term Incentive Plan subsequent to April 26, 2012. Shares available for future grants under the 2012 Long-Term Incentive Plan were 315 million at the end of 2019.

The compensation cost that has been charged against income for these plans was $977 million, $978 million and $962 million for 2019, 2018 and 2017, respectively. The total income tax benefit recognized in the income statement for share-based compensation costs was $227 million, $192 million and $275 million for 2019, 2018 and 2017, respectively. The total unrecognized compensation cost was $823 million, $827 million and $798 million for 2019, 2018 and 2017, respectively. The weighted average period for this cost to be recognized was 1.71 years, 1.73 years and 1.76 years for 2019, 2018, and 2017, respectively. Share-based compensation costs capitalized as part of inventory were insignificant in all periods.

The Company settles employee benefit equity issuances with treasury shares. Treasury shares are replenished throughout the year for the number of shares used to settle employee benefit equity issuances.

Stock Options

Stock options expire 10 years from the date of grant and vest over service periods that range from 6 months to 4 years. All options are granted at the average of the high and low prices of the Company's Common Stock on the New York Stock Exchange on the date of grant.

The fair value of each option award was estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the following table. For 2019, 2018 and 2017 grants, expected volatility represents a blended rate of 10-year weekly historical overall volatility rate, and a 5-week average implied volatility rate based on at-the-money traded Johnson & Johnson options with a life of 2 years. For all grants, historical data is used to determine the expected life of the option. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant.

The average fair value of options granted was $17.80, $17.98 and $13.38, in 2019, 2018 and 2017, respectively. The fair value was estimated based on the weighted average assumptions of:

	2019	2018	2017
Risk-free rate	2.56%	2.77%	2.25%
Expected volatility	16.27%	15.77%	15.30%
Expected life (in years)	7.0	7.0	7.0
Expected dividend yield	2.80%	2.70%	2.90%

A summary of option activity under the Plan as of December 29, 2019, December 30, 2018 and December 31, 2017, and changes during the years ending on those dates is presented below:

(Shares in Thousands)	Outstanding Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (Dollars in Millions)
Shares at January 1, 2017	113,455	$ 83.16	$ 3,636
Options granted	19,287	115.67	
Options exercised	(18,975)	70.87	
Options canceled/forfeited	(2,461)	101.40	
Shares at December 31, 2017	111,306	90.48	5,480
Options granted	17,115	129.51	
Options exercised	(16,228)	75.44	
Options canceled/forfeited	(2,541)	112.90	
Shares at December 30, 2018	109,652	98.29	3,214
Options granted	19,745	131.94	
Options exercised	(14,785)	82.43	
Options canceled/forfeited	(2,975)	125.11	
Shares at December 29, 2019	**111,637**	**$ 105.63**	**$ 4,478**

The total intrinsic value of options exercised was $807 million, $1,028 million and $1,060 million in 2019, 2018 and 2017, respectively.

The following table summarizes stock options outstanding and exercisable at December 29, 2019:

(Shares in Thousands)	Outstanding			Exercisable	
Exercise Price Range	Options	Average Life[1]	Average Exercise Price	Options	Average Exercise Price
$58.65-$66.07	7,752	1.3	$63.71	7,752	$63.71
$72.54-$90.44	23,837	3.6	$82.08	23,837	$82.08
$100.06-$101.87	29,586	5.6	$101.07	29,083	$101.05
$115.67-$129.51	31,810	7.6	$122.32	84	$120.76
$131.94-$141.06	18,652	9.1	$131.94	5	$131.94
	111,637	**6.0**	**$105.63**	**60,761**	**$88.88**

(1) Average contractual life remaining in years.

Stock options outstanding at December 30, 2018 and December 31, 2017 were 109,652 and an average life of 6.2 years and 111,306 and an average life of 6.3 years, respectively. Stock options exercisable at December 30, 2018 and December 31, 2017 were 54,862 at an average price of $82.03 and 52,421 at an average price of $73.61, respectively.

Restricted Share Units and Performance Share Units

The Company grants restricted share units which vest over service periods that range from 6 months to 3 years. The Company also grants performance share units, which are paid in shares of Johnson & Johnson Common Stock after the end of a three-year performance period. Whether any performance share units vest, and the amount that does vest, is tied to the completion of service periods that range from 6 months to 3 years and the achievement, over a three-year period, of three equally-weighted goals that directly align with or help drive long-term total shareholder return: operational sales, adjusted operational earnings per share, and relative total shareholder return. The number of shares actually earned at the end of the three-year period will vary, based only on actual performance, from 0% to 200% of the target number of performance share units granted. In the fourth quarter of 2017, the Company modified the restricted share units that were scheduled to vest between January 1, 2018 and March 15, 2018. This modification guaranteed a minimum aggregate value, below the market value of the total expected payout amount, for all awards expected to vest during this period. The amount that was committed was not material to the Company's overall financial position.

A summary of the restricted share units and performance share units activity under the Plans as of December 29, 2019 is presented below:

(Shares in Thousands)	Outstanding Restricted Share Units	Outstanding Performance Share Units
Shares at December 30, 2018	18,460	2,494
Granted	5,769	932
Issued	(6,261)	(996)
Canceled/forfeited/adjusted	(1,199)	(256)
Shares at December 29, 2019	16,769	2,174

The average fair value of the restricted share units granted was $121.31, $119.67 and $107.69 in 2019, 2018 and 2017, respectively, using the fair market value at the date of grant. The fair value of restricted share units was discounted for dividends, which are not paid on the restricted share units during the vesting period. The fair value of restricted share units issued was $585.9 million, $613.7 million and $596.5 million in 2019, 2018 and 2017, respectively.

The weighted average fair value of the performance share units granted was $124.67, $120.64 and $114.13 in 2019, 2018 and 2017, calculated using the weighted average fair market value for each of the three component goals at the date of grant.

The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. The fair value of performance share units issued was $119.1 million, $128.8 million and $132.5 million in 2019, 2018 and 2017, respectively.

18. **Segments of Business and Geographic Areas**

(Dollars in Millions)	Sales to Customers			% Change	
	2019	2018	2017	'19 vs. '18	'18 vs. '17
CONSUMER					
Baby Care					
U.S.	$ 362	422	449	(14.2)%	(6.0)
International	1,313	1,436	1,467	(8.6)	(2.1)
Worldwide	1,675	1,858	1,916	(9.9)	(3.0)
Beauty					
U.S.	2,392	2,403	2,335	(0.4)	2.9
International	2,201	1,979	1,865	11.2	6.1
Worldwide	4,593	4,382	4,200	4.8	4.3
Oral Care					
U.S.	621	637	616	(2.5)	3.4
International	906	918	915	(1.2)	0.3
Worldwide	1,528	1,555	1,531	(1.7)	1.6
OTC					
U.S.	2,010	1,850	1,716	8.6	7.8
International	2,434	2,484	2,410	(2.0)	3.1
Worldwide	4,444	4,334	4,126	2.5	5.0
Women's Health					
U.S.	12	13	12	(5.5)	8.3
International	974	1,036	1,038	(6.0)	(0.2)
Worldwide	986	1,049	1,050	(6.0)	(0.1)
Wound Care/Other					
U.S.	441	436	437	1.2	(0.2)
International	230	239	342	(3.9)	(30.1)
Worldwide	671	675	779	(0.6)	(13.4)
TOTAL CONSUMER					
U.S.	5,839	5,761	5,565	1.4	3.5
International	8,059	8,092	8,037	(0.4)	0.7
Worldwide	13,898	13,853	13,602	0.3	1.8

PHARMACEUTICAL					
Immunology					
U.S.	9,641	9,073	8,871	6.3	2.3
International	4,309	4,047	3,373	6.5	20.0
Worldwide	13,950	13,120	12,244	6.3	7.2
REMICADE®					
U.S.	3,079	3,664	4,525	(16.0)	(19.0)
U.S. Exports	294	436	563	(32.7)	(22.6)
International	1,007	1,226	1,227	(17.8)	(0.1)
Worldwide	4,380	5,326	6,315	(17.8)	(15.7)
SIMPONI / SIMPONI ARIA®					
U.S.	1,159	1,051	954	10.2	10.2
International	1,029	1,033	879	(0.4)	17.5
Worldwide	2,188	2,084	1,833	5.0	13.7
STELARA®					
U.S.	4,346	3,469	2,767	25.3	25.4
International	2,015	1,687	1,244	19.4	35.6
Worldwide	6,361	5,156	4,011	23.4	28.5
TREMFYA®					
U.S.	764	453	62	68.5	*
International	248	91	1	*	*
Worldwide	1,012	544	63	85.9	*
OTHER IMMUNOLOGY					
U.S.	—	—	—	—	—
International	10	10	22	4.5	(54.5)
Worldwide	10	10	22	4.5	(54.5)
Infectious Diseases					
U.S.	1,597	1,378	1,358	15.9	1.5
International	1,815	1,926	1,796	(5.7)	7.2
Worldwide	3,413	3,304	3,154	3.3	4.8
EDURANT® / rilpivirine					
U.S.	50	58	58	(13.7)	0.0
International	812	758	656	7.1	15.5
Worldwide	861	816	714	5.6	14.3
PREZISTA® / PREZCOBIX® / SYMTUZA® REZOLSTA® /					
U.S.	1,422	1,169	1,109	21.6	5.4
International	689	786	712	(12.3)	10.4
Worldwide	2,110	1,955	1,821	8.0	7.4
OTHER INFECTIOUS DISEASES					
U.S.	126	151	191	(16.5)	(20.9)
International	315	382	428	(17.6)	(10.7)
Worldwide	441	533	619	(17.3)	(13.9)

Neuroscience					
U.S.	2,919	2,574	2,630	13.4	(2.1)
International	3,409	3,503	3,356	(2.7)	4.4
Worldwide	6,328	6,077	5,986	4.1	1.5
CONCERTA® / Methylphenidate					
U.S.	233	229	384	1.7	(40.4)
International	463	434	407	6.6	6.6
Worldwide	696	663	791	4.9	(16.2)
INVEGA SUSTENNA® / XEPLION® / INVEGA TRINZA® / TREVICTA®					
U.S.	2,107	1,791	1,590	17.6	12.6
International	1,224	1,137	979	7.7	16.1
Worldwide	3,330	2,928	2,569	13.7	14.0
RISPERDAL CONSTA®					
U.S.	314	315	360	(0.3)	(12.5)
International	374	422	445	(11.4)	(5.2)
Worldwide	688	737	805	(6.7)	(8.4)
OTHER NEUROSCIENCE					
U.S.	266	239	296	11.4	(19.3)
International	1,349	1,510	1,525	(10.7)	(1.0)
Worldwide	1,614	1,749	1,821	(7.7)	(4.0)
Oncology					
U.S.	4,299	4,331	3,098	(0.7)	39.8
International	6,393	5,513	4,160	16.0	32.5
Worldwide	10,692	9,844	7,258	8.6	35.6
DARZALEX®					
U.S.	1,567	1,203	884	30.3	36.1
International	1,430	822	358	73.9	*
Worldwide	2,998	2,025	1,242	48.0	63.0
IMBRUVICA®					
U.S.	1,555	1,129	841	37.7	34.2
International	1,856	1,486	1,052	24.9	41.3
Worldwide	3,411	2,615	1,893	30.4	38.1
VELCADE®					
U.S.	—	—	—	—	—
International	751	1,116	1,114	(32.7)	0.2
Worldwide	751	1,116	1,114	(32.7)	0.2
ZYTIGA® /abiraterone acetate					
U.S.	810	1,771	1,228	(54.3)	44.2
International	1,985	1,727	1,277	15.0	35.2
Worldwide	2,795	3,498	2,505	(20.1)	39.6
OTHER ONCOLOGY					
U.S.	367	228	145	61.0	57.2
International	371	362	359	2.4	0.8
Worldwide	739	590	504	25.0	17.1

Pulmonary Hypertension					
U.S.	1,684	1,651	773	2.0	*
International	939	922	554	1.9	66.4
Worldwide	2,623	2,573	1,327	1.9	93.9
OPSUMIT®					
U.S.	766	700	320	9.4	*
International	562	515	253	9.0	*
Worldwide	1,327	1,215	573	9.2	*
TRACLEER® / bosentan					
U.S.	131	268	161	(51.1)	66.5
International	210	278	242	(24.3)	14.9
Worldwide	341	546	403	(37.5)	35.5
UPTRAVI®					
U.S.	714	598	238	19.3	*
International	105	65	25	62.4	*
Worldwide	819	663	263	23.5	*
OTHER					
U.S.	74	85	54	(13.7)	57.4
International	62	64	34	(3.7)	88.2
Worldwide	135	149	88	(9.4)	69.3
Cardiovascular / Metabolism / Other					
U.S.	3,734	4,279	4,744	(12.7)	(9.8)
International	1,458	1,537	1,543	(5.2)	(0.4)
Worldwide	5,192	5,816	6,287	(10.7)	(7.5)
XARELTO®					
U.S.	2,313	2,477	2,500	(6.6)	(0.9)
International	—	—	—	—	—
Worldwide	2,313	2,477	2,500	(6.6)	(0.9)
INVOKANA® / INVOKAMET®					
U.S.	536	711	944	(24.6)	(24.7)
International	199	170	167	17.3	1.8
Worldwide	735	881	1,111	(16.5)	(20.7)
PROCRIT® / EPREX®					
U.S.	505	674	675	(25.1)	(0.1)
International	285	314	297	(9.2)	5.7
Worldwide	790	988	972	(20.0)	1.6
OTHER					
U.S.	380	417	625	(9.1)	(33.3)
International	974	1,053	1,079	(7.6)	(2.4)
Worldwide	1,353	1,470	1,704	(8.0)	(13.7)
TOTAL PHARMACEUTICAL					
U.S.	23,874	23,286	21,474	2.5	8.4
International	18,324	17,448	14,782	5.0	18.0
Worldwide	42,198	40,734	36,256	3.6	12.4

MEDICAL DEVICES					
Diabetes Care					
U.S.	—	371	612	*	(39.4)
International	—	638	1,003	*	(36.4)
Worldwide	—	1,009	1,615	*	(37.5)
Diagnostics					
U.S.	—	—	—	—	—
International	—	—	1	—	*
Worldwide	—	—	1	—	*
Interventional Solutions					
U.S.	1,443	1,283	1,148	12.5	11.8
International	1,554	1,363	1,148	14.0	18.7
Worldwide	2,997	2,646	2,296	13.3	15.2
Orthopaedics					
U.S.	5,319	5,281	5,404	0.7	(2.3)
International	3,520	3,604	3,654	(2.3)	(1.4)
Worldwide	8,839	8,885	9,058	(0.5)	(1.9)
HIPS					
U.S.	863	841	827	2.6	1.7
International	575	577	567	(0.3)	1.8
Worldwide	1,438	1,418	1,394	1.4	1.7
KNEES					
U.S.	889	911	948	(2.4)	(3.9)
International	591	591	575	0.0	2.8
Worldwide	1,480	1,502	1,523	(1.4)	(1.4)
TRAUMA					
U.S.	1,652	1,599	1,576	3.3	1.5
International	1,068	1,100	1,040	(2.9)	5.8
Worldwide	2,720	2,699	2,616	0.8	3.2
SPINE & OTHER					
U.S.	1,915	1,930	2,053	(0.8)	(6.0)
International	1,286	1,336	1,472	(3.8)	(9.2)
Worldwide	3,201	3,266	3,525	(2.0)	(7.3)
Surgery					
U.S.	3,828	4,125	4,085	(7.2)	1.0
International	5,673	5,776	5,474	(1.8)	5.5
Worldwide	9,501	9,901	9,559	(4.0)	3.6
ADVANCED					
U.S.	1,637	1,657	1,620	(1.2)	2.3
International	2,458	2,345	2,136	4.8	9.8
Worldwide	4,095	4,002	3,756	2.3	6.5
GENERAL					
U.S.	1,762	1,751	1,728	0.6	1.3
International	2,718	2,806	2,735	(3.1)	2.6
Worldwide	4,480	4,557	4,463	(1.7)	2.1

SPECIALTY					
U.S.	430	717	737	(40.1)	(2.7)
International	497	625	603	(20.5)	3.6
Worldwide	926	1,342	1,340	(31.0)	0.1
Vision					
U.S.	1,794	1,777	1,575	0.9	12.8
International	2,830	2,776	2,488	2.0	11.6
Worldwide	4,624	4,553	4,063	1.6	12.1
CONTACT LENSES / OTHER					
U.S.	1,304	1,237	1,122	5.4	10.2
International	2,088	2,065	1,914	1.1	7.9
Worldwide	3,392	3,302	3,036	2.7	8.8
SURGICAL					
U.S.	490	540	453	(9.4)	19.2
International	742	711	574	4.4	23.9
Worldwide	1,232	1,251	1,027	(1.6)	21.8
TOTAL MEDICAL DEVICES					
U.S.	12,384	12,837	12,824	(3.5)	0.1
International	13,579	14,157	13,768	(4.1)	2.8
Worldwide	25,963	26,994	26,592	(3.8)	1.5
WORLDWIDE					
U.S.	42,097	41,884	39,863	0.5	5.1
International	39,962	39,697	36,587	0.7	8.5
Worldwide	$ 82,059	81,581	76,450	0.6 %	6.7

*Percentage greater than 100% or not meaningful

	Income Before Tax			Identifiable Assets	
(Dollars in Millions)	**2019 [3]**	**2018 [4]**	**2017 [5]**	**2019**	**2018**
Consumer	$ 2,061	2,320	2,524	$ 26,618	25,877
Pharmaceutical	8,816	12,568	11,083	56,292	56,636
Medical Devices	7,286	4,397	5,392	49,462	46,254
Total	18,163	19,285	18,999	132,372	128,767
Less: Expense not allocated to segments [1]	835	1,286	1,326		
General corporate [2]				25,356	24,187
Worldwide total	**$ 17,328**	**17,999**	**17,673**	**$ 157,728**	**152,954**

	Additions to Property, Plant & Equipment			Depreciation and Amortization		
(Dollars in Millions)	**2019**	**2018**	**2017**	**2019**	**2018**	**2017**
Consumer	$ 328	438	485	$ 765	688	674
Pharmaceutical	950	1,012	936	3,910	3,802	2,416
Medical Devices	1,912	1,843	1,566	2,014	2,103	2,216
Segments total	3,190	3,293	2,987	6,689	6,593	5,306
General corporate	308	377	292	320	336	336
Worldwide total	**$ 3,498**	**3,670**	**3,279**	**$ 7,009**	**6,929**	**5,642**

(Dollars in Millions)	Sales to Customers 2019	2018	2017	Long-Lived Assets (6) 2019	2018
United States	$ 42,097	41,884	39,863	$ 41,528	37,117
Europe	18,466	18,753	17,126	48,015	51,433
Western Hemisphere excluding U.S.	5,941	6,113	6,041	2,862	2,752
Asia-Pacific, Africa	15,555	14,831	13,420	5,486	2,733
Segments total	82,059	81,581	76,450	97,891	94,035
General corporate				1,049	1,064
Other non long-lived assets				58,788	57,855
Worldwide total	**$ 82,059**	**81,581**	**76,450**	**$ 157,728**	**152,954**

See Note 1 for a description of the segments in which the Company operates.

Export sales are not significant. In 2019, the Company utilized three wholesalers distributing products for all three segments that represented approximately 15.0%, 12.0% and 11.0% of the total consolidated revenues. In 2018, the Company had three wholesalers distributing products for all three segments that represented approximately 14.0%, 11.0% and 11.0% of the total consolidated revenues. In 2017, the Company had two wholesalers distributing products for all three segments that represented approximately 14.0% and 10.0% of the total consolidated revenues.

(1) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.

(2) General corporate includes cash, cash equivalents and marketable securities.

(3) The Consumer segment includes a gain of $0.3 billion related to the Company's previously held equity investment in DR. CI:LABO, litigation expense of $0.4 billion and a restructuring charge of $0.1 billion. The Pharmaceutical segment includes litigation expense of $4.3 billion including $4.0 billion related to the agreement in principle to settle opioid litigation (see Note 21 to the Consolidated Financial Statements for additional information regarding the opioid litigation), an in-process research and development expense of $0.9 billion related to the Alios asset, a research and development expense of $0.3 billion for an upfront payment related to argenx, an unrealized gain on securities of $0.6 billion, Actelion acquisition related costs of $0.2 billion and a restructuring charge of $0.1 billion. The Medical Devices segment includes a gain of $2.0 billion from the divestiture of the ASP business, a restructuring related charge of $0.4 billion, litigation expense of $0.4 billion and Auris Health acquisition related costs of $0.1 billion.

(4) The Consumer segment includes a gain of $0.3 billion from the divestiture of NIZORAL® and litigation expense of $0.3 billion. The Pharmaceutical segment includes an in-process research and development charge of $1.1 billion related to the Alios and XO1 assets and the corresponding XO1 contingent liability reversal of $0.2 billion, Actelion acquisition related costs of $0.2 billion, unrealized loss on securities of $0.2 billion and a gain of $0.2 billion from the divestiture of certain non-strategic Pharmaceutical products. The Medical Devices segment includes net litigation expense of $1.7 billion, a restructuring related charge of $0.6 billion, AMO acquisition related costs of $0.1 billion and a gain of $0.5 billion from the divestiture of the LifeScan business.

(5) The Pharmaceutical segment includes $0.8 billion for Actelion acquisition and integration related costs, an in-process research and development expense of $0.4 billion and litigation expense of $0.1 billion. The Medical Devices segment includes litigation expense of $1.1 billion, a restructuring related charge of $0.8 billion, an asset impairment of $0.2 billion primarily related to the insulin pump business and $0.1 billion for AMO acquisition related costs. The Medical Devices segment includes a gain of $0.7 billion from the divestiture of Codman Neurosurgery. The Consumer segment includes a gain of $0.5 billion from the divestiture of COMPEED®.

(6) Long-lived assets include property, plant and equipment, net for 2019, and 2018 of $17,658 and $17,035, respectively, and intangible assets and goodwill, net for 2019 and 2018 of $81,282 and $78,064, respectively.

19. Selected Quarterly Financial Data (unaudited)

Selected unaudited quarterly financial data for the years 2019 and 2018 are summarized below:

	2019				2018			
(Dollars in Millions Except Per Share Data)	First Quarter [1]	Second Quarter [2]	Third Quarter [3]	Fourth Quarter [4]	First Quarter [5]	Second Quarter [6]	Third Quarter [7]	Fourth Quarter [8]
Segment sales to customers								
Consumer	$ 3,318	3,544	3,469	3,567	3,398	3,504	3,415	3,536
Pharmaceutical	10,244	10,529	10,877	10,548	9,844	10,354	10,346	10,190
Medical Devices	6,459	6,489	6,383	6,632	6,767	6,972	6,587	6,668
Total sales	20,021	20,562	20,729	20,747	20,009	20,830	20,348	20,394
Gross profit	13,406	13,622	13,862	13,613	13,395	13,903	13,759	13,433
Earnings before provision for taxes on income	4,422	7,041	1,647	4,218	5,481	4,973	4,423	3,122
Net earnings	3,749	5,607	1,753	4,010	4,367	3,954	3,934	3,042
Basic net earnings per share	$ 1.41	2.11	0.67	1.52	1.63	1.47	1.47	1.14
Diluted net earnings per share	$ 1.39	2.08	0.66	1.50	1.60	1.45	1.44	1.12

(1) The first quarter of 2019 includes a gain of $0.3 billion after-tax ($0.3 billion before-tax) related to the Company's previously held equity investment in DR. CI:LABO, an in-process research and development expense of $703 million after-tax ($890 million before-tax) related to the Alios asset, a litigation expense of $342 million after-tax ($423 million before-tax), an unrealized gain on securities of $125 million after-tax ($158 million before-tax), a restructuring related charge of $75 million after-tax ($90 million before-tax), and acquisition related costs of $60 million after-tax ($67 million before-tax).

(2) The second quarter of 2019 includes a gain of $1.5 billion after-tax ($2.0 billion before-tax) from the divestiture of the ASP business, a litigation expense of $342 million after-tax ($409 million before-tax), an unrealized gain on securities of $117 million after-tax ($148 million before-tax), a restructuring related charge of $116 million after-tax ($142 million before-tax) and acquisition related costs of $50 million after-tax ($55 million before-tax).

(3) The third quarter of 2019 includes a litigation expense of $3,080 million after-tax ($4,000 million before-tax) related to the agreement in principle to settle opioid litigation, a restructuring related charge of $106 million after-tax ($128 million before-tax), acquisition related costs of $88 million after-tax ($107 million before-tax), a $391 million benefit after-tax from the impact of tax legislation, and an unrealized loss on securities of $71 million after-tax ($89 million before-tax).

(4) The fourth quarter of 2019 includes a litigation expense of $251 million after-tax ($264 million before-tax), an unrealized gain on securities of $277 million after-tax ($350 million before-tax), a restructuring related charge of $214 million after-tax ($251 million before-tax), a $184 million benefit after-tax from the impact of tax legislation, and acquisition related costs of $82 million after-tax ($90 million before-tax).

(5) The first quarter of 2018 includes an Actelion acquisition related cost of $92 million after-tax ($96 million before-tax) and a restructuring related charge of $81 million after-tax ($107 million before-tax).

(6) The second quarter of 2018 includes a litigation expense of $609 million after-tax ($703 million before-tax) and a restructuring related charge of $152 million after-tax ($176 million before-tax).

(7) The third quarter of 2018 includes an in-process research and development expense of $859 million after-tax ($1,126 million before-tax) related to the Alios and XO1 assets and the corresponding XO1 contingent liability reversal of $184 million after and before tax, a restructuring related charge of $162 million after-tax ($190 million before-tax) and a $265 million benefit after-tax from the impact of tax legislation.

(8) The fourth quarter of 2018 includes a litigation expense of $1,113 million after-tax ($1,288 million before-tax), a restructuring related charge of $190 million after-tax ($227 million before-tax) and a $137 million benefit after-tax from the impact of tax legislation.

20. Acquisitions and Divestitures

Certain businesses were acquired for $5.8 billion in cash and $1.4 billion of liabilities assumed during 2019. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2019 acquisitions primarily included: DR. CI:LABO, a Japanese company focused on the marketing, development and distribution of a broad range of dermocosmetic, cosmetic and skincare products; Auris Health, Inc. a privately held developer of robotic technologies, initially focused in lung cancer, with an FDA-cleared platform currently used in bronchoscopic diagnostic and therapeutic procedures and Taris Biomedical LLC a company specializing in the development of a novel drug delivery technology for the treatment of bladder diseases including cancer. The Company also acquired the assets of JointPoint, Inc., a privately held company, with navigation software to improve surgical outcomes in hip replacement.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $6.8 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

On January 17, 2019, the Company acquired DR. CI:LABO, a Japanese company focused on the marketing, development and distribution of a broad range of dermocosmetic, cosmetic and skincare products for a total purchase price of approximately ¥230 billion, which equates to approximately $2.1 billion, using the exchange rate of 109.06 Japanese Yen to each U.S. Dollar on January 16, 2019. The acquisition was completed through a series of transactions that included an all-cash tender offer to acquire the publicly held shares not already held by the Company for ¥5,900 per share. The Company previously held a 20% ownership in DR. CI:LABO. As of June 2019, the Company became the legal owner of DR. CI:LABO with the completion of the tender offer procedure in Japan. The acquired company was then delisted from the Tokyo Stock Exchange. Additionally, in the fiscal first quarter of 2019, the Company recognized a pre-tax gain recorded in Other (income) expense, net, of approximately $0.3 billion related to the Company's previously held equity investment in DR. CI:LABO.

The Company treated this transaction as a business combination and included it in the Consumer segment. The allocation of the purchase price included in the current period balance sheet is based on the best estimate of management and is preliminary and subject to change. At December 29, 2019, the fair value of the acquisition was allocated primarily to amortizable intangible assets for $1.5 billion, goodwill for $1.2 billion and liabilities of $0.4 billion subject to any subsequent valuation adjustments within the measurement period. The adjustments made since the date of acquisition were $0.1 billion to intangible assets, accrued liabilities, deferred taxes on income and property, plant and equipment with the offset to goodwill. The amortizable intangible assets were comprised of brand/trademarks and customer relationships with a weighted average life of 15.3 years The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not expected to be deductible for tax purposes.

On April 1, 2019 the Company completed the acquisition of Auris Health, Inc. for approximately $3.4 billion, net of cash acquired. Additional contingent payments of up to $2.35 billion, in the aggregate, may be payable upon reaching certain predetermined milestones. Auris Health was a privately held developer of robotic technologies, initially focused in lung cancer, with an FDA-cleared platform currently used in bronchoscopic diagnostic and therapeutic procedures. The Company treated this transaction as a business combination and included it in the Medical Devices segment. The fair value of the acquisition was allocated primarily to amortizable and non-amortizable intangible assets, primarily IPR&D for $3.0 billion, goodwill for $2.0 billion, marketable securities of $0.2 billion and liabilities assumed of $1.8 billion, which includes the fair value of the contingent payments mentioned above, subject to any subsequent valuation adjustments within the measurement period. As of December 29, 2019 there were no valuation adjustments. The fair value of the contingent consideration was $1.1 billion. A probability of success factor ranging from 55% to 95% was used in the fair value calculation to reflect inherent regulatory and commercial risk of the contingent payments and IPR&D. The discount rate applied was approximately 10%. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not expected to be deductible for tax purposes.

On December 20, 2019, the Company announced the agreement to acquire Verily's stake in Verb Surgical Inc. The transaction closed in the fiscal first quarter of 2020 and Verb Surgical Inc. is now a subsidiary of Johnson & Johnson.

On December 30, 2019, subsequent to the fiscal year end, the Company completed the acquisition of all rights to the investigational compound bermekimab, which has multiple dermatological indications, along with certain employees from XBiotech Inc., for a purchase price of $0.8 billion. XBiotech may be eligible to receive additional payments upon the receipt of certain commercialization authorizations. The transaction will be accounted for as a business combination and included in the Pharmaceutical segment.

During 2018 certain businesses were acquired for $0.9 billion in cash and $0.1 billion of liabilities assumed during 2018. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2018 acquisitions primarily included: Zarbee’s, Inc., a privately held company that is a leader in naturally-based consumer healthcare products; BeneVir Biopharm, Inc. (BeneVir), a privately-held, biopharmaceutical company specializing in the development of oncolytic immunotherapies and Orthotaxy, a privately-held developer of software-enabled surgery technologies, including a differentiated robotic-assisted surgery solution. The Company also acquired the assets of Medical Enterprises Distribution LLC, a privately held healthcare technology firm focused on surgical procedure innovation.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $1.0 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

During 2017 certain businesses were acquired for $35.2 billion in cash and $1.8 billion of liabilities assumed. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2017 acquisitions primarily included: Actelion Ltd, an established leading franchise of differentiated, innovative products for pulmonary arterial hypertension (PAH); Abbott Medical Optics (AMO), a wholly-owned subsidiary of Abbott Laboratories, which included ophthalmic products related to: cataract surgery, laser refractive surgery and consumer eye health; Neuravi Limited, a privately-held medical device company that develops and markets medical devices for neurointerventional therapy; TearScience Inc., a manufacturer of products dedicated to treating meibomian gland dysfunction; Sightbox, Inc., a privately-held company that developed a subscription vision care service that connects consumers with eye care professionals and a supply of contact lenses; Torax Medical, Inc., a privately-held medical device company that manufactures and markets the LINX™ Reflux Management System for the surgical treatment of gastroesophageal reflux disease and Megadyne Medical Products, Inc., a privately-held medical device company that develops, manufactures and markets electrosurgical tools.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $34.4 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately $1.1 billion has been identified as the value of IPR&D, primarily associated with the acquisition of Actelion Ltd. The value of the IPR&D was calculated using cash flow projections discounted for the inherent risk in the projects.

During 2017, the Company completed the acquisition of Actelion Ltd through an all cash tender offer in Switzerland for $280 per share, amounting to $29.6 billion, net of cash acquired. As part of the transaction, immediately prior to the completion of the acquisition, Actelion spun out its drug discovery operations and early-stage clinical development assets into a newly created Swiss biopharmaceutical company, Idorsia Ltd. The shares of Idorsia are listed on the SIX Swiss Exchange (SIX). In 2017 the Company held 9.9% of the shares of Idorsia and had rights to an additional 22.1% of Idorsia equity through a convertible loan with a principal amount of approximately $0.5 billion. As a result of Idorsia raising additional capital in July 2018, the Company currently holds 9.0% of the shares of Idorsia and has rights to an additional 20.8% of Idorsia equity through a convertible loan with a carrying value and a principal amount of approximately $0.5 billion. The convertible loan may be converted into 38,715,114 Idorsia shares, subject to certain restrictions, as follows: (i) up to an aggregate shareholding of 16% of Idorsia shares as a result of certain shareholders holding more than 20% of the issued Idorsia shares, and (ii) up to the balance of the remaining amount within 20 business days of the maturity date of the convertible loan, which has a 10 year term, or if Idorsia undergoes a change of control transaction. At the maturity of the loan, if the remaining amount has not yet been converted, Idorsia may elect to settle the remaining amount in cash or in ordinary shares of Idorsia. The equity investment in Idorsia and the convertible loan are recorded in Other assets in the Company's consolidated Balance Sheet. The Company also exercised the option acquired on ACT-132577, a product within Idorsia being developed for resistant hypertension currently in phase 3 of clinical development. The Company has also entered into an agreement to provide Idorsia with a Swiss franc denominated credit facility of approximately $250 million. As of December 29, 2019, Idorsia has not made any draw-downs under the credit facility. Actelion has established a leading franchise of differentiated, innovative products for pulmonary arterial hypertension (PAH) that are highly complementary to the existing portfolio of the Company. The addition of Actelion’s specialty in-market medicines and late-stage products is consistent with the Company's efforts to grow in attractive and complementary therapeutic areas and serve patients with serious illnesses and significant unmet medical need.

During the fiscal second quarter of 2018, the Company finalized the purchase price allocation for Actelion to the individual assets acquired and liabilities assumed using the acquisition method. The following table presents the amounts recognized for assets acquired and liabilities assumed as of the acquisition date with adjustments made through the second quarter of 2018:

(Dollars in Millions)	
Cash & Cash equivalents	469
Inventory[1]	759
Accounts Receivable	485
Other current assets	93
Property, plant and equipment	104
Goodwill	6,161
Intangible assets	25,010
Deferred Taxes	99
Other non-current assets	19
Total Assets Acquired	33,199
Current liabilities	956
Deferred Taxes	1,776
Other non-current liabilities	413
Total Liabilities Assumed	3,145
Net Assets Acquired	30,054

[1] Includes adjustment of $642 million to write-up the acquired inventory to its estimated fair value.

The adjustments made since the date of acquisition were $0.2 billion to the deferred taxes and $0.4 billion to the current liabilities with the offset to goodwill. The assets acquired are recorded in the Pharmaceutical segment. The acquisition of Actelion resulted in approximately $6.2 billion of goodwill. The goodwill is primarily attributable to synergies expected to arise from the acquisition. The goodwill is not expected to be deductible for tax purposes.

The purchase price allocation to the identifiable intangible assets is as follows:

(Dollars in Millions)		
Intangible assets with definite lives:		
Patents and trademarks*	$	24,230
Total amortizable intangibles		24,230
In-process research and development		780
Total intangible assets	**$**	**25,010**

*Includes $0.4 billion related to VALCHLOR®, one of the acquired products, which was divested in the fiscal second quarter of 2018.

The patents and trademarks acquired are comprised of developed technology with a weighted average life of 9 years and was primarily based on the patent life of the marketed products. The intangible assets with definite lives were assigned asset lives ranging from 4 to 10 years. The in-process research and development intangible assets were valued for technology programs for unapproved products.

The value of the IPR&D was calculated using probability adjusted cash flow projections discounted for the risk inherent in such projects. The discount rate applied was 9%.

The acquisition was accounted for using the acquisition method and, accordingly, the results of operations of Actelion were reported in the Company's financial statements beginning on June 16, 2017, the date of acquisition. For the year ended December 31, 2017, total sales and a net loss for Actelion from the date of acquisition were $1.4 billion and $1.4 billion, respectively.

The following table provides pro forma results of operations for the fiscal year ended December 31, 2017, as if Actelion had been acquired as of January 4, 2016. The pro forma results include the effect of certain purchase accounting adjustments such as the estimated changes in depreciation and amortization expense on the acquired tangible and intangible assets. However, pro forma results do not include any anticipated cost savings or other effects of the planned integration of Actelion.

Accordingly, such amounts are not necessarily indicative of the results if the acquisition had occurred on the dates indicated or which may occur in the future.

	Unaudited Pro forma Consolidated Results
(Dollars in Millions Except Per Share Data)	2017
Net Sales	77,681
Net Earnings	1,509
Diluted Net Earnings per Common Share	0.55

The Company recorded Actelion acquisition related costs before tax of approximately $0.2 billion, $0.2 billion and $0.8 billion in 2019, 2018 and 2017, respectively, which was recorded in Other (income)/expense and Cost of products sold.

During 2017, the Company acquired Abbott Medical Optics (AMO), a wholly-owned subsidiary of Abbott Laboratories, for $4.3 billion, net of cash acquired. The acquisition included ophthalmic products related to: cataract surgery, laser refractive surgery and consumer eye health. The net purchase price was primarily recorded as amortizable intangible assets for $2.3 billion and goodwill for $1.7 billion. The weighted average life of total amortizable intangibles, the majority being customer relationships, is approximately 14.4 years. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not deductible for tax purposes. The intangible assets and goodwill amounts are based on the final purchase price allocation. The assets acquired were recorded in the Medical Devices segment.

In 2012, the Company completed the acquisition of Synthes, Inc. for a purchase price of $20.2 billion in cash and stock. In connection with the acquisition of Synthes, Inc. the Company entered into two accelerated share repurchase (ASR) agreements. In 2013, the Company settled the remaining liabilities under the ASR agreements. While the Company believes that the transactions under each ASR agreement and a series of related internal transactions were consummated in a tax efficient manner in accordance with applicable law, it is possible that the Internal Revenue Service could assert one or more contrary positions to challenge the transactions from a tax perspective. If challenged, an amount up to the total purchase price for the Synthes shares could be treated as subject to applicable U.S. tax at approximately the statutory rate to the Company, plus interest.

With the exception of the Actelion Ltd acquisition, supplemental pro forma information for 2019, 2018 and 2017 in accordance with U.S. GAAP standards related to business combinations, and goodwill and other intangible assets, is not provided, as the impact of the aforementioned acquisitions did not have a material effect on the Company's results of operations, cash flows or financial position.

Divestitures

During 2019, the Company divested its Advanced Sterilization Products (ASP) business to Fortive Corporation for an aggregate value of approximately $2.8 billion, consisting of $2.7 billion of cash proceeds and $0.1 billion of retained net receivables. As of December 30, 2018, the assets held for sale on the Consolidated Balance Sheet were $0.2 billion of inventory, $0.1 billion of property, plant and equipment, net and $0.3 billion of goodwill. The Company recognized a pre-tax gain recorded in Other (income) expense, net, of approximately $2.0 billion.

During 2018, the Company divested the LifeScan Inc business for approximately $2.1 billion and retained certain net liabilities. Other divestitures in 2018 included: NIZORAL®, RoC® and certain non-strategic Pharmaceutical products. In 2018, the pre-tax gains on the divestitures were approximately $1.2 billion.

In 2018, the Company accepted a binding offer to form a strategic collaboration with Jabil Inc., one of the world's leading manufacturing services providers for health care products and technology products. The Company is expanding a 12-year relationship with Jabil to produce a range of products within the Ethicon Endo-Surgery and DePuy Synthes businesses. This transaction includes the transfer of employees and manufacturing sites. The majority of the transfers were completed in 2019 with a minor amount remaining in 2020. As of December 29, 2019, the assets held for sale on the Consolidated Balance Sheet were $0.1 billion of inventory and property, plant and equipment, net. As of December 30, 2018, the assets held for sale on the Consolidated Balance Sheet were $0.3 billion of inventory and $0.1 billion of property, plant and equipment, net. For additional details on the global supply chain restructuring see Note 22 to the Consolidated Financial Statements.

During 2017, the Company divestitures primarily included: the Codman Neurosurgery business, to Integra LifeSciences Holdings Corporation and the divestiture of COMPEED® to HRA Pharma. In 2017, the pre-tax gains on the divestitures were approximately $1.3 billion.

21. Legal Proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability, intellectual property, commercial, supplier indemnification and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of their business.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of December 29, 2019, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; or there are numerous parties involved. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution of, or increase in accruals for, one or more of these matters in any reporting period may have a material adverse effect on the Company's results of operations and cash flows for that period.

PRODUCT LIABILITY

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While the Company believes it has substantial defenses, it is not feasible to predict the ultimate outcome of litigation. From time to time, even if it has substantial defenses, the Company considers isolated settlements based on a variety of circumstances. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

The most significant of these cases include: the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System; the PINNACLE® Acetabular Cup System; pelvic meshes; RISPERDAL®; XARELTO®; body powders containing talc, primarily JOHNSONS® Baby Powder; INVOKANA®; and ETHICON PHYSIOMESH® Flexible Composite Mesh. As of December 29, 2019, in the United States there were approximately 1,100 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System; 10,300 with respect to the PINNACLE® Acetabular Cup System; 17,600 with respect to pelvic meshes; 11,900 with respect to RISPERDAL®; 29,000 with respect to XARELTO®; 17,900 with respect to body powders containing talc; 400 with respect to INVOKANA®; and 3,300 with respect to ETHICON PHYSIOMESH® Flexible Composite Mesh.

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System used in hip replacement surgery. Claims for personal injury have been made against DePuy and Johnson & Johnson. The number of pending lawsuits is expected to fluctuate as certain lawsuits are settled or dismissed and additional lawsuits are filed. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada, Australia, Ireland, Germany, India and Italy. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR Hip System plaintiffs to establish a program to settle claims with eligible ASR Hip patients in the United States who had surgery to replace their ASR Hips, known as revision surgery, as of August 31, 2013. DePuy reached additional agreements in February 2015 and March 2017, which further extended the settlement program to include ASR Hip patients who had revision surgeries after

August 31, 2013 and prior to February 15, 2017. This settlement program has resolved more than 10,000 claims, therefore bringing to resolution significant ASR Hip litigation activity in the United States. However, lawsuits in the United States remain, and the settlement program does not address litigation outside of the United States. In Australia, a class action settlement was reached that resolved the claims of the majority of ASR Hip patients in that country. In Canada, the Company has reached agreements to settle two pending class actions which have been approved by the Québec Superior Court and the Supreme Court of British Columbia. The Company continues to receive information with respect to potential additional costs associated with this recall on a worldwide basis. The Company has established accruals for the costs associated with the United States settlement program and DePuy ASR™ Hip-related product liability litigation.

Claims for personal injury have also been made against DePuy Orthopaedics, Inc. and Johnson & Johnson (collectively, DePuy) relating to the PINNACLE® Acetabular Cup System used in hip replacement surgery. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Texas. Litigation has also been filed in some state courts and in countries outside of the United States. Several adverse verdicts have been rendered against DePuy, one of which was reversed on appeal and remanded for retrial. During the first quarter of 2019, DePuy established a United States settlement program to resolve these cases. As part of the settlement program, adverse verdicts have been settled. The Company has established an accrual for product liability litigation associated with the PINNACLE® Acetabular Cup System and the related settlement program.

Claims for personal injury have been made against Ethicon, Inc. (Ethicon) and Johnson & Johnson arising out of Ethicon's pelvic mesh devices used to treat stress urinary incontinence and pelvic organ prolapse. The Company continues to receive information with respect to potential costs and additional cases. Cases filed in federal courts in the United States had been organized as a multi-district litigation (MDL) in the United States District Court for the Southern District of West Virginia. The MDL Court is remanding cases for trial to the jurisdictions where the case was originally filed and additional pelvic mesh lawsuits have been filed, and remain, outside of the MDL. The Company has settled or otherwise resolved a majority of the United States cases and the estimated costs associated with these settlements and the remaining cases are reflected in the Company's accruals. In addition, class actions and individual personal injury cases or claims have been commenced in various countries outside of the United States, including claims and cases in the United Kingdom, the Netherlands and Belgium, and class actions in Israel, Australia and Canada, seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices. In November 2019, the Federal Court of Australia issued a judgment regarding its findings with respect to liability in relation to the three Lead Applicants and generally in relation to the design, manufacture, pre and post-market assessments and testing, and supply and promotion of the devices in Australia used to treat stress urinary incontinence and pelvic organ prolapse. Orders determining the damages amounts to be awarded to the three Lead Applicants are expected in the first quarter of 2020. With respect to other group members, there will be an individual case assessment process which will require proof of use and causally related loss. The class actions in Canada are expected to be discontinued in 2020 as a result of a settlement of a group of cases, subject to court approval of the discontinuance. The Company has established accruals with respect to product liability litigation associated with Ethicon's pelvic mesh products.

Following a June 2016 worldwide market withdrawal of ETHICON PHYSIOMESH® Flexible Composite Mesh, claims for personal injury have been made against Ethicon, Inc. and Johnson & Johnson alleging personal injury arising out of the use of this hernia mesh device. Cases filed in federal courts in the United States have been organized as a multi-district litigation (MDL) in the United States District Court for the Northern District of Georgia. A multi-county litigation (MCL) has also been formed in New Jersey state court and assigned to Atlantic County for cases pending in New Jersey. In addition to the matters in the MDL and MCL, there are additional lawsuits pending in the United States District Court for the Southern District of Ohio, which are part of the MDL for polypropylene mesh devices manufactured by C.R. Bard, Inc., and lawsuits pending outside the United States.

Along with ETHICON PHYSIOMESH® lawsuits, there were a number of filings related to the PROCEED® Mesh and PROCEED® Ventral Patch products. In March 2019, the New Jersey Supreme Court entered an order consolidating all PROCEED® and PROCEED® Ventral Patch cases as an MCL in Atlantic County Superior Court. Additional cases have been filed in various federal and state courts in the US, and in jurisdictions outside the US. The Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has established accruals with respect to product liability litigation associated with ETHICON PHYSIOMESH® Flexible Composite Mesh, PROCEED® Mesh and PROCEED® Ventral Patch products. In September 2019, plaintiffs' attorney filed an application with the New Jersey Supreme Court seeking centralized management of 107 PROLENE™ Polypropylene Hernia System cases. The New Jersey Supreme Court granted plaintiffs application in January 2020 and those will be transferred to an MCL in Atlantic County Superior Court.

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and Johnson & Johnson arising out of the use of RISPERDAL®, indicated for the treatment of schizophrenia, acute manic or mixed episodes associated with bipolar I disorder and irritability associated with autism, and related compounds. Lawsuits have been primarily filed in state courts in Pennsylvania, California, and Missouri. Other actions are pending in various courts in the United States and Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has successfully defended a number of these cases but there have been verdicts against the Company, including a recent verdict in October 2019 of $8 billion of punitive damages related to one single plaintiff which was subsequently reduced in January 2020 to $6.8 million by the trial judge. The Company will appeal the final judgment. The Company has settled or otherwise resolved many of the United States cases and the costs associated with these settlements are reflected in the Company's accruals.

Claims for personal injury arising out of the use of XARELTO®, an oral anticoagulant, have been made against Janssen Pharmaceuticals, Inc. (JPI); Johnson & Johnson (J&J); and JPI's collaboration partner for XARELTO® Bayer AG and certain of its affiliates. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Eastern District of Louisiana. In addition, cases have been filed in state courts across the United States. Many of these cases have been consolidated into a state mass tort litigation in Philadelphia, Pennsylvania and in a coordinated proceeding in Los Angeles, California. Class action lawsuits also have been filed in Canada. In March 2019, JPI and J&J announced an agreement in principle to the settle the XARELTO® cases in the United States; the settlement agreement was executed in May 2019, and the settlement became final in December 2019. This will resolve the majority of cases pending in the United States. The Company has established accruals for its costs associated with the United States settlement program and XARELTO® related product liability litigation.

Personal injury claims alleging that talc causes cancer have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSON'S® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California, as well as outside the United States. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the District of New Jersey. In the multi-district litigation, the parties have moved to exclude experts, known as Daubert motions. The Court held Daubert hearings in mid-July 2019 and a final round of briefing has been submitted to the Court. The parties are awaiting a decision. The Company has successfully defended a number of these cases but there have been verdicts against the Company, including a verdict in July 2018 of $4.7 billion. The Company believes that it has strong grounds on appeal to overturn these verdicts. The Company has established an accrual primarily for defense costs in connection with product liability litigation associated with body powders containing talc.

In February 2019, the Company's talc supplier, Imerys Talc America, Inc. and two of its affiliates, Imerys Talc Vermont, Inc. and Imerys Talc Canada, Inc. (collectively, Imerys) filed a voluntary chapter 11 petition commencing a reorganization under the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware (Imerys Bankruptcy). The Imerys Bankruptcy relates to Imerys' potential liability for personal injury from exposure to talcum powder sold by Imerys (Talc Claims). In its bankruptcy filing, Imerys noted certain claims it alleges it has against the Company for indemnification and rights to joint insurance proceeds. Based on such claims as well as indemnity and insurance claims the Company has against Imerys, the Company petitioned the United States District Court for the District of Delaware to establish federal jurisdiction of the state court talc lawsuits under the Bankruptcy Code. The Company's petition was denied and the state court talc lawsuits that have been removed to federal court on such basis have been remanded. The Company formally proposed to resolve Imerys' and the Company's obligations arising out of the Talc Claims by agreeing to assume the defense of litigation of all Talc Claims involving the Company's products, lifting the automatic stay to enable the Talc Claims to proceed outside the bankruptcy forum with the Company agreeing to settle or pay any judgment against Imerys, and waiving the Company's indemnification claims against Imerys. Discussions between Imerys and the Company on this issue remain ongoing.

In February 2018, a securities class action lawsuit was filed against Johnson & Johnson and certain named officers in the United States District Court for the District of New Jersey, alleging that Johnson & Johnson violated the federal securities laws by failing to adequately disclose the alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S® Baby Powder, and that purchasers of Johnson & Johnson's shares suffered losses as a result. Plaintiffs are seeking damages. In April 2019, the Company moved to dismiss the complaint and briefing on the motion was complete as of August 2019. In December 2019, the Court denied, in part, the motion to dismiss.

In October 2018, a shareholder derivative lawsuit was filed against Johnson & Johnson as the nominal defendant and its current directors as defendants in the United States District Court for the District of New Jersey, alleging a breach of fiduciary duties related to the alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S® Baby Powder, and that Johnson & Johnson has suffered damages as a result of those alleged breaches. In June 2019, the shareholder filed an additional

complaint initiating a summary proceeding in New Jersey state court for a books and records inspection. In August 2019, Johnson & Johnson responded to the books and records complaint and filed a cross motion to dismiss. In September 2019, Plaintiff replied and the Court heard oral argument. The Court has not yet ruled in the books and records action. In September 2019, the United States District Court for the District of New Jersey granted defendants' motion to dismiss the shareholder derivative lawsuit, and dismissed the complaint without prejudice. In October 2019, the shareholder filed a notice of appeal with the United States Court of Appeals for the Third Circuit. In January 2020, the shareholder voluntarily dismissed his appeal, with prejudice. Four additional shareholder derivative lawsuits have been filed in New Jersey making similar allegations against the Company and its current directors and certain officers.

In January 2019, two ERISA class action lawsuits were filed by participants in the Johnson & Johnson Savings Plan against Johnson & Johnson, its Pension and Benefits Committee, and certain named officers in the United States District Court for the District of New Jersey, alleging that the defendants breached their fiduciary duties by offering Johnson & Johnson stock as a Johnson & Johnson Savings Plan investment option when it was imprudent to do so because of failures to disclose alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S® Baby Powder. Plaintiffs are seeking damages and injunctive relief. Defendants have filed a motion to dismiss.

A lawsuit is pending in the United States District Court for the Central District of California alleging violations of Proposition 65, California's Unfair Competition Law and False Advertising Law concerning JOHNSON'S® Baby Powder. In June 2019, plaintiffs filed a motion for voluntary dismissal of this Proposition 65 action and the Company opposed such motion to the extent it would allow plaintiffs' counsel to refile such claims with new plaintiffs. The Court granted plaintiff's motion conditioned upon payment of attorneys' fees and costs. The Court entered its award of attorneys' fees and costs in October 2019 and the case was dismissed without prejudice. Another lawsuit alleging violations of Proposition 65, California's Consumer Legal Remedies Act relating to JOHNSON'S® Baby Powder was filed in the Superior Court of California for the County of San Diego. In July 2019, the Company filed a notice of removal to the United States District Court for the Southern District of California and plaintiffs filed a second amended complaint shortly thereafter. In October 2019, the Company moved to dismiss the second amended complaint for failure to state a claim upon which relief may be granted, primarily on the basis that the plaintiffs failed to comply with Proposition 65's mandatory pre-suit notice requirement, which applies even when a plaintiff asserts only an indirect Proposition 65 claim. In response to those motions, plaintiffs filed a third amended complaint. In December 2019, the Company moved to dismiss the third amended complaint for failure to state a claim upon which relief may be granted.

In addition, the Company has received preliminary inquiries and subpoenas to produce documents regarding these matters from Senator Murray, a member of the Senate Committee on Health, Education, Labor and Pensions, the Department of Justice, the Securities and Exchange Commission and the U.S. Congressional Subcommittee on Economic and Consumer Policy. The Company is cooperating with government inquiries and continues to produce documents in response.

Claims for personal injury have been made against a number of Johnson & Johnson companies, including Janssen Pharmaceuticals, Inc. and Johnson & Johnson, arising out of the use of INVOKANA®, a prescription medication indicated to improve glycemic control in adults with Type 2 diabetes. Lawsuits filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the District of New Jersey. Cases have also been filed in state courts. Class action lawsuits have been filed in Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has settled or otherwise resolved many of the cases and claims in the United States and the costs associated with these settlements are reflected in the Company's accruals.

INTELLECTUAL PROPERTY

Certain subsidiaries of Johnson & Johnson are subject, from time to time, to legal proceedings and claims related to patent, trademark and other intellectual property matters arising out of their businesses. Many of these matters involve challenges to the coverage and/or validity of the patents on various products and allegations that certain of the Company's products infringe the patents of third parties. Although these subsidiaries believe that they have substantial defenses to these challenges and allegations with respect to all significant patents, there can be no assurance as to the outcome of these matters. A loss in any of these cases could adversely affect the ability of these subsidiaries to sell their products, result in loss of sales due to loss of market exclusivity, require the payment of past damages and future royalties, and may result in a non-cash impairment charge for any associated intangible asset. The most significant of these matters are described below.

In March 2013, Medinol Ltd. (Medinol) filed a patent infringement lawsuit against Cordis Corporation (Cordis) and Johnson & Johnson in the United States District Court for the Southern District of New York alleging that Cordis's sales of the CYPHER™ and CYPHER SELECT™ stents made in the United States since 2005 willfully infringed four of Medinol's patents directed to the geometry of articulated stents. Although Johnson & Johnson has since sold Cordis, it has retained liability for this case. After the trial in January 2014, the district court dismissed the case, finding Medinol unreasonably delayed bringing its claims (the laches defense). In September 2014, the district court denied a motion by Medinol to vacate the judgment and grant it a new trial. Medinol appealed the decision to the United States Court of Appeals for the Federal Circuit. In March 2017, the United States Supreme Court held that the laches defense is not available in patent cases. In April 2018, the United States Court of Appeals for the Federal Circuit remanded the case back to the district court to reconsider Medinol's motion for a new trial. In March 2019, the district court denied Medinol's motion for a new trial. In April 2019, Medinol filed a notice of appeal.

In November 2016, MedIdea, L.L.C. (MedIdea) filed a patent infringement lawsuit against DePuy Orthopaedics, Inc. in the United States District Court for the Northern District of Illinois alleging infringement by the ATTUNE® Knee System. In April 2017, MedIdea filed an amended complaint adding DePuy Synthes Products, Inc. and DePuy Synthes Sales, Inc. as named defendants (collectively, DePuy). MedIdea alleges infringement of United States Patent Nos. 6,558,426 ('426); 8,273,132 ('132); 8,721,730 ('730) and 9,492,280 ('280) relating to posterior stabilized knee systems. Specifically, MedIdea alleges that the SOFCAM™ Contact feature of the ATTUNE® posterior stabilized knee products infringes the patents-in-suit. MedIdea is seeking monetary damages and injunctive relief. In June 2017, the case was transferred to the United States District Court for the District of Massachusetts. A claim construction hearing was held in October 2018, and a claim construction order was issued in November 2018. In December 2018, MedIdea stipulated to non-infringement of the '132, '730 and '280 patents, based on the district court's claim construction and reserving its right to appeal that construction, leaving only the '426 patent at issue before the district court. In January 2019, the district court stayed the case pending a decision in the Inter Partes Review proceeding on the '426 patent (see below). In December 2017, DePuy Synthes Products, Inc. filed a petition for Inter Partes Review with the United States Patent and Trademark Office (USPTO), seeking to invalidate the two claims of the '426 patent asserted in the district court litigation, and in June 2018, the USPTO instituted review of those claims. A hearing was held in March 2019, and in April 2019, the USPTO issued its decision upholding the validity of the patent. In May 2019, DePuy filed a motion for summary judgment of non-infringement of the claims of the '426 patent. In November 2019, judgment was entered in favor of Depuy. In December 2019, MedIdea filed a notice of appeal.

In December 2016, Ethicon Endo-Surgery, Inc. and Ethicon Endo-Surgery, LLC (now known as Ethicon LLC) sued Covidien, Inc. in the United States District Court for the District of Massachusetts seeking a declaration that United States Patent Nos. 6,585,735 (the '735 patent); 7,118,587; 7,473,253; 8,070,748 and 8,241,284 (the '284 patent), are either invalid or not infringed by Ethicon's ENSEAL® X1 Large Jaw Tissue Sealer product. In April 2017, Covidien LP, Covidien Sales LLC, and Covidien AG (collectively, Covidien) answered and counterclaimed, denying the allegations, asserting willful infringement of the '735 patent, the '284 patent and United States Patent Nos. 8,323,310 (the '310 patent); 9,084,608; 9,241,759 (the '759 patent) and 9,113,882, and seeking damages and an injunction. Covidien filed a motion for preliminary injunction, which was denied in October 2017. The parties have entered joint stipulations such that only the '310 patent and the '759 patent remain in dispute. Trial began in September 2019, and closing arguments will be heard in March 2020.

In December 2016, Dr. Ford Albritton sued Acclarent, Inc. (Acclarent) in United States District Court for the Northern District of Texas alleging that Acclarent's RELIEVA® Spin and RELIEVEA SpinPlus® products infringe U.S. Patent No. 9,011,412 (the '412 patent). Dr. Albritton also alleges breach of contract, fraud and that he is the true owner of Acclarent's U.S. Patent No. 8,414,473. In December 2016, Acclarent filed a petition for Inter Partes Review (IPR) with the United States Patent and Trademark Office (USPTO) challenging the validity of the '412 patent. The USPTO instituted the IPR in July 2017. In July 2018, the USPTO ruled in favor of Albritton in the IPR, finding that Acclarent had not met its burden of proof that the challenged claims were invalid. In October 2019, the Court of Appeals affirmed the USPTO's Patent Trial and Appeal Board. In June 2019, the parties filed cross motions for summary judgment in the district court and the parties are awaiting a decision. The district court trial is scheduled for April 2020.

In November 2017, Board of Regents, The University of Texas System and TissueGen, Inc. (collectively, UT) filed a lawsuit in the United States District Court for the Western District of Texas against Ethicon, Inc. and Ethicon US, LLC alleging the manufacture and sale of VICRYL® Plus Antibacterial Sutures, MONOCRYL® Plus Antibacterial Sutures, PDS® Plus Antibacterial Sutures, STRATAFIX® PDS® Antibacterial Sutures and STRATAFIX® MONOCRYL® Plus Antibacterial Sutures infringe plaintiffs' United States Patent Nos. 6,596,296 and 7,033,603 (the '603 patent) directed to implantable polymer drug releasing biodegradable fibers containing a therapeutic agent. UT is seeking damages and an injunction. In December 2018, Ethicon filed petitions with the USPTO, seeking Inter Partes Review (IPR) of both asserted patents. Those petitions have been stayed by the USPTO pending a decision by the U.S. Supreme Court in an unrelated case. UT dismissed the '603 patent from

the suit and no longer accuses PDS® Plus Antibacterial Sutures or STRATAFIX® PDS® Plus Antibacterial Sutures of infringement. The district court trial is scheduled for June 2020.

In August 2018, Intuitive Surgical, Inc. and Intuitive Surgical Operations, Inc. ("Intuitive") filed a patent infringement suit against Auris Health, Inc. ("Auris") in United States District Court for the District of Delaware. In the suit, Intuitive alleges willful infringement of U.S. Patent Nos. 6,246,200 ('200 patent); 6,491,701 ('701 patent); 6,522,906 ('906 patent); 6,800,056 ('056 patent); 8,142,447 ('447 patent); 8,620,473 ('473 patent); 8,801,601 ('601 patent); and 9,452,276 ('276 patent) based on Auris' Monarch™ Platform. Auris filed Petitions for Inter Partes Review with the USPTO regarding the '200, '056, '601 '701, '447, '276 and '906 patents. In December 2019, the USPTO instituted review of the '601 patent and denied review of the '056 patent. The district court trial is scheduled to begin in January 2021.

In August 2019, RSB Spine LLC ("RSB Spine") filed a patent infringement suit against DePuy Synthes, Inc. in United States District Court for the District of Delaware. In October 2019, RSB Spine amended the complaint to change the named defendants to DePuy Synthes Sales, Inc. and DePuy Synthes Products, Inc. In the suit, RSB Spine alleges willful infringement of United States Patent Nos. 6,984,234 and 9,713, 537 by one or more of the following products: ZERO-P-VA™ Spacer, ZERO-P® Spacer, ZERO-P NATURAL™ Plate, SYNFIX® LR Spacer and SYNFIX® Evolution System. RSB Spine seeks monetary damages and injunctive relief. In November 2019, the suit was consolidated for pre-trial purposes with other patent infringement suits brought by RSB Spine in the United States District Court for the District of Delaware against Life Spine, Inc., Medacta USA, Inc., Precision Spine, Inc., and Xtant Medical Holdings, Inc.

Pharmaceutical

In August 2016, Sandoz Ltd and Hexal AG (collectively, Sandoz) filed a lawsuit in the English High Court against G.D. Searle LLC, a Pfizer company (Searle) and Janssen Sciences Ireland UC (JSI) alleging that Searle's supplementary protection certificate SPC/GB07/038 (SPC), which is exclusively licensed to JSI, is invalid and should be revoked. Janssen-Cilag Limited sells PREZISTA® (darunavir) in the United Kingdom pursuant to this license. In October 2016, Searle and JSI counterclaimed against Sandoz for threatened infringement of the SPC based on statements of its plans to launch generic darunavir in the United Kingdom. Sandoz admitted that its generic darunavir product would infringe the SPC if it is found valid. Searle and JSI are seeking an order enjoining Sandoz from marketing its generic darunavir before the expiration of the SPC. Following a trial in April 2017, the court entered a decision holding that the SPC is valid and granting a final injunction. Sandoz has appealed the court's decision and the injunction is stayed pending the appeal. In January 2018, the court referred the issue on appeal to the Court of Justice for the European Union (CJEU) and stayed the proceedings pending the CJEU's ruling on the issue. In December 2019, the parties entered into a settlement agreement.

In April 2018, Acerta Pharma B.V., AstraZeneca UK Ltd and AstraZeneca Pharmaceuticals LP filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Pharmacyclics LLC and Abbvie Inc. (collectively, Abbvie), alleging that the manufacture and sale of IMBRUVICA® infringes U.S. Patent No. 7,459,554. Janssen Biotech, Inc., which commercializes IMBRUVICA® jointly with Abbvie, intervened in the action in November 2018. In October 2019, the parties entered into a settlement agreement.

REMICADE® Related Cases

In August 2014, Celltrion Healthcare Co. Ltd. and Celltrion Inc. (collectively, Celltrion) filed an application with the United States Food and Drug Administration (FDA) for approval to make and sell its own infliximab biosimilar. In March 2015, Janssen Biotech, Inc. (JBI) filed a lawsuit in the United States District Court for the District of Massachusetts against Celltrion and Hospira Healthcare Corporation (Hospira), which has exclusive marketing rights for Celltrion's infliximab biosimilar in the United States, seeking, among other things, a declaratory judgment that their biosimilar product infringes or potentially infringes several JBI patents, including United States Patent No. 6,284,471 relating to REMICADE® (infliximab) (the '471 patent) and United States Patent No. 7,598,083 (the '083 patent) directed to the cell culture media used to make Celltrion's biosimilar. In August 2016, the district court granted both Celltrion's and Hospira's motions for summary judgment of invalidity of the '471 patent. JBI appealed those decisions to the United States Court of Appeals for the Federal Circuit. In January 2018, the Federal Circuit dismissed the appeal as moot based on its affirmance of a decision by the USPTO's Patent Trial and Appeal Board affirming invalidity of the '471 patent.

In June 2016, JBI filed two additional patent infringement lawsuits asserting the '083 patent, one against Celltrion and Hospira in the United States District Court for the District of Massachusetts and the other against HyClone Laboratories, Inc., the manufacturer of the cell culture media that Celltrion uses to make its biosimilar product, in the United States District Court for the District of Utah. JBI seeks monetary damages and other relief. In October 2017, the district court in the Massachusetts

action denied Celltrion and Hospira's motion to dismiss for lack of standing. In July 2018, the district court in the Massachusetts action granted Celltrion's motion for summary judgment of non-infringement and entered an order dismissing the '083 lawsuit against Celltrion and Hospira. JBI appealed to the United States Court of Appeals for the Federal Circuit, and Celltrion and Hospira cross-appealed on the standing issue. A hearing on the appeal and cross-appeal is scheduled for March 2020. The litigation against HyClone in Utah is stayed pending the outcome of the Massachusetts actions.

The FDA approved the first infliximab biosimilar for sale in the United States in 2016, and a number of such products have been launched.

Litigation Against Filers of Abbreviated New Drug Applications (ANDAs)

The following summarizes lawsuits pending against generic companies that have filed Abbreviated New Drug Applications (ANDAs) with the FDA or undertaken similar regulatory processes outside of the United States, seeking to market generic forms of products sold by various subsidiaries of Johnson & Johnson prior to expiration of the applicable patents covering those products. These ANDAs typically include allegations of non-infringement and invalidity of the applicable patents. In the event the subsidiaries are not successful in an action, or the automatic statutory stay of the ANDAs expires before the United States District Court rulings are obtained, the third-party companies involved would have the ability, upon approval of the FDA, to introduce generic versions of their products to the market, resulting in the potential for substantial market share and revenue losses for the applicable products, and which may result in a non-cash impairment charge in any associated intangible asset. In addition, from time to time, subsidiaries may settle these types of actions and such settlements can involve the introduction of generic versions of the products at issue to the market prior to the expiration of the relevant patents. The Inter Partes Review (IPR) process with the United States Patent and Trademark Office (USPTO), created under the 2011 America Invents Act, is also being used at times by generic companies in conjunction with ANDAs and lawsuits, to challenge the applicable patents.

ZYTIGA®

In July 2015, Janssen Biotech, Inc., Janssen Oncology, Inc. and Janssen Research & Development, LLC (collectively, Janssen) and BTG International Ltd. (BTG) initiated a patent infringement lawsuit (the main action) in the United States District Court for the District of New Jersey against a number of generic companies (and certain of their affiliates and/or suppliers) who filed ANDAs seeking approval to market a generic version of ZYTIGA® 250mg before the expiration of United States Patent No. 8,822,438 (the '438 patent). The generic companies include Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC (collectively, Amneal); Apotex Inc. and Apotex Corp. (collectively, Apotex); Citron Pharma LLC (Citron); Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, Dr. Reddy's); Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, Mylan); Par Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc. (collectively, Par); Teva Pharmaceuticals USA, Inc. (Teva); Wockhardt Bio A.G.; Wockhardt USA LLC and Wockhardt Ltd. (collectively, Wockhardt); West-Ward Pharmaceutical Corp. (West-Ward) and Hikma Pharmaceuticals, LLC (Hikma).

Janssen and BTG also initiated patent infringement lawsuits in the United States District Court for the District of New Jersey against Amerigen Pharmaceuticals Limited (Amerigen) in May 2016, and Glenmark Pharmaceuticals, Inc. (Glenmark) in June 2016, each of whom filed an ANDA seeking approval to market its generic version of ZYTIGA® before the expiration of the '438 patent. These lawsuits were consolidated with the main action.

In August 2015, Janssen and BTG filed an additional jurisdictional protective lawsuit against the Mylan defendants in the United States District Court for the Northern District of West Virginia, which has been stayed.

In August 2017, Janssen and BTG initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva, who filed an ANDA seeking approval to market a generic version of ZYTIGA® 500mg before the expiration of the '438 patent. This lawsuit has been consolidated with the main action.

In December 2017, Janssen and BTG entered into a settlement agreement with Glenmark.

In February 2018, Janssen and BTG filed a patent infringement lawsuit against MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited (collectively, MSN) in United States District Court for the District of New Jersey based on its ANDA seeking approval for a generic version of ZYTIGA® prior to the expiration of the '438 patent. In February 2019, the action was stayed pending the outcome of the main action.

In April 2018, Janssen and BTG entered into a settlement agreement with Apotex.

In October 2018, the United States District Court for the District of New Jersey issued a ruling invalidating all asserted claims of the ’438 patent. The court held that the patent claims would be infringed if the patent were valid. Janssen appealed the court’s decision.

In November 2018, Janssen and BTG initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Qilu Pharmaceutical Co., Ltd. and Qilu Pharma, Inc. (collectively, Qilu), who filed an ANDA seeking approval to market a generic version of ZYTIGA® before the expiration of the ’438 patent. Janssen is seeking an order enjoining Qilu from marketing its generic version of ZYTIGA® before the expiration of the ’438 patent.

In November 2018, the United States Court of Appeals for the Federal Circuit denied Janssen’s request for an injunction pending appeal. As a result, several generic versions of ZYTIGA® have entered the market.

Several generic companies including Amerigen, Argentum Pharmaceuticals LLC (Argentum), Mylan, Wockhardt, Actavis, Amneal, Dr. Reddy’s, Sun, Teva, West-Ward and Hikma filed Petitions for Inter Partes Review (IPR) with the USPTO, seeking to invalidate the ’438 patent. In January 2018, the USPTO issued decisions finding the ’438 patent claims unpatentable, and Janssen requested rehearing. In December 2018, the USPTO denied Janssen’s request for rehearing of the IPR decisions. Janssen filed an appeal, which was consolidated with the above-mentioned appeal of the decision of the United States District Court for the District of New Jersey. In May 2019, the Federal Circuit issued a decision affirming the USPTO's decision in the Wockhardt IPR that the ’438 patent claims are unpatentable and dismissed the remaining appeals as moot. Subsequently, Janssen dismissed its lawsuits against MSN and Qilu.

In November 2017, Janssen initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex Inc. (Apotex) and the Minister of Health in Canada in response to Apotex’s filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of ZYTIGA® before the expiration of Canadian Patent No. 2,661,422 (the ’422 patent). The final hearing concluded in May 2019. In October 2019, the court issued an order prohibiting the Canadian Minister of Health from approving Apotex’s ANDS until the expiration of the ’422 patent. In November 2019, Apotex filed an appeal.

In January 2019, Janssen initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex and the Minister of Health in Canada in response to Apotex’s filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a film-coated generic version of ZYTIGA® before the expiration of the ’422 patent.

In January 2019, Janssen initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Pharmascience Inc. (Pharmascience) and the Minister of Health in Canada in response to Pharmascience’s filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of ZYTIGA® 250 mg, before the expiration of the ’422 patent. The final hearing is scheduled to begin in October 2020.

In November 2019, Janssen initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Pharmascience and the Minister of Health in Canada in response to Pharmascience’s filing of an ANDS seeking approval to market a generic version of ZYTIGA®, 500 mg, before the expiration of the ’422 patent. The final hearing is scheduled to begin in October 2020.

In January 2019, Janssen initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Sandoz Canada Inc. (Sandoz) and the Minister of Health in Canada in response to Sandoz’s filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of ZYTIGA® before the expiration of Canadian Patent No. 2,661,422. In July 2019, the parties entered into a settlement agreement.

In June 2019, Janssen initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, DRL) and the Minister of Health in Canada in response to Apotex’s filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of ZYTIGA® before the expiration of Canadian Patent No. 2,661,422. The final hearing is scheduled to begin in October 2020.

In each of these Canadian actions, Janssen is seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance with respect to the defendants’ ANDSs before the expiration of Janssen’s patent.

XARELTO®

Beginning in October 2015, Janssen Pharmaceuticals, Inc. (JPI) and Bayer Pharma AG and Bayer Intellectual Property GmbH (collectively, Bayer) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of XARELTO® before expiration of Bayer's United States Patent Nos. 7,157,456, 7,585,860 and 7,592,339 relating to XARELTO®. JPI is the exclusive sublicensee of the asserted patents. The following generic companies are named defendants: Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. (collectively, Aurobindo); Breckenridge Pharmaceutical, Inc. (Breckenridge); InvaGen Pharmaceuticals Inc. (InvaGen); Micro Labs USA Inc. and Micro Labs Ltd (collectively, Micro); Mylan Pharmaceuticals Inc. (Mylan); Prinston Pharmaceuticals, Inc.; Sigmapharm Laboratories, LLC (Sigmapharm); Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. (collectively, Torrent). The trial concluded in April 2018. In July 2018 the district court entered judgment against Mylan and Sigmapharm, holding that the asserted compound patent is valid and infringed. In September 2018, the district court entered judgment against the remaining defendants. None of the defendants appealed the judgment.

Beginning in April 2017, JPI and Bayer Intellectual Property GmbH and Bayer AG (collectively, Bayer AG) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of XARELTO® before expiration of Bayer AG's United States Patent No. 9,539,218 ('218) relating to XARELTO®. JPI is the exclusive sublicensee of the asserted patent. The following generic companies are named defendants: Alembic Pharmaceuticals Limited, Alembic Global Holding SA and Alembic Pharmaceuticals, Inc. (Alembic); Aurobindo; Breckenridge; InvaGen; Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, Lupin); Micro; Mylan; Sigmapharm; Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals U.S.A., Inc. (collectively, Taro) and Torrent. Lupin counterclaimed for declaratory judgment of noninfringement and invalidity of United States Patent No. 9,415,053, but Lupin dismissed its counterclaims after it was provided a covenant not to sue on that patent. Aurobindo, Taro, Torrent, Micro, Breckenridge, InvaGen, Sigmapharm, Lupin and Alembic have agreed to have their cases stayed and to be bound by the outcome of any final judgment rendered against any of the other defendants. The '218 cases have been consolidated for discovery and trial. The trial began in April 2019 and closing arguments were heard in June 2019.

In December 2018, JPI and Bayer AG filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, Teva) who filed an ANDA seeking approval to market a generic version of XARELTO® before expiration of Bayer AG's '218 patent. The case against Teva has been consolidated with the other '218 cases for all purposes, and Teva has agreed to have its case stayed and to be bound by the outcome of any final judgment rendered against any of the other defendants.

In May 2018, Mylan filed a Petition for Inter Partes Review with the USPTO, seeking to invalidate the '218 patent. In December 2018, the USPTO issued a decision denying institution of Mylan's Petition for Inter Partes Review.

In May 2019, JPI and Bayer filed suit against Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. (collectively, Macleods) alleging infringement of the '218 patent. The case against Macleods has been consolidated with the other '218 cases for all purposes, and Macleods has agreed to have its case stayed and to be bound by the outcome of any final judgment rendered against any of the other defendants.

In June 2019, JPI and Bayer filed suit against Accord Healthcare Inc., Accord Healthcare Ltd., and Intas Pharmaceuticals Ltd. (collectively, Accord) alleging infringement of the '218 patent.

In August 2019, JPI and Bayer filed suit against Sunshine Lake Pharma Co., Ltd. and HEC Pharm USA Inc. alleging infringement of the '218 patent.

In October 2019, JPI and Bayer entered into a settlement agreement with Mylan. In November 2019, JPI and Bayer entered into a settlement agreement with Breckenridge. In December 2019, JPI and Bayer entered into settlement agreements with each of Accord, Micro, Sigmapharm, Sunshine, and Torrent. In January 2020, JPI and Bayer entered into a settlement agreement with Macleods.

The consolidated '218 cases involving Alembic, Aurobindo, InvaGen, Lupin, Taro, and Teva, and have been stayed until March 2020.

In each of these lawsuits, JPI is seeking an order enjoining the defendants from marketing their generic versions of XARELTO® before the expiration of the relevant patents.

PREZISTA®

In May 2018, Janssen Products, L.P. and Janssen Sciences Ireland UC (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Dr. Reddys Laboratories, Inc., Dr. Reddys Laboratories, Ltd., Laurus Labs, Ltd. and Pharmaq, Inc. (collectively, DRL) who filed an ANDA seeking approval to market generic versions of PREZISTA® before the expiration of United States Patent Nos. 8,518,987; 7,126,015; and 7,595,408. In February 2019, the parties entered into a settlement agreement.

In December 2018, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals Company GmbH, Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals Pvt Ltd., and Raks Pharma Pvt. Ltd. (collectively, Amneal), who filed an ANDA seeking approval to market generic versions of PREZISTA® before the expiration of United States Patent Nos. 8,518,987; 7,126,015; and 7,595,408. In April 2019, the parties entered into a settlement agreement.

In January 2020, Janssen Products, L.P. and Janssen Sciences Ireland Unlimited Company (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Zydus Pharmaceuticals (USA), Inc. and Cadila Healthcare Ltd. (collectively, Zydus), who filed an ANDA seeking approval to market a generic version of PREZISTA® before the expiration of United States Patent Nos. 7,700,645, 8,518,987, 7,126,015 and 7,595,408. Janssen is seeking an order enjoining Zydus from marketing its generic version of PREZISTA® before the expiration of the relevant patents.

INVOKANA®/INVOKAMET®/INVOKAMET XR®

Beginning in July 2017, Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Cilag GmbH International and Janssen Pharmaceutica NV (collectively, Janssen) and Mitsubishi Tanabe Pharma Corporation (MTPC) filed patent infringement lawsuits in the United States District Court for the District of New Jersey, the United States District Court for the District of Colorado and the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of INVOKANA® and/or INVOKAMET® before expiration of MTPC's United States Patent Nos. 7,943,582 (the '582 patent) and/or 8,513,202 (the '202 patent) relating to INVOKANA® and INVOKAMET®. Janssen is the exclusive licensee of the asserted patents. The following generic companies are named defendants: Apotex Inc. and Apotex Corp. (Apotex); Aurobindo Pharma USA Inc. (Aurobindo); Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc.; InvaGen Pharmaceuticals, Inc. (InvaGen); Prinston Pharmaceuticals Inc.; Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories Ltd; Hetero USA, Inc., Hetero Labs Limited Unit-V and Hetero Labs Limited; MSN Laboratories Private Ltd. and MSN Pharmaceuticals, Inc.; Laurus Labs Ltd.; Indoco Remedies Ltd.; Zydus Pharmaceuticals (USA) Inc. (Zydus); Sandoz, Inc. (Sandoz); Teva Pharmaceuticals USA, Inc.; and Lupin Ltd. and Lupin Pharmaceuticals, Inc. (Lupin).

Beginning in July 2017, Janssen and MTPC filed patent infringement lawsuits in the United States District Court for the District of New Jersey and the United States District Court for the District of Colorado against Sandoz and InvaGen, who filed ANDAs seeking approval to market generic versions of INVOKANA® and/or INVOKAMET® before expiration of MTPC's United States Patent No. 7,943,788 (the '788 patent) relating to INVOKANA® and INVOKAMET® and against Zydus, who filed ANDAs seeking approval to market generic versions of INVOKANA® and INVOKAMET® before expiration of the '788 patent, MTPC's United States Patent No. 8,222,219 relating to INVOKANA® and INVOKAMET® and MTPC's United States Patent No. 8,785,403 relating to INVOKAMET® (the '403 patent), and against Aurobindo, who filed an ANDA seeking approval to market a generic version of INVOKANA® before expiration of the '788 patent and the '219 patent relating to INVOKANA®. Janssen is the exclusive licensee of the asserted patents. In October 2017, the Colorado lawsuits against Sandoz were dismissed. In December 2017, the Delaware lawsuits against Apotex and Teva were dismissed.

In April 2018, Janssen and MTPC filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Prinston, who filed an ANDA seeking approval to market a generic version of INVOKANA® before expiration of the '788 patent relating to INVOKANA®.

In February 2019, Janssen and MTPC filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Lupin, who filed an ANDA seeking approval to market a generic version of INVOKAMET XR® before expiration of the '582 patent and '202 patent relating to INVOKAMET XR®.

In July 2019, Janssen and MTPC filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against MSN, who filed an ANDA seeking approval to market a generic version of INVOKAMET XR® before expiration of the '582 patent and '202 patent relating to INVOKAMET XR®.

In October 2019, Janssen and MTPC initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against MSN, who filed ANDAs seeking approval to market generic versions of INVOKANA® and INVOKAMET XR® before expiration of the '788 patent. In October 2019, Janssen and MTPC initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against DRL, who filed an ANDA seeking approval to market a generic version of INVOKAMET® before expiration of the '788 patent.

Janssen and MTPC entered into settlement agreements with Prinston and InvaGen (June 2019), Hetero (July 2019) and Apotex and Teva (August 2019).

A trial on the '582 and '202 patents is scheduled to begin in April 2020, and a trial on the '788, '219 and '403 patents is scheduled to begin in May 2020.

In each of these lawsuits, Janssen and MTPC are seeking an order enjoining the defendants from marketing their generic versions of INVOKANA®, INVOKAMET® and/or, INVOKAMET XR® before the expiration of the relevant patents.

OPSUMIT®

In January 2018, Actelion Pharmaceuticals Ltd (Actelion) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Zydus Pharmaceuticals (USA) Inc. (Zydus) and Amneal Pharmaceuticals LLC (Amneal), each of whom filed an ANDA seeking approval to market a generic version of OPSUMIT® before the expiration of United States Patent No. 7,094,781 (the '781 patent). In the lawsuit, Actelion is seeking an order enjoining Zydus and Amneal from marketing generic versions of OPSUMIT® before the expiration of the patent. Amneal and Zydus have stipulated to infringement. In February 2019, Actelion and Amneal entered into a settlement agreement. The trial against Zydus is scheduled to commence in October 2020.

In July 2019, Actelion Pharmaceuticals Ltd. filed suit against Aurobindo Pharma USA Inc. and Aurobindo Pharma Limited (Aurobindo). Aurobindo filed an ANDA seeking approval to market a generic version of OPSUMIT® before the expiration of the '781 patent. Actelion is seeking an order enjoining Defendants from marketing a generic version of OPSUMIT® before the expiration of the '781 patent. Trial against Aurobindo is scheduled to commence in July 2021.

INVEGA SUSTENNA®

In January 2018, Janssen Pharmaceutica NV and Janssen Pharmaceuticals, Inc. (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva Pharmaceuticals USA, Inc. (Teva), who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of United States Patent No. 9,439,906. Trial is scheduled to begin in June 2020.

In August 2019, Janssen Pharmaceutica NV and Janssen Pharmaceuticals, Inc. (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Mylan Laboratories Limited (Mylan), who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of the patent.

In December 2019, Janssen Pharmaceutica NV and Janssen Pharmaceuticals, Inc. (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Courts for the Districts of New Jersey and Delaware against Pharmascience Inc., Mallincrodt PLC and Specgx LLC (collectively, Pharmascience), who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of United States Patent No. 9,439,906.

In February 2018, Janssen Inc. and Janssen Pharmaceutica NV (collectively, Janssen) initiated a Notices of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Teva Canada Limited (Teva) and the Minister of Health in response to Teva's filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of Canadian Patent Nos. 2,309,629 and 2,655,335. Janssen is seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance with respect to Teva's ANDS before the expiration of these patents. The final hearing is scheduled to begin in February 2020.

In each of these lawsuits, Janssen is seeking an order enjoining the defendant from marketing a generic version of INVEGA SUSTENNA® before the expiration of the patent.

IMBRUVICA®

Beginning in January 2018, Pharmacyclics LLC (Pharmacyclics) and Janssen Biotech, Inc. (JBI) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of IMBRUVICA® 140 mg capsules before expiration of Pharmacyclics' United States Patent Nos. 8,008,309, 7,514,444, 8,697,711, 8,735,403, 8,957,079, 9,181,257, 8,754,091, 8,497,277, 8,925,015, 8,476,284, 8,754,090, 8,999,999, 9,125,889, 9,801,881, 9,801,883, 9,814,721, 9,795,604, 9,296,753, 9,540,382, 9,713,617 and/or 9,725,455 relating to IMBRUVICA®. JBI is the exclusive licensee of the asserted patents. The following generic companies are named defendants: Cipla Limited and Cipla USA Inc. (Cipla); Fresenius Kabi USA, LLC, Fresenius Kabi USA, Inc., and Fresenius Kabi Oncology Limited (Fresenius Kabi); Sandoz Inc. and Lek Pharmaceuticals d.d. (Sandoz); Shilpa Medicare Limited (Shilpa); Sun Pharma Global FZE and Sun Pharmaceutical Industries Limited (Sun); Teva Pharmaceuticals USA, Inc. (Teva); and Zydus Worldwide DMCC and Cadila Healthcare Limited (Zydus). The trial is scheduled to begin in October 2020.

In October 2018, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Sun asserting United States Patent No. 10,004,746.

In November 2018, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Hetero Labs Limited, Hetero Labs Limited Unit-1, Hetero Labs Limited Unit-V, and Hetero USA Inc. (Hetero), who filed an ANDA seeking approval to market a generic version of IMBRUVICA® 140 mg capsules, asserting infringement of United States Patent Nos. 8,754,090, 9,296,753, 9,540,382, 9,713,617 and 9,725,455.

In January 2019, Pharmacyclics and JBI amended their complaints against Fresenius Kabi, Zydus, Teva and Sandoz to further allege infringement of U.S. Patent Nos. 10,106,548, and 10,125,140.

In January 2019, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Zydus, who filed an ANDA seeking approval to market a generic version of IMBRUVICA® 70 mg before the expiration of U.S. Patent Nos. 7,514,444, 8,003,309, 8,476,284, 8,497,277, 8,697,711, 8,753,403, 8,754,090, 8,754,091, 8,952,015, 8,957,079, 9,181,257, 9,296,753, 9,540,382, 9,713,617, 9,725,455, 10,106,548, and 10,125,140.

In January 2019, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Hetero asserting infringement of United States Patent No. 10,106,548.

In February 2019, Pharmacyclics and JBI amended their complaints against Cipla, Shilpa, and Sun to allege infringement of United States Patent Nos. 10,106,548, and 10,125,140.

In February 2019, Pharmacyclics and JBI entered into settlement agreements with Teva and Hetero. In March 2019, Pharmacyclics and JBI entered into a settlement agreement with Shilpa.

In March 2019, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Alvogen Pine Brook LLC and Natco Pharma Ltd. (Alvogen), who filed an ANDA seeking approval to market generic versions of IMBRUVICA® tablets, asserting infringement of United States Patent Nos. 7,514,444, 8,003,309, 8,476,284, 8,497,277, 8,697,711, 8,753,403, 8,754,090, 8,754,091, 8,952,015, 8,957,079, 9,181,257, 9,296,753, 9,655,857, 9,725,455, 10,010,507, 10,106,548, and 10,125,140.

In May 2019, Pharmacyclics and JBI amended their complaints against Cipla to further allege infringement of United States Patent No. 10,016,435. In June 2019, Pharmacyclics and JBI amended their complaints against Alvogen to further allege infringement of United States Patent No. 10,213,386.

In August 2019, Pharmacyclics and JBI amended their complaints against Cipla, Fresenius, and Sandoz to further allege infringement of U.S. Patent Nos. 10,294,231 and 10,294,232 and amended their complaint against Sun to further allege infringement of U.S. Patent No. 10,294,232.

In March 2019, Sandoz filed an Inter Partes Review (IPR) in the USPTO, seeking to invalidate United States Patent No. 9,795,604.

In each of the lawsuits, Pharmacyclics and JBI are seeking an order enjoining the defendants from marketing generic versions of IMBRUVICA® before the expiration of the relevant patents.

TRACLEER®

In May 2019, Actelion Pharmaceuticals Ltd and Actelion Pharmaceuticals US, Inc. initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Natco Pharma Limited and Syneos Health LLC (collectively, Natco), who filed an ANDA seeking approval to market a generic version of TRACLEER®, 32 mg, before the expiration of U.S. Patent No. 8,309,126 (the '126 patent). In the lawsuit, Actelion is seeking an order enjoining Natco from marketing its generic version of TRACLEER® before the expiration of the '126 patent. In November 2019, the parties entered into a settlement agreement.

In December 2019, Actelion Pharmaceuticals Ltd and Actelion Pharmaceuticals US, Inc. initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Zydus Pharmaceuticals (USA), Inc. and Cadila Healthcare Limited (collectively, Zydus), who filed an ANDA seeking approval to market a generic version of TRACLEER®, 32 mg, before the expiration of U.S. Patent No. 8,309,126 (the '126 patent). Actelion is seeking an order enjoining Zydus from marketing its generic version of TRACLEER® before the expiration of the '126 patent.

RISPERDAL CONSTA®

In July 2019, Janssen Pharmaceuticals, Inc., Alkermes Pharma Ireland Limited and Alkermes Controlled Therapeutics, Inc. initiated a patent infringement lawsuit in the United States District Court for the District of Delaware against Luye Pharma Group Ltd., Luye Pharma (USA), Ltd., Nanjing Luye Pharmaceutical Co., Ltd. and Shandong Luye Pharmaceutical Co., Ltd. (collectively, Luye), who filed an ANDA seeking approval to market a generic version of RISPERDAL CONSTA® before the expiration of United States Patent No. 6,667,061. In November 2019, the parties entered into a settlement.

In this lawsuit, Janssen is seeking an order enjoining Luye from marketing a generic version of RISPERDAL CONSTA® before the expiration of the patent.

GOVERNMENT PROCEEDINGS

Like other companies in the pharmaceutical, consumer and medical devices industries, Johnson & Johnson and certain of its subsidiaries are subject to extensive regulation by national, state and local government agencies in the United States and other countries in which they operate. As a result, interaction with government agencies is ongoing. The most significant litigation brought by, and investigations conducted by, government agencies are listed below. It is possible that criminal charges and substantial fines and/or civil penalties or damages could result from government investigations or litigation.

Average Wholesale Price (AWP) Litigation

Johnson & Johnson and several of its pharmaceutical subsidiaries (the J&J AWP Defendants), along with numerous other pharmaceutical companies, were named as defendants in a series of lawsuits in state and federal courts involving allegations that the pricing and marketing of certain pharmaceutical products amounted to fraudulent and otherwise actionable conduct because, among other things, the companies allegedly reported an inflated Average Wholesale Price (AWP) for the drugs at issue. Payors alleged that they used those AWPs in calculating provider reimbursement levels. The plaintiffs in these cases included three classes of private persons or entities that paid for any portion of the purchase of the drugs at issue based on AWP, and state government entities that made Medicaid payments for the drugs at issue based on AWP. Many of these cases, both federal actions and state actions removed to federal court, were consolidated for pre-trial purposes in a multi-district litigation in the United States District Court for the District of Massachusetts, where all claims against the J&J AWP Defendants were ultimately dismissed. The J&J AWP Defendants also prevailed in a case brought by the Commonwealth of Pennsylvania. Other AWP cases have been resolved through court order or settlement. The case brought by Illinois was settled after trial. In New Jersey, a putative class action based upon AWP allegations is pending against Centocor, Inc. and Ortho Biotech Inc. (both now Janssen Biotech, Inc.), Johnson & Johnson and ALZA Corporation. All other cases have been resolved.

Opioid Litigation

Beginning in 2014 and continuing to the present, Johnson & Johnson and Janssen Pharmaceuticals, Inc. (JPI), along with other pharmaceutical companies, have been named in more than 2,800 lawsuits brought by certain state and local governments related to the marketing of opioids, including DURAGESIC®, NUCYNTA® and NUCYNTA® ER. The suits also raise allegations related to previously owned active pharmaceutical ingredient supplier subsidiaries, Tasmanian Alkaloids Pty, Ltd. and Noramco, Inc. (both subsidiaries were divested in 2016). Similar lawsuits have also been filed by the following groups of plaintiffs: individual plaintiffs on behalf of children suffering from Neonatal Abstinence Syndrome; hospitals; and health insurers/payors. To date, complaints against pharmaceutical companies, including Johnson & Johnson and JPI, have been filed by the state Attorneys General in Arkansas, Florida, Idaho, Illinois, Kentucky, Louisiana, Mississippi, Missouri, New

Hampshire, New Jersey, New Mexico, New York, Ohio, Oklahoma, South Dakota, Texas, Washington and West Virginia. Complaints against the manufacturers also have been filed in state or federal court by city, county and local government agencies in the following states: Alabama, Arkansas, California, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Mississippi, Missouri, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina; Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia and Wisconsin. The Government of Puerto Rico filed suit in Superior Court of San Juan. There are more than 350 cases pending in various state courts. There are over 2,500 federal cases coordinated in a federal Multi-District Litigation (MDL) pending in the U.S. District Court for the Northern District of Ohio (MDL No. 2804). In addition, the Province of British Columbia filed suit in Canada. In October 2019, an anti-trust complaint was filed by private plaintiffs in federal court in Tennessee and is pending transfer to the MDL. These actions allege a variety of claims related to opioid marketing practices, including false advertising, unfair competition, public nuisance, consumer fraud violations, deceptive acts and practices, false claims and unjust enrichment. The suits generally seek penalties and/or injunctive and monetary relief and, in some of the suits, the plaintiffs are seeking joint and several liability among the defendants. An adverse judgment in any of these lawsuits could result in the imposition of large monetary penalties and significant damages including, punitive damages, cost of abatement, substantial fines, equitable remedies and other sanctions.

The trial in the matter filed by the Oklahoma Attorney General resulted in a judgment against Johnson & Johnson and JPI in the amount of $572 million, subject to a final order to be issued by the court. The court issued a final judgment reducing the amount to $465 million. Johnson & Johnson and JPI have appealed the judgment. The Company believes that it has strong grounds to overturn this judgment. In October 2019 Johnson & Johnson and JPI announced a settlement of the first case set for trial in the MDL with two counties in Ohio.

Johnson & Johnson, JPI and other pharmaceutical companies have also received subpoenas or requests for information related to opioids marketing practices from the following state Attorneys General: Alaska, Indiana, Montana, New Hampshire, South Carolina, Tennessee, Texas and Washington. In September 2017, Johnson & Johnson and JPI were contacted by the Texas and Colorado Attorney General's Offices on behalf of approximately 38 states regarding a multi-state Attorney General investigation. In October 2019, the Company announced a proposed agreement in principle that would include the Company paying $4 billion as settlement of these lawsuits, subject to various conditions and an agreement being finalized. This agreement in principle is not an admission of liability or wrong-doing and would resolve opioid lawsuits filed and future claims by states, cities and counties. The Company cannot predict if or when the agreement will be finalized and individual cases are ongoing, including a trial in New York scheduled to commence in March 2020.

In August 2019, Johnson & Johnson received a grand jury subpoena from the United States Attorney's Office for the Eastern District of New York for documents related to the Company's anti-diversion policies and procedures and distribution of its opioid medications, in what the Company understands to be part of a broader investigation into manufacturers' and distributors' monitoring programs and reporting under the Controlled Substances Act. In September 2019, Johnson & Johnson received subpoenas from the New York State Department of Financial Services (NYDFS) as part of an industry-wide inquiry into the effect of opioid prescriptions on New York health insurance premiums. The Company is cooperating and producing documents in response to the various subpoenas and requests for information.

Other

In August 2012, DePuy Orthopaedics, Inc., DePuy, Inc. (now known as DePuy Synthes, Inc.), and Johnson & Johnson Services, Inc. (collectively DePuy) received an informal request from the United States Attorney's Office for the District of Massachusetts and the Civil Division of the United States Department of Justice (the United States) for the production of materials relating to the DePuy ASR™ XL Hip device. In July 2014, the United States notified the United States District Court for the District of Massachusetts that it had declined to intervene in a *qui tam* case filed pursuant to the False Claims Act against the companies. In February 2016, the district court granted the companies' motion to dismiss with prejudice, unsealed the *qui tam* complaint, and denied the *qui tam* relators' request for leave to file a further amended complaint. The *qui tam* relators appealed the case to the United States Court of Appeals for the First Circuit. In July 2017, the First Circuit affirmed the district court's dismissal in part, reversed in part, and affirmed the decision to deny the relators' request to file a third amended complaint. The relators' remaining claims are now pending before the district court, and fact discovery is currently scheduled to close in March 2020.

In October 2012, Johnson & Johnson was contacted by the California Attorney General's office regarding a multi-state Attorney General investigation of the marketing of surgical mesh products for hernia and urogynecological purposes by Johnson & Johnson's subsidiary, Ethicon, Inc. (Ethicon). In May 2016, California and Washington filed civil complaints against Johnson & Johnson, Ethicon and Ethicon US, LLC alleging violations of their consumer protection statutes. In April 2019, Johnson & Johnson and Ethicon settled the Washington case. The California case started trial in July 2019 and concluded in September

2019. In January 2020, the court found in favor of the state and awarded the state civil penalties of approximately $344 million. The Company intends to appeal when further proceedings are concluded in the trial court. Similar complaints were filed against the companies by Kentucky in August 2016, by Mississippi in October 2017, by West Virginia in September 2019 and by Oregon in December 2019. The trial date for the Kentucky case was scheduled for September 2019 but has been adjourned and no new trial date has been scheduled. In October 2019, Johnson & Johnson and Ethicon settled the multi-state investigation with 41 other states and the District of Columbia.

In December 2012, Therakos, Inc. (Therakos), formerly a subsidiary of Johnson & Johnson and part of the Ortho-Clinical Diagnostics, Inc. (OCD) franchise, received a letter from the civil division of the United States Attorney's Office for the Eastern District of Pennsylvania informing Therakos that the United States Attorney's Office was investigating the sales and marketing of Uvadex® (methoxsalen) and the Uvar Xts® and Cellex® Systems during the period 2000 to the present. The United States Attorney's Office requested that OCD and Johnson & Johnson preserve documents that could relate to the investigation. Therakos was subsequently acquired by an affiliate of Gores Capital Partners III, L.P. in January 2013, and OCD was divested in June 2014. Following the divestiture of OCD, Johnson & Johnson retains OCD's portion of any liability that may result from the investigation for activity that occurred prior to the sale of Therakos. In March 2014 and March 2016, the United States Attorney's Office requested that Johnson & Johnson produce certain documents, and Johnson & Johnson is cooperating with those requests.

In June 2014, the Mississippi Attorney General filed a complaint in Chancery Court of The First Judicial District of Hinds County, Mississippi against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (now known as Johnson & Johnson Consumer Inc.) (JJCI). The complaint alleges that defendants violated the Mississippi Consumer Protection Act by
failing to disclose alleged health risks associated with female consumers' use of talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product divested in 2012) and seeks injunctive and monetary relief. The matter is stayed pending interlocutory appeal of a December 2018 denial of Johnson & Johnson and JJCI's motion for summary judgment. The Mississippi Supreme Court granted J&J and JJCI's request to file an interlocutory appeal of the denial of the motion for summary judgment in late 2019 and it will soon establish a briefing schedule. The Company has also received inquiries from several other State Attorneys General.

In March 2016, Janssen Pharmaceuticals, Inc. (JPI) received a Civil Investigative Demand from the United States Attorney's Office for the Southern District of New York related to JPI's contractual relationships with pharmacy benefit managers over the period from January 1, 2006 to the present with regard to certain of JPI's pharmaceutical products. The demand was issued in connection with an investigation under the False Claims Act.

In July 2016, Johnson & Johnson and Janssen Products LP were served with a *qui tam* complaint pursuant to the False Claims Act filed in the United States District Court for the District of New Jersey alleging the off-label promotion of two HIV products, PREZISTA® and INTELENCE®, and anti-kickback violations in connection with the promotion of these products. The complaint was filed under seal in December 2012. The federal and state governments have declined to intervene, and the lawsuit is being prosecuted by the relators.

In January 2017, Janssen Pharmaceuticals, Inc. (JPI) received a Civil Investigative Demand from the United States Department of Justice relating to allegations concerning the sales and marketing practices of OLYSIO®. In December 2017, Johnson & Johnson and JPI were served with a whistleblower lawsuit filed in the United States District Court for the Central District of California alleging the off-label promotion of OLYSIO® and additional products, including NUCYNTA®, XARELTO®, LEVAQUIN® and REMICADE®. At this time, the federal and state governments have declined to intervene and the lawsuit, which is related to the Civil Investigative Demand, is being prosecuted by a former company employee. The United States District Court for the Central District of California dismissed the claim in April 2018. In May 2018, the relator filed a notice of appeal to the United States Court of Appeals for the Ninth Circuit. In January 2020, the U.S. Court of Appeals for the Ninth Circuit dismissed the relator's appeal.

In November 2018, a second whistleblower lawsuit was unsealed in the United States District Court for the Central District of California. The lawsuit was substantially similar to the lawsuit under appeal but was brought in the name of the original relator. The federal and state governments declined to intervene in the second suit, and the relator moved to dismiss the lawsuit without prejudice. In April 2019, the court granted the relator's motion and dismissed the complaint without prejudice.

In March 2017, Janssen Biotech, Inc. received a Civil Investigative Demand from the United States Department of Justice regarding a False Claims Act investigation concerning management and advisory services provided to rheumatology and gastroenterology practices that purchased REMICADE® or SIMPONI ARIA®. In August 2019, the Unites States Department of Justice notified Janssen Biotech, Inc. that it was closing the investigation. In January 2020, Janssen Biotech, Inc. was served with a newly-unsealed qui tam suit filed in the U.S. District Court for the District of Massachusetts.

In April and September 2017, Johnson & Johnson received subpoenas from the United States Attorney for the District of Massachusetts seeking documents broadly relating to pharmaceutical copayment support programs for DARZALEX®, OLYSIO®, REMICADE®, SIMPONI®, STELARA® and ZYTIGA®. The subpoenas also seek documents relating to Average Manufacturer Price and Best Price reporting to the Center for Medicare and Medicaid Services related to those products, as well as rebate payments to state Medicaid agencies.

In June 2017, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts seeking information regarding practices pertaining to the sterilization of DePuy Synthes, Inc. spinal implants at three hospitals in Boston as well as interactions of employees of Company subsidiaries with physicians at these hospitals. Johnson & Johnson and DePuy Synthes, Inc. have produced documents in response to the subpoena and are fully cooperating with the government's investigation.

In July 2018 the Public Prosecution Service in Rio de Janeiro and representatives from the Brazilian antitrust authority CADE inspected the offices of more than 30 companies including Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda. The authorities appear to be investigating allegations of possible anti-competitive behavior and possible improper payments in the medical device industry. The United States Department of Justice and the United States Securities and Exchange Commission have made additional inquiries, and Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda. is cooperating with those requests.

In January 2020, the New Mexico Attorney General's Office filed a suit against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. in the First Judicial District Court, New Mexico. The suit relates to the safety and marketing of the Company's talc products. The State included claims for violations of the New Mexico Unfair Practices Act, Medicaid Fraud Act, Fraud Against Taxpayers Act, Fraud and Negligent Misrepresentation, Negligence and Unjust Enrichment. Other state Attorneys General have informed the Company that they are conducting an inquiry into this matter.

From time to time, the Company has received requests from a variety of United States Congressional Committees to produce information relevant to ongoing congressional inquiries. It is the policy of Johnson & Johnson to cooperate with these inquiries by producing the requested information.

GENERAL LITIGATION

In May 2014, two purported class actions were filed in federal court, one in the United States District Court for the Central District of California and one in the United States District Court for the Southern District of Illinois, against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (now known as Johnson & Johnson Consumer Inc.) (JJCI) alleging violations of state consumer fraud statutes based on nondisclosure of alleged health risks associated with talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product no longer sold by JJCI). Both cases seek injunctive relief and monetary damages; neither includes a claim for personal injuries. In October 2016, both cases were transferred to the United States District Court for the District Court of New Jersey as part of a newly created federal multi-district litigation. In July 2017, the district court granted Johnson & Johnson's and JJCI's motion to dismiss one of the cases. In September 2018, the United States Court of Appeals for the Third Circuit affirmed this dismissal. In September 2017, the plaintiff in the second case voluntarily dismissed the complaint. In March 2018, the plaintiff in the second case refiled in Illinois State Court.

In August 2014, United States Customs and Border Protection (US CBP) issued a Penalty Notice against Janssen Ortho LLC (Janssen Ortho), assessing penalties for the alleged improper classification of darunavir ethanolate (the active pharmaceutical ingredient in PREZISTA®) in connection with its importation into the United States. In October 2014, Janssen Ortho submitted a Petition for Relief in response to the Penalty Notice. In May 2015, US CBP issued an Amended Penalty Notice assessing substantial penalties and Janssen Ortho filed a Petition for Relief in July 2015. In May 2019, US CBP issued its Mitigation Decision and determined that Janssen Ortho had negligently misrepresented that darunavir ethanolate is entitled to duty free treatment. In June 2019, Janssen Ortho filed a Supplemental Petition for Relief. The Penalties Proceeding will be impacted by the related Classification Litigation pending in the United States Court of International Trade. The Classification Litigation will determine whether darunavir ethanolate was properly classified as exempt from duties upon importation into the United States. The trial in the Classification Litigation was held in July 2019. In February 2020, the Court ruled that darunavir ethanolate is eligible for duty free treatment.

In March and April 2015, over 30 putative class action complaints were filed by contact lens patients in a number of courts around the United States against Johnson & Johnson Vision Care, Inc. (JJVCI) and other contact lens manufacturers, distributors, and retailers, alleging vertical and horizontal conspiracies to fix the retail prices of contact lenses. The complaints

allege that the manufacturers reached agreements with each other and certain distributors and retailers concerning the prices at which some contact lenses could be sold to consumers. The plaintiffs are seeking damages and injunctive relief. All of the class action cases were transferred to the United States District Court for the Middle District of Florida in June 2015. The plaintiffs filed a consolidated class action complaint in November 2015. In December 2018, the district court granted the plaintiffs' motion for class certification. Defendants filed two motions for interlocutory appeal of class certification to the United States Court of Appeals for the Eleventh Circuit. Both motions were denied. Defendants' motions for summary judgment were denied in November 2019. Trial is scheduled for June 2020.

In August 2015, two third-party payors filed a purported class action in the United States District Court for the Eastern District of Louisiana against Janssen Research & Development, LLC, Janssen Ortho LLC, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Johnson & Johnson (as well as certain Bayer entities), alleging that the defendants improperly marketed and promoted XARELTO® as safer and more effective than less expensive alternative medications while failing to fully disclose its risks. The complaint seeks damages.

In September 2017, Pfizer, Inc. (Pfizer) filed an antitrust complaint against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) in United States District Court for the Eastern District of Pennsylvania. Pfizer alleges that Janssen has violated federal antitrust laws through its contracting strategies for REMICADE®. The complaint seeks damages and injunctive relief. Discovery is ongoing.

Beginning in September 2017, multiple purported class actions of direct and indirect purchasers were filed against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) alleging that Janssen's REMICADE® contracting strategies violated federal and state antitrust and consumer laws and seeking damages and injunctive relief. In November 2017, the cases were consolidated for pre-trial purposes in United States District Court for the Eastern District of Pennsylvania as In re Remicade Antitrust Litigation. Motions to dismiss were denied in both the direct and indirect purchaser cases. A motion to compel arbitration of the direct purchaser case was denied by the district court. The United States Court of Appeals for the Third Circuit reversed the district court's ruling.

In June 2018, Walgreen Co. and Kroger Co, filed an antitrust complaint against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) in the United States District Court for the Eastern District of Pennsylvania. The complaint alleges that Janssen has violated federal antitrust laws through its contracting strategies for REMICADE®. The complaint seeks damages and injunctive relief. In March 2019, summary judgment was granted in favor of Janssen. This ruling is on appeal to the United States Court of Appeals for the Third Circuit.

In June 2019, the United States Federal Trade Commission (FTC) issued a Civil Investigative Demand to Johnson & Johnson in connection with its investigation of whether Janssen's REMICADE® contracting practices violate federal antitrust laws. The Company has produced documents and information responsive to the Civil Investigative Demand.

In October 2017, certain United States service members and their families brought a complaint against a number of pharmaceutical and medical devices companies, including Johnson & Johnson and certain of its subsidiaries, alleging that the defendants violated the United States Anti-Terrorism Act. The complaint alleges that the defendants provided funding for terrorist organizations through their sales practices pursuant to pharmaceutical and medical device contracts with the Iraqi Ministry of Health. In January 2019, plaintiffs' motion to file a Second Amended Complaint adding plaintiffs to the lawsuit was granted. In April 2019, the Company moved to dismiss the Second Amended Complaint.

In October 2018, two separate putative class actions were filed against Actelion Pharmaceutical Ltd., Actelion Pharmaceuticals US, Inc., and Actelion Clinical Research, Inc. (collectively Actelion) in United States District Court for the District of Maryland and United States District Court for the District of Columbia. The complaints allege that Actelion violated state and federal antitrust and unfair competition laws by allegedly refusing to supply generic pharmaceutical manufacturers with samples of TRACLEER®. TRACLEER® is subject to a Risk Evaluation and Mitigation Strategy, which imposes restrictions on distribution of the product. In January 2019, the plaintiffs dismissed the District of Columbia case and filed a consolidated complaint in the United States District Court for the District of Maryland. In October 2019, the Court granted Actelion's motion to dismiss the amended complaint. Plaintiffs have appealed the decision.

In December 2018, Janssen Biotech, Inc., Janssen Oncology, Inc, Janssen Research & Development, LLC, and Johnson & Johnson (collectively, Janssen) were served with a *qui tam* complaint filed on behalf of the United States, 28 states, and the District of Columbia. The complaint, which was filed in December 2017 in United States District Court for the Northern District of California, alleges that Janssen violated the federal False Claims Act and state law when providing pricing information for ZYTIGA® to the government in connection with direct government sales and government-funded drug

reimbursement programs. At this time, the federal and state governments have declined to intervene. The case has been transferred to United States District Court for the District of New Jersey. Janssen has moved to dismiss the complaint.

In April 2019, Blue Cross & Blue Shield of Louisiana and HMO Louisiana, Inc. filed a class action complaint against Janssen Biotech, Inc, Janssen Oncology, Inc, Janssen Research & Development, LLC and BTG International Limited in the United States District Court for the Eastern District of Virginia. Several additional complaints were filed thereafter. The complaints generally allege that the defendants violated the antitrust and consumer protections laws of several states and the Sherman Act
by pursuing patent litigation relating to ZYTIGA® in order to delay generic entry. The case has been transferred to the United States District Court for the District of New Jersey and consolidated for pretrial purposes.

In May 2019, a class action antitrust complaint was filed against Janssen R&D Ireland (Janssen) and Johnson & Johnson. The complaint alleges that Janssen violated federal and state antitrust and consumer protection laws by agreeing to exclusivity provisions in its agreements with Gilead concerning the development and marketing of combination antiretroviral therapies (cART) to treat HIV. The complaint also alleges that Gilead entered into similar agreements with Bristol-Myers-Squibb and Japan Tobacco. The case is pending in the United States District Court for the District of Northern California. The defendants have filed motions to dismiss the complaint.

In October 2019, Innovative Health, LLC filed a complaint against Biosense Webster, Inc. (BWI) in the United States District Court for the Middle District of California. The complaint alleges that certain of BWI's business practices and contractual terms violate the antitrust laws of the United States and the State of California by restricting competition in the sale of High Density Mapping Catheters and Ultrasound Catheters. BWI filed a motion to dismiss the complaint.

The Company received notices from Pfizer, Inc. and Sanofi Consumer Health, Inc. in November 2019 and Boehringer Ingelheim Pharmaceuticals, Inc. in January 2020 tendering for defense and indemnification of legal claims related to personal injury matters and putative class actions in the U.S. and Canada related to Zantac (ranitidine) products. The notices were based on certain indemnification provisions regarding assumed liabilities in connection with the Stock and Asset Purchase Agreement between Pfizer, Inc. and the Company in 2006. Plaintiffs in the underlying suits allege generally that Zantac and other over-the-counter ranitidine medications contain unsafe levels of NDMA (N-nitrosodimethylamine) and can cause and/or have caused various cancers in patients using the products, for which plaintiffs are seeking injunctive and monetary relief.

Johnson & Johnson or its subsidiaries are also parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the cost of past and/or future remediation.

22. Restructuring

The Company announced plans to implement a series of actions across its Global Supply Chain that are intended to focus resources and increase investments in the critical capabilities, technologies and solutions necessary to manufacture and supply its product portfolio, enhance agility and drive growth. The Global Supply Chain actions will include expanding the use of strategic collaborations and bolstering initiatives to reduce complexity, improve cost-competitiveness, enhance capabilities and optimize the Supply Chain network. For additional details on the global supply chain restructuring strategic collaborations see Note 20 to the Consolidated Financial Statements. In 2019, the Company recorded a pre-tax charge of $0.6 billion, which is included on the following lines of the Consolidated Statement of Earnings, $0.3 billion in restructuring, $0.2 billion in other (income) expense and $0.1 billion in cost of products sold. Total project costs of approximately $0.8 billion have been recorded since the restructuring was announced. See the following table for additional details on the restructuring program.

In total, the Company expects the Global Supply Chain actions to generate approximately $0.6 billion to $0.8 billion in annual pre-tax cost savings that will be substantially delivered by 2022. The Company expects to record pre-tax restructuring charges of approximately $1.9 billion to $2.3 billion, over the 4 to 5 year period of this activity. These costs are associated with network optimizations, exit costs and accelerated depreciation and amortization.

The following table summarizes the severance charges and the associated spending under these initiatives through the fiscal year ended 2019:

(Dollars in Millions)	Severance	Asset Write-offs	Other[2]	Total
Reserve balance, December 31, 2017	229	—	38	267
2018 activity	(35)	—	10	(25)
Reserve balance, December 30, 2018	194	—	48	242
Current year activity:				
Charges	—	151	460	611
Cash payments	(30)	—	(424)	(454)
Settled non cash	—	(151)	(68) [3]	(219)
Reserve balance, December 29, 2019[1]	$ 164	—	16	180

[1] Cash outlays for severance are expected to be substantially paid out over the next 2 years in accordance with the Company's plans and local laws.
[2] Other includes project expense such as salaries for employees supporting these initiatives and consulting expenses.
[3] Relates to pension related actuarial losses associated with the transfer of employees to Jabil Inc. as part of the strategic collaboration.

The Company continuously reevaluates its severance reserves related to restructuring and the timing of payments due to the planned release of associates regarding several longer-term projects. The Company believes that the existing severance reserves are sufficient to cover the Global Supply Chain plans given the period over which the actions will take place. The Company will continue to assess and make adjustments as necessary if additional amounts become probable and estimable.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Johnson & Johnson

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Johnson & Johnson and its subsidiaries (the "Company") as of December 29, 2019 and December 30, 2018, and the related consolidated statements of earnings, of comprehensive income, of equity, and of cash flows for each of the three fiscal years in the period ended December 29, 2019, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 29, 2019 based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 29, 2019 and December 30, 2018, and the results of its operations and its cash flows for each of the three fiscal years in the period ended December 29, 2019 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 29, 2019, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As described in Management's Report on Internal Control Over Financial Reporting, management has excluded Ci:z Holdings Co., Ltd., ("DR. CI:LABO") from its assessment of internal control over financial reporting as of December 29, 2019, because it was acquired by the Company in a business combination during 2019. We have also excluded DR. CI:LABO from our audit of internal control over financial reporting. DR. CI:LABO is wholly-owned subsidiary whose total assets, excluding intangible assets and goodwill, and total sales excluded from management's assessment and our audit of internal control over financial reporting represent less than 1% of each of the related consolidated financial statement amounts as of and for the fiscal year ended December 29, 2019.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and

dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

U.S. Pharmaceutical Rebate Reserves - Managed Care, Medicare and Medicaid

As described in Note 1 to the consolidated financial statements, the Company recognizes revenue from product sales when obligations under the terms of a contract with the customer are satisfied. Rebates and discounts provided to customers are accounted for as variable consideration and recorded as a reduction in sales. The liability for such rebates and discounts is recognized within Accrued Rebates, Returns and Promotions on the consolidated balance sheet. A significant portion of the liability related to rebates is from the sale of pharmaceutical goods within the U.S., primarily the Managed Care, Medicare and Medicaid programs, which amounted to $7.0 billion as of December 29, 2019. For significant rebate programs, which include the U.S. Managed Care, Medicare and Medicaid rebate programs, rebates and discounts estimated by management are based on contractual terms, historical experience, patient outcomes, trend analysis, and projected market conditions in the U.S. pharmaceutical market.

The principal considerations for our determination that performing procedures relating to U.S. pharmaceutical rebate reserves - Managed Care, Medicare and Medicaid is a critical audit matter are the use of significant judgment by management due to the significant measurement uncertainty involved in developing these reserves. This in turn led to a high degree of auditor judgment and subjectivity and audit effort in applying procedures for the assumptions related to contractual terms with customers, historical experience, patient outcomes, trend analysis, and projected market conditions in the U.S.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to U.S. pharmaceutical rebate reserves - Managed Care, Medicare and Medicaid, including controls over the assumptions used to estimate these rebates. These procedures also included, among others, (i) developing an independent estimate of the rebates by utilizing third party information on price and market conditions in the U.S., the terms of the specific rebate programs, and the historical trend of actual rebate claims paid; (ii) testing rebate claims processed by the Company, including evaluating those claims for consistency with the contractual and mandated terms of the Company's rebate arrangements; and (iii) comparing the independent estimate to management's estimates.

Litigation Contingencies - Talc

As described in Notes 1 and 21 to the consolidated financial statements, the Company records accruals for loss contingencies associated with legal matters, including talc, when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. To the extent adverse verdicts have been rendered against the Company, management does not record an accrual until a loss is determined to be probable and can be reasonably estimated. For these matters, management is unable to estimate the reasonably possible loss or range of loss. The ability to make such estimates and judgments can be affected by various factors, including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; or there are numerous parties involved. There have been verdicts against the Company for this matter, including a verdict in July 2018 of $4.7 billion. As described by management, the Company believes

that it has strong grounds on appeal to overturn these verdicts. The Company has established an accrual primarily for defense costs in connection with product liability litigation associated with body powders containing talc.

The principal considerations for our determination that performing procedures relating to the talc litigation is a critical audit matter are the use of significant judgment by management when assessing the likelihood of a loss being incurred and management's determination of whether a reasonable estimate of the loss or range of loss for each claim can be made. This in turn led to a high degree of auditor judgment and effort in evaluating management's assessment of the loss contingencies associated with this litigation.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's evaluation of the talc litigation, including controls over determining whether a loss is probable and whether the amount of loss can be reasonably estimated, as well as financial statement disclosures. These procedures also included, among others, (i) gaining an understanding of the Company's process around the accounting and reporting for the talc litigation; (ii) discussing the status of significant known actual and potential litigation with the Company's in-house legal counsel, as well as external counsel when deemed necessary; (iii) obtaining and evaluating the letters of audit inquiry with internal and external legal counsel for significant litigation; (iv) evaluating the reasonableness of management's assessment regarding whether an unfavorable outcome is reasonably possible or probable and reasonably estimable; and (v) evaluating the sufficiency of the Company's litigation contingencies disclosures.

Litigation - Opioids

As described in Notes 18 and 21 to the consolidated financial statements, the Company records accruals for loss contingencies associated with legal matters, including opioids, when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. To the extent adverse verdicts have been rendered against the Company, management does not record an accrual until a loss is determined to be probable and can be reasonably estimated. For these matters, management is unable to estimate the reasonably possible loss or range of loss. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors, including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; or there are numerous parties involved. The Company has been named in numerous lawsuits brought by certain state and local governments related to opioids matters. The trial in the matter filed by the Oklahoma Attorney General resulted in a judgment against the Company in the amount of $572 million which was subsequently reduced to $465 million. The Company has appealed the judgment and, as described by management, believes that it has strong grounds to overturn this judgment. Separately in October 2019, the Company announced a proposed agreement in principle that would include the Company paying $4 billion as settlement of these lawsuits, subject to various conditions and an agreement being finalized. The Company cannot predict if or when the agreement will be finalized. The Company has recorded a pre-tax charge of $4 billion during the fiscal year ended December 29, 2019 for this matter.

The principal considerations for our determination that performing procedures relating to the opioids litigation is a critical audit matter are the use of significant judgment by management when assessing the likelihood of a loss being incurred for the judgment against the Company in Oklahoma and management's determination of whether a reasonable estimate of the range of loss for the proposed agreement in principle to settle opioids litigation can be made. This in turn led to a high degree of auditor judgment and effort in evaluating management's assessment of the loss contingencies associated with this litigation.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's evaluation of the opioid litigation, including controls over determining whether a loss is probable and whether the amount of loss can be reasonably estimated, as well as financial statement disclosures. These procedures also included, among others, (i) gaining an understanding of the Company's process around the accounting and reporting for the opioids litigation; (ii) discussing the status of significant known actual and potential litigation and ongoing settlement negotiations with the Company's in-house legal counsel, as well as external counsel when deemed necessary; (iii) obtaining and evaluating the letters of audit inquiry with internal and external legal counsel for significant litigation; (iv) evaluating the reasonableness of management's assessment regarding whether an unfavorable outcome is reasonably possible or probable and reasonably estimable; and (v) evaluating the sufficiency of the Company's litigation contingencies disclosures.

/s/ PricewaterhouseCoopers LLP Florham Park, New Jersey February 18, 2020

We have served as the Company's auditor since at least 1920. We have not been able to determine the specific year we began serving as auditor of the Company.

Management's Report on Internal Control Over Financial Reporting

Under Section 404 of the Sarbanes-Oxley Act of 2002, management is required to assess the effectiveness of the Company's internal control over financial reporting as of the end of each fiscal year and report, based on that assessment, whether the Company's internal control over financial reporting is effective.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is designed to provide reasonable assurance as to the reliability of the Company's financial reporting and the preparation of external financial statements in accordance with generally accepted accounting principles.

Internal controls over financial reporting, no matter how well designed, have inherent limitations. Therefore, internal control over financial reporting determined to be effective can provide only reasonable assurance with respect to financial statement preparation and may not prevent or detect all misstatements. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management has assessed the effectiveness of the Company's internal control over financial reporting as of December 29, 2019. In making this assessment, the Company used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework (2013)." These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. The Company's assessment included extensive documenting, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

The Company acquired Ci:z Holdings Co., Ltd., (DR. CI:LABO), in a business combination during January 2019. DR. CI:LABO's total assets, excluding intangible assets and goodwill, and total sales represented less than 1% of each of the related consolidated financial statement amounts as of and for the fiscal year ended December 29, 2019. As the acquisition occurred in the fiscal year 2019, the scope of the Company's assessment of the design and effectiveness of internal control over financial reporting for the fiscal year 2019 excluded the above mentioned acquisition. This exclusion is in accordance with the SEC's general guidance that an assessment of a recently acquired business may be omitted from the scope in the year of acquisition.

Based on the Company's processes and assessment, as described above, management has concluded that, as of December 29, 2019, the Company's internal control over financial reporting was effective.

The effectiveness of the Company's internal control over financial reporting as of December 29, 2019 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which appears herein.

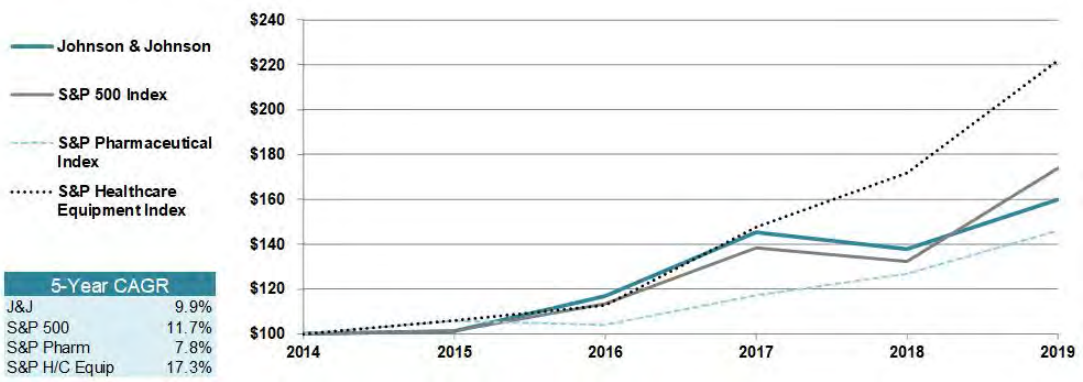
/s/ Alex Gorsky
Alex Gorsky
Chairman, Board of Directors
Chief Executive Officer

/s/ Joseph J. Wolk
Joseph J. Wolk
Executive Vice President, Chief Financial Officer

Shareholder Return Performance Graphs

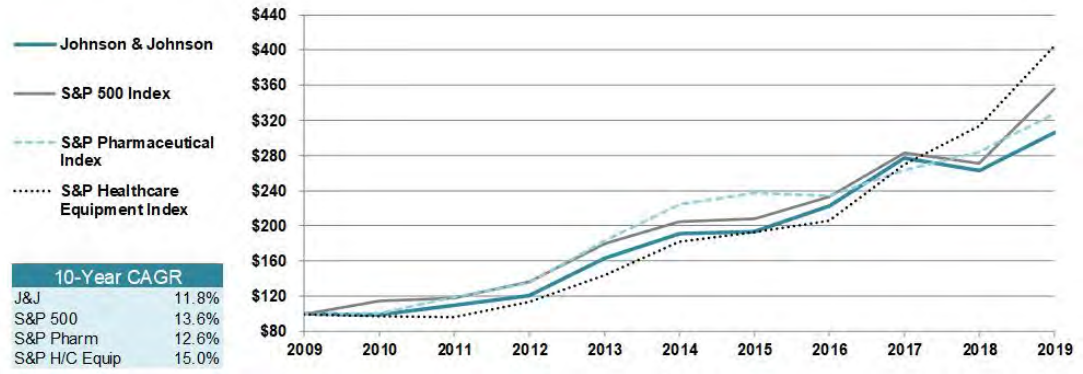
Set forth below are line graphs comparing the cumulative total shareholder return on the Company's Common Stock for periods of five years and ten years ending December 31, 2019, against the cumulative total return of the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index. The graphs and tables assume that $100 was invested on December 31, 2014 and December 31, 2009 in each of the Company's Common Stock, the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index and that all dividends were reinvested.

5 Year Shareholder Return Performance J&J vs. Indices



	2014	2015	2016	2017	2018	2019
Johnson & Johnson	$100.00	$101.16	$116.66	$145.13	$137.67	$159.99
S&P 500 Index	$100.00	$101.37	$113.49	$138.26	$132.19	$173.80
S&P Pharmaceutical Index	$100.00	$105.79	$104.13	$117.22	$126.71	$145.83
S&P Healthcare Equipment Index	$100.00	$105.97	$112.85	$147.71	$171.70	$222.04

10 Year Shareholder Return Performance J&J vs. Indices



	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Johnson & Johnson	$100.00	$99.42	$109.25	$121.08	$162.99	$191.25	$193.46	$223.10	$277.55	$263.30	$305.98
S&P 500 Index	$100.00	$115.06	$117.48	$136.27	$180.39	$205.06	$207.88	$232.73	$283.51	$271.06	$356.39
S&P Pharmaceutical Index	$100.00	$100.77	$118.67	$135.79	$183.63	$224.43	$237.41	$233.70	$263.08	$284.37	$327.28
S&P Healthcare Equipment Index	$100.00	$97.29	$96.51	$113.18	$144.52	$182.49	$193.40	$205.94	$269.56	$313.34	$405.21

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE 1113

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures. At the end of the period covered by this Report, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Alex Gorsky, Chairman and Chief Executive Officer, and Joseph J. Wolk, Executive Vice President, Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Gorsky and Wolk concluded that, as of the end of the period covered by this Report, the Company's disclosure controls and procedures were effective

Reports on Internal Control Over Financial Reporting. The information called for by this item is incorporated herein by reference to "Management's Report on Internal Control Over Financial Reporting", and the attestation regarding internal controls over financial reporting included in the "Report of Independent Registered Public Accounting Firm" included in Item 8 of this Report.

Changes in Internal Control Over Financial Reporting. During the fiscal quarter ended December 29, 2019, there were no changes in the Company's internal control over financial reporting identified in connection with the evaluation required under Rules 13a-15 and 15d-15 under the Exchange Act that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

The Company is implementing a multi-year, enterprise-wide initiative to integrate, simplify and standardize processes and systems for the human resources, information technology, procurement, supply chain and finance functions. These are enhancements to support the growth of the Company's financial shared service capabilities and standardize financial systems. This initiative is not in response to any identified deficiency or weakness in the Company's internal control over financial reporting. In response to this initiative, the Company has and will continue to align and streamline the design and operation of its financial control environment.

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information called for by this item is incorporated herein by reference to the discussion of the Audit Committee under the caption "Item 1. Election of Directors - Board Committees"; and the material under the captions "Item 1. Election of Directors" and "Stock Ownership and Section 16 Compliance – Delinquent Section 16(a) Reports" in the Proxy Statement; and the material under the caption "Executive Officers of the Registrant" in Part I of this Report.

The Company's Code of Business Conduct, which covers all employees (including the Chief Executive Officer, Chief Financial Officer and Controller), meets the requirements of the SEC rules promulgated under Section 406 of the Sarbanes-Oxley Act of 2002. The Code of Business Conduct is available on the Company's website at *www.jnj.com/code-of-business-conduct*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code of Business Conduct or any waiver of the Code granted to the Chief Executive Officer, the Chief Financial Officer or the Controller will be posted on the Company's website at *www.investor.jnj.com/gov.cfm* within five business days (and retained on the website for at least one year).

In addition, the Company has adopted a Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers. The Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers is available on the Company's website at *www.investor.jnj.com/gov/boardconduct.cfm*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code or any waiver of the Code granted to any member of the Board of Directors or any executive officer will be posted

on the Company's website at *www.investor.jnj.com/gov.cfm* within five business days (and retained on the website for at least one year).

Item 11. EXECUTIVE COMPENSATION

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1. Election of Directors – Director Compensation," and "Item 2. Compensation Committee Report," "Compensation Discussion and Analysis" and "Executive Compensation Tables" in the Proxy Statement.

The material incorporated herein by reference to the material under the caption "Compensation Committee Report" in the Proxy Statement shall be deemed furnished, and not filed, in this Report and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, as a result of this furnishing, except to the extent that the Company specifically incorporates it by reference.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information called for by this item is incorporated herein by reference to the material under the caption "Item 1. Stock Ownership and Section 16 Compliance" in the Proxy Statement; and Note 17 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements in Item 8 of this Report.

Equity Compensation Plan Information

The following table provides certain information as of December 29, 2019 concerning the shares of the Company's Common Stock that may be issued under existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights	Weighted Average Exercise Price of Outstanding Options and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans[2][3]
Equity Compensation Plans Approved by Security Holders[1]	130,579,915	$90.31	314,776,315
Equity Compensation Plans Not Approved by Security Holders		-	-
Total	130,579,915	$90.31	314,776,315

(1) Included in this category are the following equity compensation plans which have been approved by the Company's shareholders: 2005 Long-Term Incentive Plan and 2012 Long-Term Incentive Plan.

(2) This column excludes shares reflected under the column "Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights."

(3) The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1. Election of Directors - Director Independence" and "Related Person Transactions" in the Proxy Statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information called for by this item is incorporated herein by reference to the material under the caption "Item 3. Ratification of Appointment of Independent Registered Public Accounting Firm" in the Proxy Statement.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this report:

1. *Financial Statements*

   Consolidated Balance Sheets at end of Fiscal Years 2019 and 2018

   Consolidated Statements of Earnings for Fiscal Years 2019, 2018 and 2017

   Consolidated Statements of Comprehensive Income for Fiscal Years 2019, 2018 and 2017

   Consolidated Statements of Equity for Fiscal Years 2019, 2018 and 2017

   Consolidated Statements of Cash Flows for Fiscal Years 2019, 2018 and 2017

   Notes to Consolidated Financial Statements

   Report of Independent Registered Public Accounting Firm

   All schedules are omitted because they are not applicable or the required information is included in the financial statements or notes.

2. *Exhibits* Required *to be Filed by Item 60l of Regulation S-K*

   The information called for by this item is incorporated herein by reference to the Exhibit Index in this Report.

Item 16. FORM 10-K SUMMARY

Registrants may voluntarily include a summary of information required by Form 10-K under this Item 16. The Company has elected not to include such summary information.

SIGNATURES

Pursuant to the requirements of Section 13 of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 18, 2020

JOHNSON & JOHNSON

(Registrant)

By /s/ A. Gorsky

A. Gorsky, Chairman, Board of Directors,
and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ A. Gorsky A. Gorsky	Chairman, Board of Directors Chief Executive Officer (Principal Executive Officer)	February 18, 2020
/s/ J. J. Wolk J. J. Wolk	Chief Financial Officer (Principal Financial Officer)	February 18, 2020
/s/ R. J. Decker Jr. R. J. Decker Jr.	Controller and Chief Accounting Officer (Principal Accounting Officer)	February 18, 2020
/s/ M. C. Beckerle M. C. Beckerle	Director	February 18, 2020
/s/ D. S. Davis D. S. Davis	Director	February 18, 2020
/s/ I. E. L. Davis I. E. L. Davis	Director	February 18, 2020
/s/ J. A. Doudna J. A. Doudna	Director	February 18, 2020

Signature	Title	Date
/s/ M. A. Hewson M. A. Hewson	Director	February 18, 2020
/s/ H. Joly H. Joly	Director	February 18, 2020
/s/ M. B. McClellan M. B. McClellan	Director	February 18, 2020
/s/ A. M. Mulcahy A. M. Mulcahy	Director	February 18, 2020
/s/ W. D. Perez W. D. Perez	Director	February 18, 2020
/s/ C. Prince C. Prince	Director	February 18, 2020
/s/ A. E. Washington A. E. Washington	Director	February 18, 2020
/s/ M. A. Weinberger M. A. Weinberger	Director	February 18, 2020
/s/ R. A. Williams R. A. Williams	Director	February 18, 2020

EXHIBIT INDEX

Reg. S-K Exhibit Table Item No.	Description of Exhibit
3(i)	Restated Certificate of Incorporation effective February 19, 2016 — Incorporated herein by reference to Exhibit 3(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.
3(ii)	By-Laws of the Company, as amended effective January 26, 2016 — Incorporated herein by reference to Exhibit 3.1 the Registrant's Form 8-K Current Report filed January 26, 2016.
4(a)	Upon the request of the Securities and Exchange Commission, the Registrant will furnish a copy of all instruments defining the rights of holders of long-term debt of the Registrant.
10(a)	2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 4 of the Registrant's S-8 Registration Statement filed with the Commission on May 10, 2005 (file no. 333-124785).*
10(b)	Form of Stock Option Certificate under the 2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 8-K Current Report filed January 13, 2012.*
10(c)	2012 Long-Term Incentive Plan — Incorporated herein by reference to Appendix A of the Registrant's Proxy Statement filed with the Commission on March 15, 2017 .*
10(d)	Form of Stock Option Certificate, Restricted Share Unit Certificate and Performance Share Unit Certificate under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.2, 10.3 and 10.4 of the Registrant's Form 10-Q Quarterly Report filed May 7, 2012.*
10(e)	Global NonQualified Stock Option Award Agreement, Global Restricted Share Unit Award Agreement and Global Performance Share Unit Award Agreement under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.1, 10.2 and 10.3 of the Registrant's Form 10-Q Quarterly Report filed May 1, 2018.*
10(f)	Johnson & Johnson Executive Incentive Plan (Amended as of November 28, 2018) — Incorporated herein by reference to Exhibit 10(a) of the Registrant's Form 10-Q Quarterly Report for filed May 1, 2019.*
10(g)	Domestic Deferred Compensation (Certificate of Extra Compensation) Plan — Incorporated herein by reference to Exhibit 10(g) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2003.*
10(h)	Amendments to the Certificate of Extra Compensation Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(i)	2009 Certificates of Long-Term Performance Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 27, 2009.*
10(j)	Amended and Restated Deferred Fee Plan for Directors (Amended as of January 17, 2012) — Incorporated herein by reference to Exhibit 10(k) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 1, 2012.*
10(k)	The Johnson & Johnson Executive Income Deferral Plan (Amended and Restated Effective January 1, 2010) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*
10(l)	Excess Savings Plan (Effective as of January 1, 1996) — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 29, 1996.*
10(m)	Amendments to the Johnson & Johnson Excess Savings Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(p) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2008.*
10(n)**	Excess Benefit Plan (Supplemental Retirement Plan) — Incorporated herein by reference to Exhibit 10(h) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 1993.*
10(o)	Amendments to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(r) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2008.*
10(p)	Amendment to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies, effective as of January 1, 2015 — Incorporated herein by reference to Exhibit 10(q) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2014.*
10(q)**	Executive Life Plan Agreement — Incorporated herein by reference to Exhibit 10(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 1993.*
10(r)	Executive Life Plan Agreement Closure Letter — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended March 29, 2015.*
10(s)	Employment Agreement for Dr. Paulus Stoffels - Incorporated herein by reference to Exhibit 10.2 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*

Reg. S-K Exhibit Table Item No.	Description of Exhibit
10(t)	Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies, Amended and Restated as of October 1, 2014 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 28, 2014.*
10(u)	First Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended June 28, 2015.*
10(v)	Second Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10(x) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.*
21	Subsidiaries - Filed with this document.
23	Consent of Independent Registered Public Accounting Firm — Filed with this document.
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
32.1	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
32.2	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
Exhibit 101:	
EX-101.INS	Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
EX-101.SCH	Inline XBRL Taxonomy Extension Schema
EX-101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
EX-101.LAB	Inline XBRL Taxonomy Extension Label Linkbase
EX-101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
EX-101.DEF	Inline XBRL Taxonomy Extension Definition Document
Exhibit 104:	Cover Page Interactive Data File—the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

* Management contract or compensatory plan.

** Paper filing.

A copy of any of the Exhibits listed above will be provided without charge to any shareholder submitting a written request specifying the desired exhibit(s) to the Secretary at the principal executive offices of the Company. Pursuant to Item 601(b)(4)(iii)(A) of Regulation S-K, the Company has not filed as exhibits to this Form 10-K certain long-term debt instruments, including indentures, under which the total amount of securities authorized does not exceed 10% of the total assets of the Company and its subsidiaries on a consolidated basis. The Company hereby agrees to furnish a copy of any such instrument to the SEC upon request.

Exhibit “J18”

This is Exhibit “J18” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended January 3, 2021

or

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from to**

Commission file number 1-3215

JOHNSON & JOHNSON

(Exact name of registrant as specified in its charter)

New Jersey	**22-1024240**
(State of incorporation)	(I.R.S. Employer Identification No.)
One Johnson & Johnson Plaza **New Brunswick, New Jersey**	**08933**
(Address of principal executive offices)	(Zip Code)

One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
(Address of principal executive offices)

Registrant's telephone number, including area code: **(732) 524-0400**

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, Par Value $1.00	JNJ	New York Stock Exchange
0.250% Notes Due January 2022	JNJ22	New York Stock Exchange
0.650% Notes Due May 2024	JNJ24C	New York Stock Exchange
5.50% Notes Due November 2024	JNJ24BP	New York Stock Exchange
1.150% Notes Due November 2028	JNJ28	New York Stock Exchange
1.650% Notes Due May 2035	JNJ35	New York Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☑ No ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $363 billion.

On February 16, 2021, there were 2,628,679,824 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Parts I and III: Portions of registrant's proxy statement for its 2021 annual meeting of shareholders filed within 120 days after the close of the registrant's fiscal year (the "Proxy Statement"), are incorporated by reference to this report on Form 10-K (this "Report").

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and Johnson & Johnson's other publicly available documents contain "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Management and representatives of Johnson & Johnson and its subsidiaries (the "Company") also may from time to time make forward-looking statements. Forward-looking statements do not relate strictly to historical or current facts and reflect management's assumptions, views, plans, objectives and projections about the future. Forward-looking statements may be identified by the use of words such as "plans," "expects," "will," "anticipates," "estimates" and other words of similar meaning in conjunction with, among other things: discussions of future operations; expected operating results and financial performance; impact of planned acquisitions and dispositions; the Company's strategy for growth; product development; regulatory approvals; market position and expenditures.

Because forward-looking statements are based on current beliefs, expectations and assumptions regarding future events, they are subject to uncertainties, risks and changes that are difficult to predict and many of which are outside of the Company's control. Investors should realize that if underlying assumptions prove inaccurate, or known or unknown risks or uncertainties materialize, the Company's actual results and financial condition could vary materially from expectations and projections expressed or implied in its forward-looking statements. Investors are therefore cautioned not to rely on these forward-looking statements. Risks and uncertainties include, but are not limited to:

Risks Related to Product Development, Market Success and Competition

- Challenges and uncertainties inherent in innovation and development of new and improved products and technologies on which the Company's continued growth and success depend, including uncertainty of clinical outcomes, additional analysis of existing clinical data, obtaining regulatory approvals, health plan coverage and customer access, and initial and continued commercial success;
- Challenges to the Company's ability to obtain and protect adequate patent and other intellectual property rights for new and existing products and technologies in the United States and other important markets;
- The impact of patent expirations, typically followed by the introduction of competing biosimilars and generics and resulting revenue and market share losses;
- Increasingly aggressive and frequent challenges to the Company's patents by competitors and others seeking to launch competing generic, biosimilar or other products and increased receptivity of courts, the United States Patent and Trademark Office and other decision makers to such challenges, potentially resulting in loss of market exclusivity and rapid decline in sales for the relevant product sooner than expected;
- Competition in research and development of new and improved products, processes and technologies, which can result in product and process obsolescence;
- Competition to reach agreement with third parties for collaboration, licensing, development and marketing agreements for products and technologies;
- Competition based on cost-effectiveness, product performance, technological advances and patents attained by competitors; and
- Allegations that the Company's products infringe the patents and other intellectual property rights of third parties, which could adversely affect the Company's ability to sell the products in question and require the payment of money damages and future royalties.

Risks Related to Product Liability, Litigation and Regulatory Activity

- Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the United States Food and Drug Administration (or international counterparts), declining sales, reputational damage, increased litigation expense and share price impact;
- Impact, including declining sales and reputational damage, of significant litigation or government action adverse to the Company, including product liability claims and allegations related to pharmaceutical marketing practices and contracting strategies;
- Impact of an adverse judgment or settlement and the adequacy of reserves related to legal proceedings, including patent litigation, product liability, personal injury claims, securities class actions, government investigations, employment and other legal proceedings;

- Increased scrutiny of the health care industry by government agencies and state attorneys general resulting in investigations and prosecutions, which carry the risk of significant civil and criminal penalties, including, but not limited to, debarment from government business;
- Failure to meet compliance obligations in the McNEIL-PPC, Inc. Consent Decree or any other compliance agreements with governments or government agencies, which could result in significant sanctions;
- Potential changes to applicable laws and regulations affecting United States and international operations, including relating to: approval of new products; licensing and patent rights; sales and promotion of health care products; access to, and reimbursement and pricing for, health care products and services; environmental protection and sourcing of raw materials;
- Compliance with local regulations and laws that may restrict the Company's ability to manufacture or sell its products in relevant markets, including requirements to comply with medical device reporting regulations and other requirements such as the European Union's Medical Devices Regulation;
- Changes in domestic and international tax laws and regulations, including changes related to the Tax Cuts and Jobs Act in the United States, increasing audit scrutiny by tax authorities around the world and exposures to additional tax liabilities potentially in excess of existing reserves; and
- Issuance of new or revised accounting standards by the Financial Accounting Standards Board and regulations by the Securities and Exchange Commission.

Risks Related to the Company's Strategic Initiatives and Healthcare Market Trends

- Pricing pressures resulting from trends toward health care cost containment, including the continued consolidation among health care providers and other market participants, trends toward managed care, the shift toward governments increasingly becoming the primary payers of health care expenses, significant new entrants to the health care markets seeking to reduce costs and government pressure on companies to voluntarily reduce costs and price increases;
- Restricted spending patterns of individual, institutional and governmental purchasers of health care products and services due to economic hardship and budgetary constraints;
- Challenges to the Company's ability to realize its strategy for growth including through externally sourced innovations, such as development collaborations, strategic acquisitions, licensing and marketing agreements, and the potential heightened costs of any such external arrangements due to competitive pressures;
- The potential that the expected strategic benefits and opportunities from any planned or completed acquisition or divestiture by the Company may not be realized or may take longer to realize than expected; and
- The potential that the expected benefits and opportunities related to past and ongoing restructuring actions may not be realized or may take longer to realize than expected.

Risks Related to Economic Conditions, Financial Markets and Operating Internationally

- The risks associated with global operations on the Company and its customers and suppliers, including foreign governments in countries in which the Company operates.
- Impact of inflation and fluctuations in interest rates and currency exchange rates and the potential effect of such fluctuations on revenues, expenses and resulting margins;
- Potential changes in export/import and trade laws, regulations and policies of the United States and other countries, including any increased trade restrictions or tariffs and potential drug reimportation legislation;
- The impact on international operations from financial instability in international economies, sovereign risk, possible imposition of governmental controls and restrictive economic policies, and unstable international governments and legal systems;
- The impact of global public health crises and pandemics, including the outbreak of the novel coronavirus (COVID-19) pandemic;
- Changes to global climate, extreme weather and natural disasters that could affect demand for the Company's products and services, cause disruptions in manufacturing and distribution networks, alter the availability of goods and services within the supply chain, and affect the overall design and integrity of the Company's products and operations; and
- The impact of armed conflicts and terrorist attacks in the United States and other parts of the world including social and economic disruptions and instability of financial and other markets.

Risks Related to Supply Chain and Operations

- Difficulties and delays in manufacturing, internally, through third party providers or otherwise within the supply chain, that may lead to voluntary or involuntary business interruptions or shutdowns, product shortages, withdrawals or suspensions of products from the market, and potential regulatory action;
- Interruptions and breaches of the Company's information technology systems or those of the Company's vendors, which could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action;
- Reliance on global supply chains and production and distribution processes that are complex and subject to increasing regulatory requirements that may adversely affect supply, sourcing and pricing of materials used in the Company's products; and
- The potential that the expected benefits and opportunities related to restructuring actions contemplated for the global supply chain, including the Company's transaction with Jabil, may not be realized or may take longer to realize than expected, including due to any required approvals from applicable regulatory authorities. Disruptions associated with the announced global supply chain actions may adversely affect supply and sourcing of materials used in the Company's products.

Investors also should carefully read the Risk Factors described in Item 1A of this Annual Report on Form 10-K for a description of certain risks that could, among other things, cause the Company's actual results to differ materially from those expressed in its forward-looking statements. Investors should understand that it is not possible to predict or identify all such factors and should not consider the risks described above and in Item 1A to be a complete statement of all potential risks and uncertainties. The Company does not undertake to publicly update any forward-looking statement that may be made from time to time, whether as a result of new information or future events or developments.

PART I

Item 1. BUSINESS

General

Johnson & Johnson and its subsidiaries (the Company) have approximately 134,500 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. Johnson & Johnson is a holding company, with operating companies conducting business in virtually all countries of the world. The Company's primary focus is products related to human health and well-being. Johnson & Johnson was incorporated in the State of New Jersey in 1887.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Company's three business segments: Consumer Health (previously referred to as Consumer), Pharmaceutical and Medical Devices. Within the strategic parameters provided by the Committee, senior management groups at U.S. and international operating companies are each responsible for their own strategic plans and the day-to-day operations of those companies. Each subsidiary within the business segments is, with limited exceptions, managed by residents of the country where located.

Segments of Business

The Company is organized into three business segments: Consumer Health, Pharmaceutical and Medical Devices. Additional information required by this item is incorporated herein by reference to the narrative and tabular descriptions of segments and operating results under: "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition" of this Report; and Note 17 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Consumer Health

The Consumer Health segment includes a broad range of products focused on personal healthcare used in the skin health/beauty, over-the-counter medicines, baby care, oral care, women's health and wound care markets. Major brands in skin health/beauty include the AVEENO®; CLEAN & CLEAR®; DR. CI:LABO®; NEUTROGENA® and OGX® product lines. Over-the-counter (OTC) medicines include the broad family of TYLENOL® acetaminophen products; SUDAFED® cold, flu and allergy products; BENADRYL® and ZYRTEC® allergy products; MOTRIN® IB ibuprofen products; NICORETTE® smoking cessation products outside the U.S.; ZARBEE'S NATURALS® and the PEPCID® line of acid reflux products. Baby Care includes the JOHNSON'S® and AVEENO Baby® line of products. Oral Care includes the LISTERINE® product line. Major brands in Women's Health outside of North America are STAYFREE® and CAREFREE® sanitary pads and o.b.® tampon brands. Wound Care brands include the BAND-AID® Brand Adhesive Bandages and NEOSPORIN® First Aid product lines. These products are marketed to the general public and sold online (eCommerce) and to retail outlets and distributors throughout the world.

Pharmaceutical

The Pharmaceutical segment is focused on six therapeutic areas: Immunology (e.g., rheumatoid arthritis, inflammatory bowel disease and psoriasis), Infectious Diseases (e.g., HIV/AIDS), Neuroscience (e.g., mood disorders, neurodegenerative disorders and schizophrenia), Oncology (e.g., prostate cancer and hematologic malignancies), Cardiovascular and Metabolism (e.g., thrombosis and diabetes) and Pulmonary Hypertension (e.g., Pulmonary Arterial Hypertension). Medicines in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. Key products in the Pharmaceutical segment include: REMICADE® (infliximab), a treatment for a number of immune-mediated inflammatory diseases; SIMPONI® (golimumab), a subcutaneous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis and moderately active to severely active ulcerative colitis; SIMPONI ARIA® (golimumab), an intravenous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis and active ankylosing spondylitis; STELARA® (ustekinumab), a treatment for adults and children with moderate to severe plaque psoriasis, for adults with active psoriatic arthritis, for adults with moderately to severely active Crohn's disease and treatment of moderately to severely active ulcerative colitis; TREMFYA® (guselkumab), a treatment for adults with moderate to severe plaque psoriasis; EDURANT® (rilpivirine), PREZISTA® (darunavir) and PREZCOBIX®/REZOLSTA® (darunavir/cobicistat), antiretroviral medicines for the treatment of human immunodeficiency virus (HIV-1) in combination with other antiretroviral products and SYMTUZA® (darunavir/cobicistat/emtricitabine/tenofovir alafenamide), a once-daily single tablet regimen for the treatment of HIV; CONCERTA® (methylphenidate HCl) extended-release tablets CII, a treatment for attention deficit hyperactivity disorder; INVEGA SUSTENNA®/XEPLION® (paliperidone palmitate), for the treatment of schizophrenia and schizoaffective disorder in adults; INVEGA TRINZA®/TREVICTA® (paliperidone palmitate), for the treatment of schizophrenia in patients after they have been adequately treated with INVEGA SUSTENNA® for at least four months; RISPERDAL CONSTA® (risperidone long-acting injection), for the treatment of schizophrenia and the

maintenance treatment of Bipolar 1 Disorder in adults; ZYTIGA® (abiraterone acetate), a treatment for metastatic castration-resistant prostate cancer (CRPC) and metastatic high-risk castration-sensitive prostate cancer; IMBRUVICA® (ibrutinib), a treatment for certain B-cell malignancies, or blood cancers, chronic graft versus host disease and Waldenström's Macroglobulinemia; DARZALEX® (daratumumab), a treatment for relapsed/refractory multiple myeloma; ERLEADA® (apalutamide), a next-generation androgen receptor inhibitor for the treatment of patients with prostate cancer; VELCADE® (bortezomib), a treatment for multiple myeloma mantle cell lymphoma; PROCRIT®/EPREX® (epoetin alfa), a treatment for chemotherapy-induced anemia and patients with chronic kidney disease; XARELTO® (rivaroxaban), an oral anticoagulant for the prevention of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery, to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, and for the treatment and reduction of risk of recurrence of DVT and PE; INVOKANA® (canagliflozin), for the treatment of adults with type 2 diabetes; INVOKAMET®/VOKANAMET® (canagliflozin/metformin HCl), a combination therapy of fixed doses of canagliflozin and metformin hydrochloride for the treatment of adults with type 2 diabetes; and INVOKAMET® XR (canagliflozin/metformin hydrochloride extended-release), a once-daily, fixed-dose combination therapy of canagliflozin and metformin hydrochloride extended-release, for the treatment of adults with type 2 diabetes; OPSUMIT® (macitentan) as monotherapy or in combination, indicated for the long-term treatment of pulmonary arterial hypertension (PAH); UPTRAVI® (selexipag), the only approved oral, selective IP receptor agonist targeting a prostacyclin pathway in PAH. Many of these medicines were developed in collaboration with strategic partners or are licensed from other companies and maintain active lifecycle development programs.

Medical Devices

The Medical Devices segment includes a broad range of products used in the Interventional Solutions, Orthopaedics, Surgery, and Vision fields. Medical Devices in Interventional Solutions include Electrophysiology products (Biosense Webster) to treat cardiovascular diseases, Neurovascular care (Cerenovus) that treats hemorrhagic and ischemic stroke; the Orthopaedics portfolio (DePuy Synthes) is comprised of products in support of Hips, Knees, Trauma, and Spine, Sports & Other; the Surgery portfolios (Ethicon) include advanced and general surgery offerings, solutions that focus on Breast Aesthetics (Mentor) and Ear, Nose and Throat (Acclarent) procedures; and Johnson & Johnson Vision products such as ACUVUE® Brand disposable contact lenses and ophthalmic products related to cataract and laser refractive surgery. These products are distributed to wholesalers, hospitals and retailers, and used predominantly in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

Geographic Areas

Johnson & Johnson and its subsidiaries (the Company) have approximately 134,500 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The products made and sold in the international business include many of those described above under "– Segments of Business – Consumer Health," "– Pharmaceutical" and "– Medical Devices." However, the principal markets, products and methods of distribution in the international business vary with the country and the culture. The products sold in international business include those developed in the U.S. and by subsidiaries abroad.

Investments and activities in some countries outside the U.S. are subject to higher risks than comparable U.S. activities because the investment and commercial climate may be influenced by financial instability in international economies, restrictive economic policies and political and legal system uncertainties.

Raw Materials

Raw materials essential to the Company's business are generally readily available from multiple sources. Where there are exceptions, the temporary unavailability of those raw materials would not likely have a material adverse effect on the financial results of the Company.

Patents

The Company's subsidiaries have made a practice of obtaining patent protection on their products and processes where possible. They own, or are licensed under, a significant number of patents in the U.S. and other countries relating to their products, product uses, formulations and manufacturing processes, which in the aggregate are believed to be of material importance to the Company in the operation of its businesses. The Company's subsidiaries face patent challenges from third parties, including challenges seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. Significant legal proceedings and claims involving the Company's patent and other intellectual property are described in Note 19, "Legal Proceedings—Intellectual Property" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Sales of the Company's largest product, STELARA® (ustekinumab), accounted for approximately 9.3% of the Company's total revenues for fiscal 2020. Accordingly, the patents related to this product are believed to be material to the Company. Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson, owns patents specifically related to STELARA®. The latest expiring United States patent expires in 2023. The latest expiring European patent expires in 2024.

Sales of the Company's second largest product, DARZALEX® (daratumumab) and DARZALEX FASPRO™ (daratumumab and hyaluronidase-fihj), accounted for approximately 5.1% of the Company's total revenues for fiscal 2020.
Accordingly, the patents related to this product are believed to be material to the Company. Genmab A/S owns patents related to DARZALEX®, and Janssen Biotech, Inc. has an exclusive license to those patents. The latest expiring licensed United States patent expires in 2029. The latest expiring licensed European patent expires in 2031. Janssen Biotech, Inc. owns a separate patent portfolio related to DARZALEX FASPRO™.

Sales of the Company's third largest product, IMBRUVICA® (ibrutinib), accounted for approximately 5.0% of the Company's total revenues for fiscal 2020. Accordingly, patents related to this product are believed to be material to the Company. Pharmacyclics LLC (an AbbVie company) owns the patents related to IMBRUVICA®, and Janssen Biotech, Inc. has an exclusive license to those patents. The Pharmacyclics patents and their expiration dates are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). Pharmacyclics LLC and Janssen Biotech, Inc. have entered into confidential settlement agreements with certain generic companies granting licenses to market their generic ibrutinib products in the United States before the expiration of certain patents.

Trademarks

The Company's subsidiaries have made a practice of selling their products under trademarks and of obtaining protection for these trademarks by all available means. These trademarks are protected by registration in the U.S. and other countries where such products are marketed. The Company considers these trademarks in the aggregate to be of material importance in the operation of its businesses.

Seasonality

Worldwide sales do not reflect any significant degree of seasonality; however, spending has been heavier in the fourth quarter of each year than in other quarters. This reflects increased spending decisions, principally for advertising and research and development activity.

Competition

In all of their product lines, the Company's subsidiaries compete with companies both locally and globally. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, both internally and externally sourced, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products, as well as protecting the underlying intellectual property of the Company's product portfolio, is important to the Company's success in all areas of its business. The competitive environment requires substantial investments in continuing research. In addition, the development and maintenance of customer demand for the Company's consumer products involve significant expenditures for advertising and promotion.

Environment

The Company is subject to a variety of U.S. and international environmental protection measures. The Company believes that its operations comply in all material respects with applicable environmental laws and regulations. The Company's compliance with these requirements did not change during the past year, and is not expected to have a material effect upon its capital expenditures, cash flows, earnings or competitive position.

Regulation

The Company's businesses are subject to varying degrees of governmental regulation in the countries in which operations are conducted, and the general trend is toward increasingly stringent regulation and enforcement. The Company is subject to costly and complex U.S. and foreign laws and governmental regulations and any adverse regulatory action may materially adversely affect the Company's financial condition and business operations. In the U.S., the drug, device and cosmetic industries have long been subject to regulation by various federal and state agencies, primarily as to product safety, efficacy, manufacturing, advertising, labeling and safety reporting. The exercise of broad regulatory powers by the U.S. Food and Drug Administration (the U.S. FDA) continues to result in increases in the amounts of testing and documentation required for U.S. FDA approval of new drugs and devices and a corresponding increase in the expense of product introduction. Similar trends are also evident in major markets outside of the U.S. The new medical device regulatory framework and the new privacy regulations in Europe and in other countries are examples of such increased regulation.

The regulatory agencies under whose purview the Company operates have administrative powers that may subject it to actions such as product withdrawals, recalls, seizure of products and other civil and criminal sanctions. In some cases, the Company's subsidiaries may deem it advisable to initiate product recalls.

The U.S. FDA and regulatory agencies around the globe are also increasing their enforcement activities. If the U.S. FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our drugs or medical devices are ineffective or pose an unreasonable health risk, the U.S. FDA could ban such products, detain or seize adulterated or misbranded products, order a recall, repair, replacement, or refund of such products, refuse to grant pending applications for marketing authorization or require certificates of foreign governments for exports, and/or require us to notify health professionals and others that the products present unreasonable risks of substantial harm to the public health. The U.S. FDA may also assess civil or criminal penalties against us, our officers or employees and impose operating restrictions on a company-wide basis, or enjoin and/or restrain certain conduct resulting in violations of applicable law. The U.S. FDA may also recommend prosecution to the US Department of Justice. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and limit our ability to obtain future clearances or approvals, and could result in a substantial modification to our business practices and operations. Equivalent enforcement mechanisms exist in different countries in which we conduct business.

The costs of human health care have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. In the U.S., attention has been focused by states, regulatory agencies and congress on drug prices and profits and programs that encourage doctors to write prescriptions for particular drugs, or to recommend, use or purchase particular medical devices. Laws and regulations have been enacted to require adherence to strict compliance standards and prevent fraud and abuse in the healthcare industry. There is increased focus on interactions and financial relationships between healthcare companies and health care providers. Various transparency laws and regulations require disclosures of payments and other transfers of value made to physicians and teaching hospitals and, beginning with disclosures in 2022, to certain non-physician practitioners. Federal and foreign laws governing international business practices require strict compliance with anti-bribery standards and certain prohibitions with respect to payments to any foreign government official. Payers have become a more potent force in the market place and increased attention is being paid to drug and medical device pricing, appropriate drug and medical device utilization and the quality and costs of health care generally.

U.S. government agencies continue efforts to repeal, modify, or invalidate provisions of the Patient Protection and Affordable Care Act (the ACA) which passed in 2010. For example, federal legislation repealed the ACA's individual mandate tax penalty as well as the tax on generous employer-sponsored healthcare plans; the Center for Medicare & Medicaid Services (CMS) began permitting states to impose work requirements on persons covered by Medicaid expansion plans; certain federal subsidies to insurers have ended; and certain short-term insurance plans not offering the full array of ACA benefits have been allowed to extend in duration. Some of these changes are being challenged in U.S. courts and so their long-term impact remains uncertain. The ACA has also been subject to judicial challenge. In November 2020, the U.S. Supreme Court heard argument in *Texas v. Azar*, which challenges the constitutionality of the ACA. Pending resolution of the litigation, all of the ACA but the individual mandate to buy health insurance remains in effect. The U.S. government also continues to propose and implement changes to the Medicare Part D benefit including the size of manufacturer discounts in the coverage gap and catastrophic phases of the benefit. There are a number of additional bills pending in Congress and healthcare reform proposals at the state level that would affect drug pricing in the Medicare and Medicaid programs. This changing federal landscape has both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of federal law, and potential modification or repeal of these laws, will ultimately affect the industry.

In addition, business practices in the health care industry have come under increased scrutiny, particularly in the U.S., by government agencies and state attorneys general, and resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Further, the Company relies on global supply chains, and production and distribution processes, that are complex, are subject to increasing regulatory requirements, and may be faced with unexpected changes such as those resulting from the COVID-19 pandemic and Brexit, that may affect sourcing, supply and pricing of materials used in the Company's products. These processes also are subject to complex and lengthy regulatory approvals.

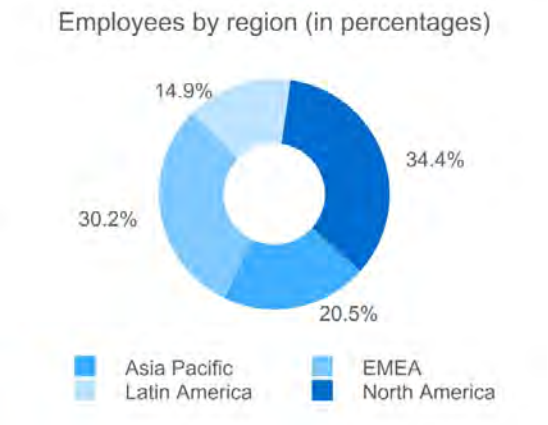
The global regulatory landscape is also subject to change as the COVID-19 pandemic continues to affect the U.S. and global economies. The U.S. FDA and other health authorities have shifted resources and priorities to meet the many challenges presented by the pandemic. Pandemic-related disruptions could negatively impact the processing of regulatory submissions and slow agency review times necessary for the approval or clearance of new drugs and devices. The duration and severity of the COVID-19 pandemic is unpredictable and difficult to assess.

Employees and Human Capital Management

As of January 3, 2021 and December 29, 2019, the number of employees were approximately:

	2020	2019
Employees[1]	136,400	133,200
Full-time equivalent (FTE) positions[2]	134,500	132,200

[1] "Employee" is defined as an individual working full-time or part-time, excluding fixed term employees, interns and co-op employees. Employee data may not include full population from more recently acquired companies and individuals on long-term disability are excluded. Contingent workers, contractors and subcontractors are also excluded.
[2] FTE represents the total number of full-time equivalent positions and does not reflect the total number of individual employees as some work part-time.



Strategy

The Company believes that its employees are critical to its continued success and are an essential element of its long-term strategy. Management is responsible for ensuring that its policies and processes reflect and reinforce the Company's desired corporate culture, including policies and processes related to strategy, risk management, and ethics and compliance. The Company's human capital management strategy is built on three fundamental focus areas:

- Attracting and recruiting the best talent
- Developing and retaining talent
- Empowering and inspiring talent

Underpinning these focus areas are ongoing efforts to cultivate and foster a culture built on diversity, equity and inclusion (DEI), innovation, health, well-being and safety, where the Company's employees are encouraged to succeed both professionally and personally while helping the Company achieve its business goals.

Culture and Employee Engagement

At Johnson & Johnson, employees are guided by Our Credo which sets forth the Company's responsibilities to patients, consumers, customers, healthcare professionals, employees, communities and shareholders. Employees worldwide are further guided by the Company's Code of Business Conduct which sets basic requirements for business conduct and serves as a foundation for the Company policies, procedures and guidelines, all of which provide additional guidance on expected employee behaviors in every market where it operates. The Company conducts global surveys that offer its employees the ability to provide feedback and valuable insight to help address potential human resources risks and identify opportunities to improve. In 2020, 93% of global employees across 78 countries participated in Our Credo Survey which is offered in 36 languages.

Growth and Development

To continue to lead in the changing healthcare landscape, it is crucial that the Company continue to attract and retain top talent. The Company believes that its employees must be equipped with the right knowledge and skills and be provided with opportunities to grow and develop in their careers. Accordingly, professional development programs and educational resources

are available to all employees. The Company's objective is to foster a learning culture that helps shape each person's unique career path while creating a robust pipeline of talent to deliver on the Company's long-term strategies. In furtherance of this objective, the Company deploys a global approach to ensure development is for everyone, regardless of where they are on their career journey. In 2020, 44.6% of employees in Manager and above job categories took advantage of career opportunities by moving across functions, country or business segment lines (including upward promotion or lateral transfer and excluding employees in the research and development organizations). The Company's voluntary turnover rate was 5.2%.

Diversity, Equity, and Inclusion (DEI)

The Company is committed to workplace diversity and to cultivating, fostering, and advancing a culture of equity and inclusion. Enabling employees to perform at their best while being themselves is fundamental to the Company's continued success. The Company's DEI vision is: *Be yourself, change the world*. The Company's DEI strategy focuses on three pillars that reflect the strategic priorities identified to enable the Company to address the challenges and opportunities presented by this evolving understanding of diversity:

- Accelerate the Company's efforts to advance a culture of inclusion and innovation
- Build a diverse workforce for the future
- Enhance business results and reputation

The Company's DEI strategy is guided by internal and external insights, global best practices and continual employee feedback which remind the Company that while diversity changes by location, inclusion is the same everywhere.

Compensation and Benefits

As part of the Company's total rewards philosophy, the Company offers competitive compensation and benefits to attract and retain top talent. The Company is committed to fairness and equitable treatment in its compensation and benefits for employees at all levels. The Company observes legal minimum wage provisions and exceeds them where possible. The Company's total rewards offerings include an array of programs to support its employees' financial, physical, and mental well-being, including annual performance incentive opportunities, pension and retirement savings programs, health and welfare benefits, paid time off, leave programs, flexible work schedules and employee assistance programs.

Health, Wellness and Safety

The Company's investment in employee health, well-being and safety is built on its conviction that advancing health for humanity starts with advancing the health of its employees. With the right awareness, focus, practices and tools, the Company ensures that all its employees around the world, as well as temporary contractors and visitors to the Company's sites, can work safely. The Company has continuously expanded health and well-being programs throughout the Company and across the globe, incorporating new thinking and technologies to keep its offerings best-in-class and to help employees achieve their personal mind and body health goals. The programs and practices the Company advances covers three core dimensions: Healthy Eating, Healthy Movement and Healthy Mind.

Available Information

The Company's main corporate website address is *www.jnj.com.* All of the Company's SEC filings are also available on the Company's website at *www.investor.jnj.com/sec.cfm*, as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*.

Investors and the public should note that the Company also announces information at *www.factsaboutourprescriptionopioids.com* and *www.factsabouttalc.com.* We use these websites to communicate with investors and the public about our products, litigation and other matters. It is possible that the information we post to these websites could be deemed to be material information. Therefore, we encourage investors and others interested in the Company to review the information posted to these websites in conjunction with *www.jnj.com,* the Company's SEC filings, press releases, public conference calls and webcasts.

In addition, the Amended and Restated Certificate of Incorporation, By-Laws, the written charters of the Audit Committee, the Compensation & Benefits Committee, the Nominating & Corporate Governance Committee, the Regulatory Compliance Committee and the Science, Technology & Sustainability Committee of the Board of Directors and the Company's Principles of Corporate Governance, Code of Business Conduct (for employees), Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers, and other corporate governance materials, are available at *www.investor.jnj.com/gov.cfm* on the Company's website and will be provided without charge to any shareholder submitting a written request, as provided above. The information on *www.jnj.com*, *www.factsaboutourprescriptionopioids.com* and *www.factsabouttalc.com* is not, and will not be deemed, a part of this Report or incorporated into any other filings the Company makes with the SEC.

Item 1A. RISK FACTORS

An investment in the Company's common stock or debt securities involves risks and uncertainties. The Company seeks to identify, manage and mitigate risks to our business, but uncertainties and risks are difficult to predict and many are outside of the Company's control and cannot therefore be eliminated. In addition to the other information in this report and the Company's other filings with the SEC, investors should consider carefully the factors set forth below. Investors should be aware that it is not possible to predict or identify all such factors and that the following is not meant to be a complete discussion of all potential risks or uncertainties. If known or unknown risks or uncertainties materialize, the Company's business, results of operations or financial condition could be adversely affected, potentially in a material way.

Risks Related to Our Business, Industry and Operations

The Company's businesses operate in highly competitive product markets and competitive pressures could adversely affect the Company's earnings.
The Company faces substantial competition in all three operating segments and in all geographic markets. The Company's businesses compete with companies of all sizes on the basis of cost-effectiveness, technological innovations, intellectual property rights, product performance, real or perceived product advantages, pricing and availability and rate of reimbursement. The Company also competes with other market participants in securing rights to acquisitions, collaborations and licensing agreements with third parties. Competition for rights to product candidates and technologies may result in significant investment and acquisition costs and onerous agreement terms for the Company. Competitors' development of more effective or less costly products, and/or their ability to secure patent and other intellectual property rights and successfully market products ahead of the Company, could negatively impact sales of the Company's existing products as well as its ability to bring new products to market despite significant prior investment in the related product development.

For the Company's pharmaceutical businesses, loss of patent exclusivity for a product often is followed by a substantial reduction in sales as competitors gain regulatory approval for generic and other competing products and enter the market. Similar competition can be triggered by the loss of exclusivity for a biological product. For the Company's medical device businesses, technological innovation, product quality, reputation and customer service are especially important to competitiveness. Development by other companies of new or improved products, processes and technologies could threaten to make the Company's products or technologies less desirable, less economical or obsolete. The Company's consumer health businesses face intense competition from other branded products and retailers' private-label brands. If the Company fails to sufficiently differentiate and market its brand name consumer products, this could adversely affect revenues and profitability of those products.

Interruptions and delays in manufacturing operations could adversely affect the Company's business, sales and reputation.
The Company's manufacture of products requires the timely delivery of sufficient amounts of complex, high-quality components and materials. The Company's subsidiaries operate 90 manufacturing facilities as well as sourcing from hundreds of suppliers around the world. The Company has in the past, and may in the future, face unanticipated interruptions and delays in manufacturing through its internal or external supply chain. Manufacturing disruptions can occur for many reasons including regulatory action, production quality deviations or safety issues, labor disputes, site-specific incidents (such as fires), natural disasters such as hurricanes and other severe weather events, raw material shortages, political unrest, terrorist attacks and epidemics or pandemics. Such delays and difficulties in manufacturing can result in product shortages, declines in sales and reputational impact as well as significant remediation and related costs associated with addressing the shortage.

The Company relies on third parties to manufacture certain of our products. Any failure by or loss of a third-party manufacturer could result in delays and increased costs, which may adversely affect our business.
The Company relies on third parties to manufacture certain of our products. We depend on these third party manufacturers to allocate to us a portion of their manufacturing capacity sufficient to meet our needs, to produce products of acceptable quality and at acceptable manufacturing yields and to deliver those products to us on a timely basis and at acceptable prices. However, we cannot guarantee that these third-party manufacturers will be able to meet our near-term or long-term manufacturing requirements, which could result in lost sales and have an adverse effect on our business.

Other risks associated with our reliance on third parties, including the Company's strategic partnership with Jabil in the Medical Devices segment, to manufacture these products include reliance on the third party for regulatory compliance and quality assurance, misappropriation of the Company's intellectual property, limited ability to manage our inventory, possible breach of the manufacturing agreement by the third party and the possible termination or nonrenewal of the manufacturing agreement by the third party at a time that is costly or inconvenient for us. Moreover, if any of our third party manufacturers suffer any damage to facilities, lose benefits under material agreements, experience power outages, encounter financial difficulties, are unable to secure necessary raw materials from their suppliers or suffer any other reduction in efficiency, the Company may

experience significant business disruption. In the event of any such disruption, the Company would need to seek and source other qualified third-party manufacturers, likely resulting in further delays and increased costs which could affect our business adversely.

Counterfeit versions of our products could harm our patients and have a negative impact on our revenues, earnings, reputation and business.
Our industry continues to be challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Third parties may illegally distribute and sell counterfeit versions of our products, which do not meet our rigorous manufacturing and testing standards. To distributors and patients, counterfeit products may be visually indistinguishable from the authentic version. Counterfeit medicines pose a risk to patient health and safety because of the conditions under which they are manufactured – often in unregulated, unlicensed, uninspected and unsanitary sites – as well as the lack of regulation of their contents.

The industry's failure to mitigate the threat of counterfeit medicines could adversely impact our business and reputation by impacting patient confidence in our authentic products, potentially resulting in lost sales, product recalls, and an increased threat of litigation. In addition, diversion of our products from their authorized market into other channels may result in reduced revenues and negatively affect our profitability.

The COVID-19 pandemic has adversely impacted certain aspects of the Company's business and could cause disruptions or future impact to the Company's business, results of operations and financial condition.
We are subject to risks associated with global health crises and pandemics, including the global outbreak of the novel coronavirus and its mutations (COVID-19). The COVID-19 pandemic has adversely impacted, and is expected to continue to adversely impact, certain aspects of the Company's business, results of operations and financial condition, including lower sales and reduced customer demand and usage of certain of our products. The spread of COVID-19 has caused the Company to modify its business practices (including instituting remote work for many of the Company's employees), and the Company may take further actions as may be required by government authorities or as the Company determines are in the best interests of our patients, customers, employees and business partners. The Company continues to monitor the situation and while we have robust business continuity plans in place across our global supply chain network to help mitigate the impact of COVID-19, these efforts may not completely prevent our business from being adversely affected and future impacts remain uncertain.

While the U.S. and other countries have begun or will begin to reopen their economies, the extent to which COVID-19 will impact the Company's future operations will depend on many factors which cannot be predicted with confidence, including the duration of the outbreak. Any resurgence in COVID-19 infections could result in the imposition of new mandates and prolonged restrictive measures implemented in order to control the spread of the disease. The continued global spread of COVID-19 could adversely impact the Company's operations, including, among other things, our manufacturing operations, supply chain, including third-party suppliers, sales and marketing and clinical trial operations. Any of these factors could adversely affect the Company's business, financial results, and global economic conditions generally.

We also face uncertainties related to our efforts to develop a COVID-19 vaccine candidate, including uncertainties related to the risk that our development programs may not be successful, commercially viable or receive approval or Emergency Use Authorization from regulatory authorities; risks associated with clinical trial data, including further analyses of existing preclinical or clinical trial data that may be inconsistent with the data used for selection of the JNJ-78436735 vaccine candidate and dose level for the Phase 3 (ENSEMBLE) trial; the risk that clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; disruptions in the relationships between us, our third-party suppliers and external manufacturers; the risk that other companies may produce superior or competitive products; the risk that demand for any products we may develop may no longer exist; risks related to the availability of raw materials to manufacture any such products; the risk that we may not be able to recoup costs associated with our R&D and manufacturing efforts and risks associated with any changes in the way we approach or provide additional research funding for potential drug development related to COVID-19; the risk that we may not be able to create or scale up manufacturing capacity on a timely basis, that we may experience manufacturing delays once a manufacturing site is activated, or have access to logistics or supply channels commensurate with global demand for any potential approved vaccine or product candidate, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine candidate within the projected time periods indicated, and other challenges and risks associated with the pace of our vaccine development program; and pricing and access challenges for such products, including in the U.S.

In addition, to the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section and those incorporated by reference herein, including risks relating to the Company's effective tax rate as a result of changes in consumption as well as changes in

laws relating to supply of the Company's products. Given that developments concerning the COVID-19 pandemic have been constantly evolving, additional impacts and risks may arise, including litigation, that are not presently known to the Company.

Risk Related to the Government Regulation and Legal Proceedings

Global sales in the Company's pharmaceutical and medical devices segments may be negatively impacted by healthcare reforms and increasing pricing pressures.

Sales of the Company's pharmaceutical and medical device products are significantly affected by reimbursements by third-party payers such as government healthcare programs, private insurance plans and managed care organizations. As part of various efforts to contain healthcare costs, these payers are putting downward pressure on prices at which products will be reimbursed. In the U.S., increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, in part due to continued consolidation among health care providers, could result in further pricing pressures. In addition, increased political scrutiny could result in additional pricing pressures. Outside the U.S., numerous major markets, including the EU, United Kingdom and Japan, have pervasive government involvement in funding healthcare and, in that regard, directly or indirectly impose price controls, limit access to, or reimbursement for, the Company's products, or reduce the value of its intellectual property protection.

The Company is subject to significant legal proceedings that can result in significant expenses, fines and reputational damage.

In the ordinary course of business, Johnson & Johnson and its subsidiaries are subject to numerous claims and lawsuits involving various issues such as patent disputes, product liability and claims that their product sales, marketing and pricing practices violate various antitrust, unfair trade practices and/or consumer protection laws. The Company's more significant legal proceedings are described in Note 19, "Legal Proceedings" under Notes to the Consolidated Financial Statements included in Item 8 of this Report. Litigation, in general, and securities, derivative action, class action and multi-district litigation, in particular, can be expensive and disruptive. Some of these matters may include thousands of plaintiffs, may involve parties seeking large and/or indeterminate amounts, including punitive or exemplary damages, and may remain unresolved for several years. For example, the Company is a defendant in numerous lawsuits arising out of the use of body powders containing talc, primarily JOHNSONS® Baby Powder, and the Company's sale, manufacturing and marketing of opioids. While the Company believes it has substantial defenses in these matters, it is not feasible to predict the ultimate outcome of litigation. The Company could in the future be required to pay significant amounts as a result of settlements or judgments in these matters, potentially in excess of accruals, including matters where the Company could be held jointly and severally liable among other defendants. The resolution of, or increase in accruals for, one or more of these matters in any reporting period could have a material adverse effect on the Company's results of operations and cash flows for that period. The Company does not purchase third-party product liability insurance; however the Company utilizes a wholly-owned captive insurance company subject to certain limits.

Product reliability, safety and effectiveness concerns can have significant negative impacts on sales and results of operations, lead to litigation and cause reputational damage.

Concerns about product safety, whether raised internally or by litigants, regulators or consumer advocates, and whether or not based on scientific evidence, can result in safety alerts, product recalls, governmental investigations, regulatory action on the part of the U.S. Food and Drug Administration (or its counterpart in other countries), private claims and lawsuits, payment of fines and settlements, declining sales and reputational damage. These circumstances can also result in damage to brand image, brand equity and consumer trust in the Company's products. Product recalls have in the past, and could in the future, prompt government investigations and inspections, the shutdown of manufacturing facilities, continued product shortages and related sales declines, significant remediation costs, reputational damage, possible civil penalties and criminal prosecution.

The Company faces significant regulatory scrutiny which imposes significant compliance costs and exposes the Company to government investigations, legal actions and penalties.

Like other companies in the healthcare industry, the Company is subject to extensive regulation, investigations and legal action, by national, state and local government agencies in the U.S. and other countries in which they operate. Regulatory issues regarding compliance with current Good Manufacturing Practices (cGMP) (and comparable quality regulations in foreign countries) by manufacturers of drugs, devices and consumer products can lead to fines and penalties, product recalls, product shortages, interruptions in production, delays in new product approvals and litigation. In addition, the marketing, pricing and sale of the Company's products are subject to regulation, investigations and legal actions including under the Federal Food, Drug, and Cosmetic Act, the Medicaid Rebate Program, federal and state false claims acts, state unfair trade practices acts and consumer protection laws. Scrutiny of health care industry business practices by government agencies and state attorneys general in the U.S., and any resulting investigations and prosecutions, carry risk of significant civil and criminal penalties including, but not limited to, debarment from participation in government healthcare programs. Any such debarment could have a material adverse effect on the Company's business and results of operations. The most significant current investigations and

litigation brought by government agencies are described in Note 19, "Legal Proceedings-Government Proceedings" under Notes to the Consolidated Financial Statements included in Item 8 of this Report.

Changes in tax laws or exposures to additional tax liabilities could negatively impact the Company's operating results.
Changes in tax laws or regulations around the world could negatively impact the Company's effective tax rate and results of operations. A change in statutory tax rate in any country would result in the revaluation of the Company's deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is enacted. This change would result in an expense or benefit recorded to the Company's Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries where it operates. Changes to the statutory tax rate may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted.

See Note 8 on income taxes for additional information.

The Company conducts business and files tax returns in numerous countries and is addressing tax audits and disputes with many tax authorities. In connection with the 2015 Organization for Economic Cooperation and Development Base Erosion and Profit Shifting (BEPS) project, companies are required to disclose more information to tax authorities on operations around the world, which may lead to greater audit scrutiny of profits earned in other countries. The Company regularly assesses the likely outcomes of its tax audits and disputes to determine the appropriateness of its tax reserves. However, any tax authority could take a position on tax treatment that is contrary to the Company's expectations, which could result in tax liabilities in excess of reserves.

Risks Related to Our Intellectual Property

The Company may not be able to successfully secure and defend intellectual property rights essential to the Company's businesses.
The Company owns or licenses a significant number of patents and other proprietary rights, relating to its products and manufacturing processes. These rights are essential to the Company's businesses and materially important to the Company's results of operations. Public policy, both within and outside the U.S., has become increasingly unfavorable toward intellectual property rights. The Company cannot be certain that it will obtain adequate patent protection for new products and technologies in the United States and other important markets or that such protections, once granted, will last as long as originally anticipated.

Competitors routinely challenge the validity or extent of the Company's owned or licensed patents and proprietary rights through litigation, interferences, oppositions and other proceedings, such as inter partes review (IPR) proceedings before the United States Patent & Trademark Office (USPTO). These proceedings absorb resources and can be protracted as well as unpredictable. In addition, challenges that the Company's products infringe the patents of third parties could result in the need to pay past damages and future royalties and adversely affect the competitive position and sales of the products in question.

The Company has faced increasing patent challenges from third parties seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the U.S., manufacturers of generic versions of innovative human pharmaceutical products may challenge the validity, or claim non-infringement, of innovator products through the Abbreviated New Drug Application, or ANDA, process with the FDA and related ANDA litigation. The Biologics Price Competition and Innovation Act (BPCIA), enacted in 2010, which created a new regulatory pathway for the approval by the FDA of biosimilar alternatives to innovator-developed biological products, also created mechanisms for biosimilar applicants to challenge the patents on the innovator biologics. The IPR process with the USPTO is also being used by competitors to challenge patents asserted in litigation.

In the event the Company is not successful in defending its patents against such challenges, or upon the "at-risk" launch (despite pending patent infringement litigation) by the generic or biosimilar firm of its product, the Company can lose a major portion of revenues for the referenced product in a very short period of time. Current legal proceedings involving the Company's patents and other intellectual property rights are described in Note 19, "Legal Proceedings—Intellectual Property" of the Notes to the Consolidated Financial Statements included in Item 8 of this Report.

Risks Related to Product Development, Regulatory Approval and Commercialization

Significant challenges or delays in the Company's innovation and development of new products, technologies and indications could have an adverse impact on the Company's long-term success.

The Company's continued growth and success depends on its ability to innovate and develop new and differentiated products and services that address the evolving health care needs of patients, providers and consumers. Development of successful products and technologies is also necessary to offset revenue losses when the Company's existing products lose market share due to various factors such as competition and loss of patent exclusivity. New products introduced within the past five years accounted for approximately 25% of 2020 sales. The Company cannot be certain when or whether it will be able to develop, license or otherwise acquire companies, products and technologies, whether particular product candidates will be granted regulatory approval, and, if approved, whether the products will be commercially successful.

The Company pursues product development through internal research and development as well as through collaborations, acquisitions, joint ventures and licensing or other arrangements with third parties. In all of these contexts, developing new products, particularly pharmaceutical and biotechnology products and medical devices, requires significant investment of resources over many years. Only a very few biopharmaceutical research and development programs result in commercially viable products. The process depends on many factors including the ability to discern patients' and health care providers' future needs; develop promising new compounds, strategies and technologies; achieve successful clinical trial results; secure effective intellectual property protection; obtain regulatory approvals on a timely basis; and, if and when they reach the market, successfully differentiate the Company's products from competing products and approaches to treatment. New products or enhancements to existing products may not be accepted quickly or significantly in the marketplace due to product and price competition, changes in customer preferences or healthcare purchasing patterns, resistance by healthcare providers or uncertainty over third-party reimbursement. Even following initial regulatory approval, the success of a product can be adversely impacted by safety and efficacy findings in larger real-world patient populations, as well as market entry of competitive products.

Risk Related to Financial and Economic Market Conditions

The Company faces a variety of risks associated with conducting business internationally.
The Company's extensive operations and business activity outside the U.S. are accompanied by certain financial, economic and political risks, including those listed below.

Foreign Currency Exchange: In fiscal 2020, approximately 48% of the Company's sales occurred outside of the U.S., with approximately 23% in Europe, 7% in the Western Hemisphere, excluding the U.S., and 18% in the Asia-Pacific and Africa region. Changes in non-U.S. currencies relative to the U.S. dollar impact the Company's revenues and expenses. While the Company uses financial instruments to mitigate the impact of fluctuations in currency exchange rates on its cash flows, unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the U.S. dollar may result in significant favorable or unfavorable translation effects when the operating results of the Company's non-U.S. business activity are translated into U.S. dollars.

Inflation and Currency Devaluation Risks: The Company faces challenges in maintaining profitability of operations in economies experiencing high inflation rates. The Company has accounted for operations in Argentina (beginning in the fiscal third quarter of 2018) and Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. While the Company strives to maintain profit margins in these areas through cost reduction programs, productivity improvements and periodic price increases, it might experience operating losses as a result of continued inflation. In addition, the impact of currency devaluations in countries experiencing high inflation rates or significant currency exchange fluctuations could negatively impact the Company's operating results.

Illegal Importation of Pharmaceutical Products: The illegal importation of pharmaceutical products from countries where government price controls or other market dynamics result in lower prices may adversely affect the Company's sales and profitability in the U.S. and other countries in which the Company operates. With the exception of limited quantities of prescription drugs for personal use, foreign imports of pharmaceutical products are illegal under current U.S. law. However, the volume of illegal imports continues to rise as the ability of patients and other customers to obtain the lower-priced imports has grown significantly.

Anti-Bribery and Other Regulations: The Company is subject to various federal and foreign laws that govern its international business practices with respect to payments to government officials. Those laws include the U.S. Foreign Corrupt Practices Act (FCPA), which prohibits U.S. publicly traded companies from promising, offering, or giving anything of value to foreign officials with the corrupt intent of influencing the foreign official for the purpose of helping the Company obtain or retain business or gain any improper advantage. The Company's business is heavily regulated and therefore involves significant interaction with foreign officials. Also, in many countries outside the U.S., the health care providers who prescribe human pharmaceuticals are employed by the government and the purchasers of human pharmaceuticals are government entities;

therefore, the Company's interactions with these prescribers and purchasers are subject to regulation under the FCPA. In addition to the U.S. application and enforcement of the FCPA, various jurisdictions in which the Company operates have laws and regulations, including the U.K Bribery Act 2010, aimed at preventing and penalizing corrupt and anticompetitive behavior. Enforcement activities under these laws could subject the Company to additional administrative and legal proceedings and actions, which could include claims for civil penalties, criminal sanctions, and administrative remedies, including exclusion from health care programs.

Other Legal, Social and Political Risks. Other risks inherent in conducting business globally include:

- protective economic policies taken by governments such as trade protection measures and import/export licensing requirements;
- compliance with local regulations and laws including, in some countries, regulatory requirements restricting the Company's ability to manufacture or sell its products in the relevant market;
- diminished protection of intellectual property and contractual rights in certain jurisdictions;
- potential nationalization or expropriation of the Company's foreign assets;
- political or social upheavals, economic instability, repression, or human rights issues; and
- geopolitical events, including natural disasters, disruptions to markets due to war, armed conflict, terrorism, epidemics or pandemics.

Failure to maintain a satisfactory credit rating could adversely affect our liquidity, capital position, borrowing costs and access to capital markets.
We currently maintain investment grade credit ratings with Moody's Investors Service and Standard & Poor's Ratings Services. Rating agencies routinely evaluate us, and their ratings of our long-term and short-term debt are based on a number of factors. Any downgrade of our credit ratings by a credit rating agency, whether as a result of our actions or factors which are beyond our control, can increase the cost of borrowing under any indebtedness we may incur, reduce market capacity for our commercial paper or require the posting of additional collateral under our derivative contracts. There can be no assurance that we will be able to maintain our credit ratings, and any additional actual or anticipated changes or downgrades in our credit ratings, including any announcement that our ratings are under review for a downgrade, may have a negative impact on our liquidity, capital position and access to capital markets.

Other Risks

Our business depends on our ability to recruit and retain talented, highly skilled employees and a diverse workforce.
Our continued growth requires us to recruit and retain talented employees representing diverse backgrounds, experiences, and skill sets. The market for highly skilled workers and leaders in our industry is extremely competitive and our ability to compete depends on our ability to hire, develop and motivate highly skilled personnel in all areas of our organization. Maintaining our brand and reputation, as well as a diverse, equitable and inclusive work environment enables us to attract top talent. If we are less successful in our recruiting efforts, or if we cannot retain highly skilled workers and key leaders, our ability to develop and deliver successful products and services may be adversely affected. In addition, effective succession planning is important to our long-term success. Any unsuccessful implementation of our succession plans or failure to ensure effective transfer of knowledge and smooth transitions involving key employees could adversely affect our business, financial condition, or results of operations.

An information security incident, including a cybersecurity breach, could have a negative impact to the Company's business or reputation.
To meet business objectives, the Company relies on both internal technology (IT) systems and networks, and those of third parties and their vendors, to process and store sensitive data, including confidential research, business plans, financial information, intellectual property, and personal data that may be subject to legal protection, and ensure the continuity of the Company's supply chain. The extensive information security and cybersecurity threats, which affect companies globally, pose a risk to the security and availability of these systems and networks, and the confidentiality, integrity, and availability of the Company's sensitive data. The Company continually assesses these threats and makes investments to increase internal protection, detection, and response capabilities, as well as ensure the Company's third-party providers have required capabilities and controls, to address this risk. To date, the Company has not experienced any material impact to the business or operations resulting from information or cybersecurity attacks; however, because of the frequently changing attack techniques, along with the increased volume and sophistication of the attacks, there is the potential for the Company to be adversely impacted. This impact could result in reputational, competitive, operational or other business harm as well as financial costs and

regulatory action. The Company maintains cybersecurity insurance in the event of an information security or cyber incident; however, the coverage may not be sufficient to cover all financial, legal, business or reputational losses.

Climate change or legal, regulatory or market measures to address climate change may negatively affect our business and results of operations.
Climate change resulting from increased concentrations of carbon dioxide and other greenhouse gases in the atmosphere could present risks to our operations, including an adverse impact on global temperatures, weather patterns and the frequency and severity of extreme weather and natural disasters. Natural disasters and extreme weather conditions, such as a hurricane, tornado, earthquake, wildfire or flooding, may pose physical risks to our facilities and disrupt the operation of our supply chain. The impacts of the changing climate on water resources may result in water scarcity, limiting our ability to access sufficient high-quality water in certain locations, which may increase operational costs.

Concern over climate change may also result in new or additional legal or regulatory requirements designed to reduce greenhouse gas emissions and/or mitigate the effects of climate change on the environment. If such laws or regulations are more stringent than current legal or regulatory obligations, we may experience disruption in, or an increase in the costs associated with sourcing, manufacturing and distribution of our products, which may adversely affect our business, results of operations or financial condition

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

The Company's subsidiaries operate 90 manufacturing facilities occupying approximately 15.2 million square feet of floor space. The manufacturing facilities are used by the industry segments of the Company's business approximately as follows:

Segment	Square Feet (in thousands)
Consumer Health	4,684
Pharmaceutical	5,559
Medical Devices	4,951
Worldwide Total	15,194

Within the U.S., five facilities are used by the Consumer Health segment, five by the Pharmaceutical segment and 19 by the Medical Devices segment. Outside of the U.S., 24 facilities are used by the Consumer Health segment, 14 by the Pharmaceutical segment and 23 by the Medical Devices segment.

The locations of the manufacturing facilities by major geographic areas of the world are as follows:

Geographic Area	Number of Facilities	Square Feet (in thousands)
United States	29	4,351
Europe	25	5,992
Western Hemisphere, excluding U.S.	10	1,777
Africa, Asia and Pacific	26	3,074
Worldwide Total	90	15,194

In addition to the manufacturing facilities discussed above, the Company maintains numerous office and warehouse facilities throughout the world. Research facilities are also discussed in Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition of this Report.

The Company's subsidiaries generally seek to own, rather than lease, their manufacturing facilities, although some, principally in non-U.S. locations, are leased. Office and warehouse facilities are often leased. The Company also engages contract manufacturers.

The Company is committed to maintaining all of its properties in good operating condition.

McNEIL-PPC, Inc. (now Johnson & Johnson Consumer Inc.) (McNEIL-PPC) continues to operate under a consent decree, signed in 2011 with the FDA, which governs certain McNeil Consumer Healthcare manufacturing operations, and requires McNEIL-PPC to remediate the facilities it operates in Lancaster, Pennsylvania, Fort Washington, Pennsylvania, and Las Piedras, Puerto Rico (the "Consent Decree"). Following FDA inspections McNEIL-PPC received notifications from the FDA that all three manufacturing facilities are in conformity with applicable laws and regulations, and commercial production restarted in 2015.

Under the Consent Decree, after receiving notice from the FDA of being in compliance with applicable laws and regulations, each of the three facilities is subject to a five-year audit period by a third-party cGMP expert. A third-party expert continued to reassess the sites at various times through 2020. McNEIL-PPC is awaiting FDA inspections of the facilities which have been delayed due to COVID-19.

Segment information on additions to property, plant and equipment is contained in Note 17 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 3. LEGAL PROCEEDINGS

The information called for by this item is incorporated herein by reference to the information set forth in Note 19 "Legal Proceedings" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

In addition, Johnson & Johnson and its subsidiaries are also parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the cost of past and/or future remediation.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

EXECUTIVE OFFICERS OF THE REGISTRANT

Listed below are the executive officers of the Company. There are no family relationships between any of the executive officers, and there is no arrangement or understanding between any executive officer and any other person pursuant to which the executive officer was selected. At the annual meeting of the Board of Directors, the executive officers are elected by the Board to hold office for one year and until their respective successors are elected and qualified, or until earlier resignation or removal.

Information with regard to the directors of the Company, including information for Alex Gorsky, who is also an executive officer, is incorporated herein by reference to the material captioned "Item 1. Election of Directors" in the Proxy Statement.

Name	Age	Position
Joaquin Duato	58	Vice Chairman, Executive Committee[a]
Peter M. Fasolo, Ph.D.	58	Member, Executive Committee; Executive Vice President, Chief Human Resources Officer[b]
Alex Gorsky	60	Chairman, Board of Directors; Chairman, Executive Committee; Chief Executive Officer
Ashley McEvoy	50	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Medical Devices[c]
Thibaut Mongon	51	Member, Executive Committee, Executive Vice President, Worldwide Chairman, Consumer Health[d]
Michael E. Sneed	61	Member, Executive Committee; Executive Vice President, Global Corporate Affairs and Chief Communication Officer[e]
Paulus Stoffels, M.D.	58	Vice Chairman, Executive Committee; Chief Scientific Officer[f]
Jennifer L. Taubert	57	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Pharmaceuticals[g]
Michael H. Ullmann	62	Member, Executive Committee; Executive Vice President, General Counsel[h]
Kathryn E. Wengel	55	Member, Executive Committee; Executive Vice President, Chief Global Supply Chain Officer[i]
Joseph J. Wolk	54	Member, Executive Committee; Executive Vice President, Chief Financial Officer[j]

(a) Mr. J. Duato joined the Company in 1989 with Janssen-Farmaceutica S.A. (Spain), a subsidiary of the Company, and held executive positions of increasing responsibility in the Pharmaceutical sector. In 2009, he was named Company Group Chairman, Pharmaceuticals, and in 2011, he was named Worldwide Chairman, Pharmaceuticals. In 2016, Mr. Duato became a member of the Executive Committee and was named Executive Vice President, Worldwide Chairman, Pharmaceuticals. In July 2018, Mr. Duato was promoted to Vice Chairman of the Executive Committee, with responsibility for the company's Pharmaceutical and Consumer Health sectors, supply chain, information technology, global services and the Health & Wellness groups.

(b) Dr. P. M. Fasolo joined the Company in 2004 as Vice President, Worldwide Human Resources for Cordis Corporation, a subsidiary of the Company, and was subsequently named Vice President, Global Talent Management for the Company. He left Johnson & Johnson in 2007 to join Kohlberg Kravis Roberts & Co. as Chief Talent Officer. Dr. Fasolo returned to the Company in 2010 as the Vice President, Global Human Resources, and in 2011, he became a member of the Executive Committee. In April 2016, he was named Executive Vice President, Chief Human Resources Officer. Dr. Fasolo has responsibility for global talent, recruiting, diversity, compensation, benefits, employee relations and all aspects of the human resources agenda for the Company.

(c) Ms. A. McEvoy joined the Company in 1996 as Assistant Brand Manager of McNeil Consumer Health, a subsidiary of the Company, advancing through positions of increasing responsibilities until she was appointed Company Group Chairman, Vision Care in 2012, followed by Company Group Chairman, Consumer Medical Devices in 2014. In July 2018, Ms. McEvoy was promoted to Executive Vice President, Worldwide Chairman, Medical Devices, and became a member of the Executive Committee. Ms. McEvoy has responsibility for the surgery, orthopaedics, interventional solutions and eye health businesses across Ethicon, DePuy Synthes, Biosense Webster and Johnson & Johnson Vision.

(d) Mr. T. Mongon joined the Company in 2000 as Director of Marketing for the Vision Care group in France and subsequently held general management positions as Country Manager France, Belgium and North Africa, Managing Director Latin America, and President Asia-Pacific. Mr. Mongon transitioned to the Pharmaceutical sector in 2012 as the Global Commercial Strategy Leader for the Neuroscience therapeutic area, before joining the Consumer Health sector as Company Group Chairman Asia-Pacific. In 2019, he was promoted to Executive Vice President and Worldwide Chairman, Consumer Health, and became a member of the Executive Committee. Mr. Mongon has responsibility for the global development of Johnson & Johnson's health and wellness products and solutions in beauty, OTC, oral care, baby care, women's health, and wound care.

(e) Mr. M. E. Sneed joined the Company in 1983 as Marketing Assistant for Personal Products Company, a subsidiary of the Company, and gained increased responsibilities in executive positions across the global enterprise. In 2004, Mr. Sneed was appointed Company Group Chairman, Consumer North America, followed by Company Group Chairman, Vision Care Franchise in 2007. In 2012, he became the Vice President, Global Corporate Affairs and Chief Communications Officer. Mr. Sneed was appointed Executive Vice President, Global Corporate Affairs and Chief Communications Officer in January 2018, and became a member of the Executive Committee in July 2018, leading the Company's global marketing, communication, design and philanthropy functions.

(f) Dr. P. Stoffels rejoined the Company in 2002 with the acquisition of Tibotec Virco NV, where he was Chief Executive Officer of Virco NV and Chairman of Tibotec NV. In 2005, he was appointed Company Group Chairman, Global Virology. In 2006, he assumed the role of Company Group Chairman, Pharmaceuticals. Dr. Stoffels was appointed Global Head, Research & Development, Pharmaceuticals in 2009, and in 2011, became Worldwide Chairman, Pharmaceuticals. In 2012, Dr. Stoffels was appointed Chief Scientific Officer, and became a member of the Executive Committee. In 2016, Dr. Stoffels was named Executive Vice President, Chief Scientific Officer. In 2018, Dr. Stoffels was promoted to Vice Chairman of the Executive Committee, Chief Scientific Officer. He is responsible for the Company's innovation agenda across the Pharmaceutical, Medical Devices and Consumer Health sectors, product safety strategy, and the Company's global public health strategy.

(g) Ms. J. L. Taubert joined the Company in 2005 as Worldwide Vice President at Johnson & Johnson Pharmaceutical Services, a subsidiary of the Company. She held several executive positions of increasing responsibility in the Pharmaceutical sector until 2012 when she was appointed Company Group Chairman, North America Pharmaceuticals, and in 2015 became Company Group Chairman, The Americas, Pharmaceuticals. In July 2018, Ms. Taubert was promoted to Executive Vice President, Worldwide Chairman, Pharmaceuticals, and became a member of the Executive Committee. Ms. Taubert has responsibility for the Immunology, Infectious Diseases, Neuroscience, Oncology, Cardiovascular and Metabolism, and Pulmonary Hypertension businesses throughout Janssen.

(h) Mr. M. H. Ullmann joined the Company in 1989 as a corporate attorney in the Law Department. He was appointed Corporate Secretary in 1999 and served in that role until 2006. During that time, he also held various management positions in the Law Department. In 2006, he was named General Counsel, Medical Devices and Diagnostics and was appointed Vice President, General Counsel and became a member of the Executive Committee in 2012. In April 2016, Mr. Ullmann was named Executive Vice President, General Counsel. Mr. Ullmann has worldwide responsibility for legal, government affairs & policy, global security, aviation, health care compliance, global brand protection and privacy.

(i) Ms. K. E. Wengel joined the Company in 1988 as Project Engineer and Engineering Supervisor at Janssen, a subsidiary of the Company. During her tenure with the Company, she has held a variety of strategic leadership and executive positions across the global enterprise, in roles within operations, quality, engineering, new products, information technology, and other technical and business functions. In 2010, Ms. Wengel became the first Chief Quality Officer of the Company. In 2014, she was promoted to Vice President, Johnson & Johnson Supply Chain. In

July 2018, she was promoted to Executive Vice President, Chief Global Supply Chain Officer, and became a member of the Executive Committee.

(j) Mr. J. J. Wolk joined the Company in 1998 as Finance Manager, Business Development for Ortho-McNeil, a subsidiary of the Company, and through the years held a variety of senior leadership roles in several segments and functions across the Company's subsidiaries, in Pharmaceuticals, Medical Devices and Supply Chain. From 2014 to 2016, he served as Vice President, Finance and Chief Financial Officer of the Janssen Pharmaceutical Companies of Johnson & Johnson. In 2016, Mr. Wolk became the Vice President, Investor Relations. In July 2018, he was appointed Executive Vice President, Chief Financial Officer and became a member of the Executive Committee. Mr. Wolk plays a strategic role in the overall management of the Company, and leads the development and execution of the Company's global long-term financial strategy.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

As of February 16, 2021, there were 132,376 record holders of common stock of the Company. Additional information called for by this item is incorporated herein by reference to the following sections of this Report: Note 16 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements included in Item 8; and Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters – Equity Compensation Plan Information."

Issuer Purchases of Equity Securities

The following table provides information with respect to common stock purchases by the Company during the fiscal fourth quarter of 2020. Common stock purchases on the open market are made as part of a systematic plan to meet the needs of the Company's compensation programs. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal fourth quarter.

Fiscal Period	Total Number of Shares Purchased[1]	Avg. Price Paid Per Share	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
September 28, 2020 through October 25, 2020	350,000	$ 145.57	-	-
October 26, 2020 through November 22, 2020	369,000	148.53	-	-
November 23, 2020 through January 3, 2021	1,432,333	150.50	-	-
Total	2,151,333			

(1) During the fiscal fourth quarter of 2020, the Company repurchased an aggregate of 2,151,333 shares of Johnson & Johnson Common Stock in open-market transactions, all of which were purchased in open-market transactions as part of a systematic plan to meet the needs of the Company's compensation programs.

Item 6. Reserved

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF RESULTS OF OPERATIONS AND FINANCIAL CONDITION

Organization and Business Segments

Description of the Company and Business Segments

Johnson & Johnson and its subsidiaries (the Company) have approximately 134,500 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The Company is organized into three business segments: Consumer Health (previously referred to as Consumer), Pharmaceutical and Medical Devices. The Consumer Health segment includes a broad range of products used in the baby care, oral care, skin health/beauty, over-the-counter pharmaceutical, women's health and wound care markets. These products are marketed to the general public and sold online (eCommerce) and to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on six therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, pulmonary hypertension, and cardiovascular and metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, interventional solutions (cardiovascular and neurovascular) and eye health fields. These products are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Consumer Health, Pharmaceutical and Medical Devices business segments.

In all of its product lines, the Company competes with other companies both locally and globally, throughout the world. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products, as well as protecting the underlying intellectual property of the Company's product portfolio, is important to the Company's success in all areas of its business. The competitive environment requires substantial investments in continuing research. In addition, the development and maintenance of customer demand for the Company's consumer products involves significant expenditures for advertising and promotion.

Management's Objectives

With "Our Credo" as the foundation, the Company's purpose is to blend heart, science and ingenuity to profoundly change the trajectory of health for humanity. The Company is committed to bringing its full breadth and depth to ensure health for people today and for future generations. United around this common ambition, the Company is poised to fulfill its purpose and successfully meet the demands of the rapidly evolving markets in which it competes.

The Company is broadly based in human healthcare, and is committed to creating value by developing accessible, high quality, innovative products and services. New products introduced within the past five years accounted for approximately 25% of 2020 sales. In 2020, $12.2 billion was invested in research and development and $7.3 billion spent on acquisitions, reflecting management's commitment to create life-enhancing innovations and to create value through partnerships that will profoundly change the trajectory of health for humanity.

A critical driver of the Company's success is the 134,500 diverse employees worldwide. Employees are empowered and inspired to lead with the Company's Our Credo and purpose as guides. This allows every employee to use the Company's reach and size to advance the Company's purpose, and to also lead with agility and urgency. Leveraging the extensive resources across the enterprise enables the Company to innovate and execute with excellence. This ensures the Company can remain focused on addressing the unmet needs of society every day and invest for an enduring impact, ultimately delivering value to its patients, consumers and healthcare professionals, employees, communities and shareholders.

Results of Operations

Analysis of Consolidated Sales

For discussion on results of operations and financial condition pertaining to the fiscal years 2019 and 2018 see the Company's Annual Report on Form 10-K for the fiscal year ended December 29, 2019, Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition.

In 2020, worldwide sales increased 0.6% to $82.6 billion as compared to an increase of 0.6% in 2019. These sales changes consisted of the following:

Sales increase/(decrease) due to:	2020	2019
Volume	3.5 %	3.7 %
Price	(2.3)	(0.9)
Currency	(0.6)	(2.2)
Total	**0.6 %**	**0.6 %**

The net impact of acquisitions and divestitures on the worldwide sales growth was a negative impact of 0.3% in 2020 and a negative impact of 1.7% in 2019.

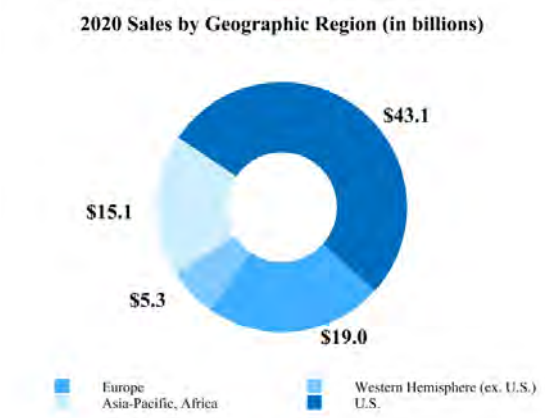
Sales by U.S. companies were $43.1 billion in 2020 and $42.1 billion in 2019. This represents increases of 2.5% in 2020 and 0.5% in 2019. Sales by international companies were $39.5 billion in 2020 and $40.0 billion in 2019. This represents a decrease of 1.3% in 2020 and an increase of 0.7% in 2019.

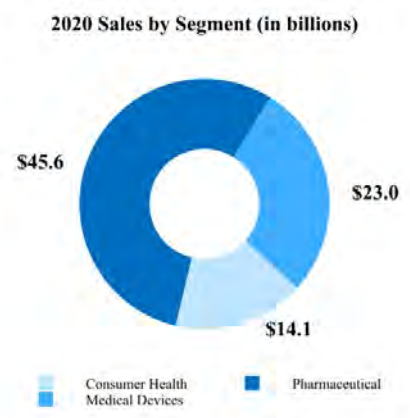
The five-year compound annual growth rates for worldwide, U.S. and international sales were 3.3%, 3.9% and 2.8%, respectively. The ten-year compound annual growth rates for worldwide, U.S. and international sales were 3.0%, 3.9% and 2.1%, respectively.

In 2020, sales by companies in Europe achieved growth of 2.8% as compared to the prior year, which included operational growth of 2.0% and a positive currency impact of 0.8%. Sales by companies in the Western Hemisphere (excluding the U.S.) experienced a sales decline of 10.2% as compared to the prior year, which included operational growth of 0.4% offset by a negative currency impact of 10.6%. Sales by companies in the Asia-Pacific, Africa region experienced a sales decline of 2.7% as compared to the prior year, including an operational decline of 3.1% partially offset by a positive currency impact of 0.4%.

The 2020 results benefited from the inclusion of a 53rd week. (See Note 1 to the Consolidated Financial Statements for Annual Closing Date details). The Company estimated that the fiscal year 2020 sales growth rate was enhanced by approximately 1.0%. While the additional week added a few days to sales, it also added a full week's worth of operating costs; therefore, the net earnings impact was negligible.

In 2020, the Company utilized three wholesalers distributing products for all three segments that represented approximately 16.0%, 12.0% and 12.0% of the total consolidated revenues. In 2019, the Company had three wholesalers distributing products for all three segments that represented approximately 15.0%, 12.0% and 11.0% of the total consolidated revenues.





Note: values may have been rounded

Analysis of Sales by Business Segments

Consumer Health Segment

Consumer Health segment sales in 2020 were $14.1 billion, an increase of 1.1% from 2019, which included 3.0% operational growth and a negative currency impact of 1.9%. U.S. Consumer Health segment sales were $6.4 billion, an increase of 9.0%. International sales were $7.7 billion, a decrease of 4.6%, which included an operational decline of 1.3% and a negative currency impact of 3.3%. In 2020, acquisitions and divestitures had a net negative impact of 0.1% on the operational sales growth of the worldwide Consumer Health segment.

Major Consumer Health Franchise Sales*:

(Dollars in Millions)	2020	2019	% Change '20 vs. '19
OTC	$ 4,824	4,444	8.5 %
Skin Health/Beauty**	4,450	4,593	(3.1)
Oral Care	1,641	1,528	7.4
Baby Care	1,517	1,675	(9.4)
Women's Health	901	986	(8.6)
Wound Care/Other	720	671	7.2
Total Consumer Health* Sales	**$ 14,053**	**13,898**	**1.1 %**

* Previously referred to as Consumer
** Previously referred to as Beauty

The OTC franchise sales of $4.8 billion increased 8.5% as compared to the prior year. Growth was primarily attributable to sales from TYLENOL® driven by COVID-19 stocking demand, ZYRTEC® due to competitor product out of stock and PEPCID® due to competitive product withdrawal both in the U.S., and increased consumption in anti-smoking aids. International sales were negatively impacted by COVID-19 and low incidence of cough and flu.

The Skin Health/Beauty franchise sales were $4.5 billion in 2020, a decrease of 3.1% as compared to the prior year. The decline was primarily due to negative COVID-19 related impacts and SKU rationalization partially offset by growth in eCommerce and new product innovation.

The Oral Care franchise sales of $1.6 billion increased 7.4% as compared to the prior year primarily attributable to sales of LISTERINE® mouthwash due to U.S. eCommerce and club channel growth, increased stocking demand related to COVID-19 and new product launches in Asia Pacific.
The Baby Care franchise sales were $1.5 billion in 2020, a decrease of 9.4% compared to the prior year. The decline was primarily due to COVID-19 related impacts, SKU rationalization and the Baby Center divestiture in the U.S. partially offset by strength in AVEENO® baby.

The Women's Health franchise sales were $0.9 billion in 2020, a decrease of 8.6% as compared to the prior year. The decline was primarily driven by COVID-19 impacts.

The Wound Care/Other franchise sales were $0.7 billion in 2020, an increase of 7.2% as compared to the prior year. Growth was due to strong performance of NEOSPORIN® and BAND-AID® Brand Adhesive Bandages and COVID-19 related demand in the Asia Pacific region.

Pharmaceutical Segment

Pharmaceutical segment sales in 2020 were $45.6 billion, an increase of 8.0% from 2019, which included operational growth of 8.2% and a negative currency impact of 0.2%. U.S. sales were $25.7 billion, an increase of 7.8%. International sales were $19.8 billion, an increase of 8.3%, which included 8.8% operational growth and a negative currency impact of 0.5%. In 2020, acquisitions and divestitures had a net negative impact of 0.2% on the operational sales growth of the worldwide Pharmaceutical segment. Adjustments to previous reserve estimates positively impacted the Pharmaceutical segment operational growth by approximately 1.0% in both fiscal years 2020 and 2019.

Major Pharmaceutical Therapeutic Area Sales*:

(Dollars in Millions)	2020	2019	% Change '20 vs. '19
Total Immunology	**$ 15,055**	**13,950**	**7.9 %**
REMICADE®	3,747	4,380	(14.4)
SIMPONI®/SIMPONI ARIA®	2,243	2,188	2.6
STELARA®	7,707	6,361	21.1
TREMFYA®	1,347	1,012	33.2
Other Immunology	11	10	6.4
Total Infectious Diseases	**3,574**	**3,413**	**4.7**
EDURANT®/rilpivirine	964	861	11.9
PREZISTA®/ PREZCOBIX®/REZOLSTA®/SYMTUZA®	2,184	2,110	3.5
Other Infectious Diseases	427	441	(3.2)
Total Neuroscience	**6,548**	**6,328**	**3.5**
CONCERTA®/methylphenidate	622	696	(10.6)
INVEGA SUSTENNA®/XEPLION®/INVEGA TRINZA®/TREVICTA®	3,653	3,330	9.7
RISPERDAL CONSTA®	642	688	(6.8)
Other Neuroscience	1,632	1,614	1.1
Total Oncology	**12,367**	**10,692**	**15.7**
DARZALEX®	4,190	2,998	39.8
ERLEADA®(1)	760	332	**
IMBRUVICA®	4,128	3,411	21.0
VELCADE®	408	751	(45.7)
ZYTIGA® /abiraterone acetate	2,470	2,795	(11.6)
Other Oncology	413	407	1.7
Total Pulmonary Hypertension	**3,148**	**2,623**	**20.0**
OPSUMIT®	1,639	1,327	23.5
UPTRAVI®	1,093	819	33.5
Other Pulmonary Hypertension (2)	416	476	(12.8)
Total Cardiovascular / Metabolism / Other	**4,878**	**5,192**	**(6.0)**
XARELTO®	2,345	2,313	1.4
INVOKANA®/ INVOKAMET®	795	735	8.2
PROCRIT®/EPREX®	552	790	(30.2)
Other	1,186	1,353	(12.4)
Total Pharmaceutical Sales	**$ 45,572**	**42,198**	**8.0 %**

*Certain prior year amounts have been reclassified to conform to current year presentation
** Percentage greater than 100% or not meaningful
(1) Previously included in Other Oncology
(2) Inclusive of TRACLEER® which was previously disclosed separately

Immunology products sales were $15.1 billion in 2020, representing an increase of 7.9% as compared to the prior year driven by strong uptake of STELARA® (ustekinumab) in Crohn's disease and Ulcerative Colitis and strength in TREMFYA® (guselkumab) in Psoriasis. This was partially offset by COVID-19 related demand and lower sales of REMICADE® (infliximab) due to increased discounts/rebates and biosimilar competition.

The patents for REMICADE® (infliximab) in certain countries in Europe expired in February 2015. Biosimilar versions of REMICADE® have been introduced in certain markets outside the United States, resulting in a reduction in sales of REMICADE® in those markets. Additional biosimilar competition will likely result in a further reduction in sales of REMICADE® in markets outside the United States. In the United States, a biosimilar version of REMICADE® was introduced in 2016, and additional competitors continue to enter the market. Continued infliximab biosimilar competition in the U.S. market will result in a further reduction in U.S. sales of REMICADE®.

Infectious disease products sales were $3.6 billion in 2020, representing an increase of 4.7% as compared to the prior year primarily due to strong sales of SYMTUZA® and JULUCA®. This was partially offset by lower sales of PREZISTA® and PREZCOBIX®/REZOLSTA® due to increased competition and loss of exclusivity of PREZISTA® in certain countries outside the U.S.

Neuroscience products sales were $6.5 billion, representing an increase of 3.5% as compared to the prior year. Paliperidone long-acting injectables growth driven by sales of INVEGA SUSTENNA®/XEPLION® (paliperidone palmitate) and INVEGA TRINZA®/TREVICTA® from new patient starts and persistence. The growth was partially offset by migration from RISPERDAL CONSTA® (risperidone) and declines in CONCERTA® (methylphenidate) due to competitive entrants.

Oncology products achieved sales of $12.4 billion in 2020, representing an increase of 15.7% as compared to the prior year. Contributors to the growth were strong sales of DARZALEX® (daratumumab) driven by patient uptake in all lines of therapy and the launch of a subcutaneous formulation in the U.S. and E.U.; IMBRUVICA® (ibrutinib) due to market growth globally and maintaining strong share and the continued global launch uptake and share gains of ERLEADA® (apalutamide). Additionally, the growth was negatively impacted by declining sales of ZYTIGA® (abiraterone acetate) and VELCADE® (bortezomib) due to generic competition.

Pulmonary Hypertension products achieved sales of $3.1 billion, representing an increase of 20.0% as compared to the prior year. Sales growth of OPSUMIT® (macitentan) and UPTRAVI® (selexipag) were due to continued share gains and market growth. Additionally, sales of TRACLEER® (bosentan) were negatively impacted by generics and migration to OPSUMIT®.

Cardiovascular/Metabolism/Other products sales were $4.9 billion, a decline of 6.0% as compared to the prior year. Sales growth of INVOKANA®/INVOKAMET® (canagliflozin) were due to market growth and favorable channel mix dynamics in the U.S. and strength in the European region partially offset by U.S. share declines due to competitive pressures. The growth of XARELTO® (rivaroxaban) was due to demand growth partially offset by higher rebates. Lower sales of PROCRIT®/ EPREX® (epoetin alfa) were due to biosimilar competition.

During 2020, the Company advanced its pipeline with several regulatory submissions and approvals for new drugs and additional indications for existing drugs as follows:

Product Name (Chemical Name)	Indication	US Approval	EU Approval	US Filing	EU Filing
Amivantamab	Treatment of Patients with Metastatic Non-Small Cell Lung Cancer with EGFR Exon 20 Insertion Mutations			▯	▯
DARZALEX® (daratumumab)	Combination Regimen for Newly Diagnosed, Transplant-eligible Patients with Multiple Myeloma		▯		
DARZALEX® (daratumumab)	Combination with Carfilzomib and Dexamethasone for patients with Relapsed/Refractory Multiple Myeloma	▯			
DARZALEX® FASPRO (daratumumab and hyaluronidase)	Subcutaneous Formulation of Daratumumab in the Treatment of Patients with Multiple Myeloma	▯	▯		
ERLEADA® (apalutamide)	Treatment of Metastatic Castration-Sensitive Prostate Cancer		▯		
IMBRUVICA® (ibrutinib)	In combination with Rituximab for treatment of Chronic Lymphocytic Leukemia	▯			
INVOKANA® (canagliflozin)	Treatment of Diabetic Kidney Disease		▯		
rilpivirine and cabotegravir	For Monthly, Injectable, Two Drug Regimen for Treatment of HIV			▯	▯
Paliperidone Pamitate 6-month	Treatment of Schizophrenia			▯	▯
Ponesimod	Treatment of adults with Relapsed Multiple Sclerosis			▯	▯
SIMPONI ARIA® (golimumab)	Treatment of Polyarticular Juvenile Idiopathic Arthritis and Juvenile Psoriatic Arthritis	▯			
SIRTURO® (bedaquiline)	Combination Therapy to Treat Children with Pulmonary Multidrug-Resistant Tuberculosis	▯			▯
SPRAVATO® (esketamine)	Rapid Reduction of Depressive Symptoms in Adults with Major Depressive Disorder who have Active Suicidal Ideation with Intent	▯			
STELARA® (ustekinumab)	Treatment of Pediatric Patients with Moderate to Severe Plaque Psoriasis	▯	▯		
TREMFYA® (guselkumab)	Treatment of Adults with Active Psoriatic Arthritis	▯	▯		
Uptravi® IV	Pulmonary arterial hypertension			▯	
XARELTO® (rivaroxaban)	New Indication to Expand Use in Patients with Peripheral Artery Disease			▯	
ZABDENO (Ad26.ZEBOV) and MVABEA (MVA-BN-Filo)	Preventive Ebola Vaccine		▯		

Medical Devices Segment
The Medical Devices segment sales in 2020 were $23.0 billion, a decrease of 11.6% from 2019, which included an operational decrease of 11.4% and a negative currency impact of 0.2%. U.S. sales were $11.0 billion, a decrease of 10.9% as compared to the prior year. International sales were $11.9 billion, a decrease of 12.2% as compared to the prior year, with an operational decrease of 11.8% and a negative currency impact of 0.4%. In 2020, the net impact of acquisitions and divestitures on the Medical Devices segment worldwide operational sales growth was a negative 0.9% of which, the divestiture of Advanced Sterilization Products (ASP) had an impact of approximately 0.8%. Growth was negatively impacted by COVID-19 and associated deferral of medical procedures.

Major Medical Devices Franchise Sales*:

(Dollars in Millions)	2020	2019	% Change '20 vs. '19
Surgery	**$ 8,232**	**9,501**	**(13.4)%**
Advanced	3,839	4,095	(6.2)
General[1]	4,392	5,406	(18.8)
Orthopaedics	**7,763**	**8,839**	**(12.2)**
Hips	1,280	1,438	(11.0)
Knees	1,170	1,480	(21.0)
Trauma	2,614	2,720	(3.9)
Spine, Sports & Other[2]	2,699	3,201	(15.7)
Vision	**3,919**	**4,624**	**(15.2)**
Contact Lenses/Other	2,994	3,392	(11.7)
Surgical	925	1,232	(24.9)
Interventional Solutions	**3,046**	**2,997**	**1.6**
Total Medical Devices Sales	**$ 22,959**	**25,963**	**(11.6)%**

*Certain prior year amounts have been reclassified to conform to current year presentation
[1] Includes Specialty Surgery which was previously disclosed separately
[2] Previously referred to as Spine & Other

The Surgery franchise sales were $8.2 billion in 2020, a decrease of 13.4% from 2019. The decline in Advanced Surgery was primarily driven by the negative impact of COVID-19 and competitive pressures in the U.S. This was partially offset by the success of new products outside the U.S. and the recovery of an isolated supply disruption in the prior year related to SURGIFLO®. The decline in General Surgery was primarily driven by the negative impact of COVID-19 and the ASP divestiture.

The Orthopaedics franchise sales were $7.8 billion in 2020, a decrease of 12.2% from 2019. The decline in hips was driven by the negative impact of COVID-19 partially offset by a leadership position in the Anterior approach, strong market demand for the ACTIS® stem and enabling technologies – KINCISE™ and VELYS™ Hip Navigation. The decline in knees was driven by the negative impact of COVID-19. The decline in Trauma was driven by the negative impact of COVID-19 partially offset by strength from new products. The decline in Spine, Sports & Other was driven by the negative impact of COVID-19 partially offset by the uptake of new products.

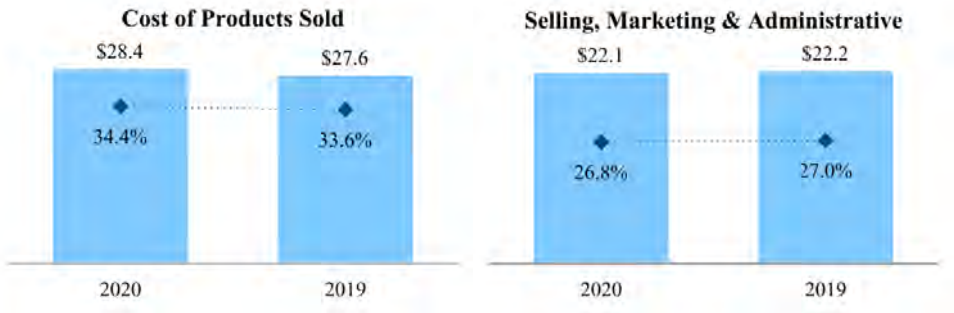
The Vision franchise sales were of $3.9 billion in 2020, a decrease of 15.2% from 2019. The Contact Lenses/Other operational decline was due to the negative impact of COVID-19. The Surgical operational decline was primarily driven by the negative impact of COVID-19 and competitive pressures in the U.S.

The Interventional Solutions franchise achieved sales of $3.0 billion in 2020, an increase of 1.6% from 2019. Growth in the electrophysiology business was driven by Atrial Fibrillation procedure growth coupled with strength from new products and market recovery offsetting negative impacts from COVID-19.

Analysis of Consolidated Earnings Before Provision for Taxes on Income
Consolidated earnings before provision for taxes on income was $16.5 billion and $17.3 billion for the years 2020 and 2019, respectively. As a percent to sales, consolidated earnings before provision for taxes on income was 20.0% and 21.1%, in 2020 and 2019, respectively.

(Dollars in billions. Percentages in chart are as a percent to total sales)

Cost of Products Sold and Selling, Marketing and Administrative Expenses:



(Dollars in billions. Percentages in chart are as a percent to total sales)

Cost of products sold increased as a percent to sales driven by:
- Medical Device idle capacity costs associated with COVID-19 related production slow downs
- Establishment of obsolescence reserves and fixed cost deleveraging associated with the impact of COVID-19 in the Medical Devices business
- Supply chain costs associated with the development of the COVID-19 vaccine in the Pharmaceutical business

partially offset by:
- Favorable mix within the Pharmaceutical business
- Favorable product mix with a higher percentage of sales coming from the Pharmaceutical business

The intangible asset amortization expense included in cost of products sold was $4.7 billion and $4.5 billion, for the years 2020 and 2019, respectively.

Selling, Marketing and Administrative Expenses decreased as a percent to sales driven by:
- Leveraging in the Pharmaceutical and Consumer Health businesses
- Portfolio and investment optimization including execution of the ongoing SKU rationalization program in the Consumer Health business

- Favorable segment mix with a higher percentage of sales coming from the Pharmaceutical business

partially offset by:

- The negative impact on sales resulting from COVID-19 in the Medical Devices business

Research and Development Expense:
Research and development expense by segment of business was as follows:

	2020		2019	
(Dollars in Millions)	**Amount**	**% of Sales***	**Amount**	**% of Sales***
Consumer Health	$ 422	3.0 %	$ 493	3.5 %
Pharmaceutical	9,563	21.0	8,834	20.9
Medical Devices	2,174	9.5	2,028	7.8
Total research and development expense	$ 12,159	14.7 %	$ 11,355	13.8 %
Percent increase/(decrease) over the prior year	7.1 %		5.4 %	

*As a percent to segment sales

Research and development activities represent a significant part of the Company's business. These expenditures relate to the processes of discovering, testing and developing new products, upfront payments and developmental milestones, improving existing products, as well as ensuring product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products.

Research and Development increased as a percent to sales primarily driven by:

- Segment mix driven by a higher percentage of sales generated by the Pharmaceutical business versus the prior year
- The negative COVID-19 impact on Medical Devices sales
- Increased investment in the Medical Devices business related to robotics and digital programs
- Portfolio progression including the COVID-19 vaccine in the Pharmaceutical business, net of governmental reimbursements

Research facilities are located in the U.S., Belgium, Brazil, China, France, Germany, India, Israel, the Netherlands, Poland, Singapore, Sweden, Switzerland and the United Kingdom with additional R&D support in over 30 other countries.

In-Process Research and Development (IPR&D): In fiscal year 2020, the Company recorded an IPR&D charge of $0.2 billion primarily related to a partial impairment due to timing and progression of one of the digital surgery platforms acquired with the Auris Health acquisition. In the fiscal year 2019, the Company recorded an IPR&D charge of $0.9 billion for the remaining intangible asset value related to the development program of AL-8176, an investigational drug for the treatment of Respiratory Syncytial Virus (RSV) and human metapneumovirus (hMPV) acquired with the 2014 acquisition of Alios Biopharma Inc. The impairment charge was based on additional information, including clinical data, which became available and led to the Company's decision to abandon the development of AL-8176.

Other (Income) Expense, Net: Other (income) expense, net is the account where the Company records gains and losses related to the sale and write-down of certain investments in equity securities held by Johnson & Johnson Innovation - JJDC, Inc. (JJDC), unrealized gains and losses on investments, gains and losses on divestitures, certain transactional currency gains and losses, acquisition-related costs, litigation accruals and settlements, as well as royalty income.

Other (income) expense, net for the fiscal year 2020 was unfavorable by $0.4 billion as compared to the prior year primarily due to the following:

(Dollars in Billions)(Income)/Expense	2020	2019	Change
Litigation expense[1]	$ 5.1	5.1	—
Acquisition and Integration related[2]	(1.1)	0.3	(1.4)
Unrealized (gains)/losses on securities	(0.5)	(0.6)	0.1
Equity step-up gain related to DR. CI:LABO	0.0	(0.3)	0.3
Divestiture Gains[3]	(0.2)	(2.2)	2.0
Restructuring related	0.1	0.2	(0.1)
Other	(0.5)	0.0	(0.5)
Total Other (Income) Expense, Net	$ 2.9	2.5	0.4

(1)2020 litigation expense primarily associated with Talc related reserves and certain settlements ($4.0 billion). 2019 litigation expense primarily related to the agreement in principle to settle opioid litigation ($4.0 billion).
(2)2020 is primarily driven by a contingent consideration reversal of approximately $1.1 billion related to the timing of certain developmental milestones associated with the Auris Health acquisition.
(3) 2019 included the divestiture of ASP

Interest (Income) Expense: The fiscal year 2020 included net interest expense of $90 million as compared to income of $39 million in the fiscal year 2019. This was primarily due to reduced interest income resulting from lower rates of interest earned on cash balances and a higher average debt balance. This was partially offset by a lower average debt interest rate and a higher average cash balance. Cash, cash equivalents and marketable securities totaled $25.2 billion at the end of 2020, and averaged $22.2 billion as compared to the cash, cash equivalents and marketable securities total of $19.3 billion and $19.5 billion average cash balance in 2019. The total debt balance at the end of 2020 was $35.3 billion with an average debt balance of $31.5 billion as compared to $27.7 billion at the end of 2019 and an average debt balance of $29.1 billion. In the fiscal third quarter of 2020, the Company issued approximately $5.0 billion of commercial paper, with approximately $0.8 billion outstanding at year end. In the fiscal third quarter of 2020, the Company issued senior unsecured notes for a total of $7.5 billion.

Income Before Tax by Segment
Income (loss) before tax by segment of business were as follows:

	Income Before Tax		Segment Sales		Percent of Segment Sales	
(Dollars in Millions)	**2020**	**2019**	**2020**	**2019**	**2020**	**2019**
Consumer Health	$ (1,064)	2,061	14,053	13,898	(7.6)%	14.8
Pharmaceutical	15,462	8,816	45,572	42,198	33.9	20.9
Medical Devices	3,044	7,286	22,959	25,963	13.3	28.1
Total (1)	17,442	18,163	82,584	82,059	21.1	22.1
Less: Net expense not allocated to segments (2)	945	835				
Earnings before provision for taxes on income	$ 16,497	17,328	82,584	82,059	20.0 %	21.1

(1) See Note 17 to the Consolidated Financial Statements for more details.
(2) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.

Consumer Health Segment:
In 2020, the Consumer Health segment loss before tax as a percent of sales was (7.6)% versus income before tax of 14.8% in 2019. The decrease in the income before tax as a percent of sales was primarily driven by the following:

- Higher litigation expense of $3.9 billion in 2020 vs. $0.4 billion in 2019 (primarily associated with talc related reserves and certain settlements)
- The fiscal year 2019 included a gain of $0.3 billion related to the Company's previously held equity investment in DR. CI:LABO

partially offset by:

- Portfolio and investment optimization including execution of the ongoing SKU rationalization program

Pharmaceutical Segment:
In 2020, the Pharmaceutical segment income before tax as a percent to sales was 33.9% versus 20.9% in 2019. The increase in the income before tax as a percent of sales was primarily driven by the following:

- Lower litigation expense of $0.8 billion in 2020 vs. $4.3 billion in 2019 (primarily related to the agreement in principle to settle opioid litigation, of which $1.0 billion is in 2020 and $4.0 billion is in 2019)
- An in-process research and development charge of $0.9 billion in fiscal 2019 related to Alios
- Lower acquisition and integration related costs in fiscal 2020
- Leveraging in selling, marketing and administrative expense

Medical Devices Segment: In 2020, the Medical Devices segment income before tax as a percent to sales was 13.3% versus 28.1% in 2019. The decrease in the income before tax as a percent to sales was primarily driven by the following:

- A gain of $2.0 billion related to the ASP divestiture recorded in the fiscal 2019
- Idle capacity costs associated with COVID-19 related production slow downs in fiscal 2020
- Establishment of obsolescence reserves and fixed cost deleveraging associated with the impact of COVID-19 in fiscal 2020
- The negative impact of COVID-19 on sales in fiscal 2020

- An in-process research and development charge of $0.2 billion in fiscal 2020 primarily related to the Auris Health acquisition

partially offset by:

- A contingent consideration reversal of approximately $1.1 billion in fiscal 2020 related to the timing of certain developmental milestones associated with the Auris Health acquisition
- Litigation expense was $0.3 billion in 2020 vs. $0.4 billion in 2019

Restructuring: In the fiscal second quarter of 2018, the Company announced plans to implement actions across its global supply chain that are intended to enable the Company to focus resources and increase investments in critical capabilities, technologies and solutions necessary to manufacture and supply its product portfolio of the future, enhance agility and drive growth. The Company expects these supply chain actions will include expanding its use of strategic collaborations, and bolstering its initiatives to reduce complexity, improving cost-competitiveness, enhancing capabilities and optimizing its network. Discussions regarding specific future actions are ongoing and are subject to all relevant consultation requirements before they are finalized. In total, the Company expects these actions to generate approximately $0.6 to $0.8 billion in annual pre-tax cost savings that will be substantially delivered by 2022. The Company expects to record pre-tax restructuring charges of approximately $1.9 to $2.3 billion. The Company estimates that approximately 70% of the cumulative pre-tax costs will result in cash outlays. In 2020, the Company recorded a pre-tax charge of $0.4 billion, which is included on the following lines of the Consolidated Statement of Earnings, $0.2 billion in restructuring, $0.1 billion in other (income) expense and $0.1 billion in cost of products sold. Total project costs of approximately $1.3 billion have been recorded since the restructuring was announced.

See Note 20 to the Consolidated Financial Statements for additional details related to the restructuring programs.

Provision for Taxes on Income: The worldwide effective income tax rate was 10.8% in 2020 and 12.7% in 2019. During the fiscal first quarter of 2021, the Internal Revenue Service published final regulations addressing the requirements for tax deductibility of settlement payments. The Company recorded a pre-tax reserve for $4.0 billion in the fiscal year 2019 based on the agreement in principle to settle opioid litigation and recorded an additional pre-tax $1.0 billion in the fiscal third quarter of 2020 upon which an effective rate of 21.4% has been applied.

For discussion related to the fiscal 2020 provision for taxes refer to Note 8 to the Consolidated Financial Statements.

Liquidity and Capital Resources

Liquidity & Cash Flows

Cash and cash equivalents were $14.0 billion at the end of 2020 as compared to $17.3 billion at the end of 2019.
The primary sources and uses of cash that contributed to the $3.3 billion decrease were:

(Dollars In Billions)	
$ 17.3	Q4 2019 Cash and cash equivalents balance
23.5	cash generated from operating activities
(20.8)	net cash used by investing activities
(6.1)	net cash used by financing activities
0.1	effect of exchange rate and rounding
$ 14.0	Q4 2020 Cash and cash equivalents balance

In addition, the Company had $11.2 billion in marketable securities at the end of fiscal year 2020 and $2.0 billion at the end of fiscal year 2019. See Note 1 to the Consolidated Financial Statements for additional details on cash, cash equivalents and marketable securities.

Cash flow from operations of $23.5 billion was the result of:

(Dollars In Billions)	
$ 14.7	Net Earnings
7.3	non-cash expenses and other adjustments primarily for depreciation and amortization, stock-based compensation, asset write-downs and credit losses and accounts receivable allowances partially offset by the deferred tax provision and net gain on sale of assets/businesses
0.8	decrease in accounts receivable
5.9	an increase in accounts payable and accrued liabilities and other current and non-current liabilities
(4.0)	an increase in inventories and other current and non-current assets
(1.2)	contingent consideration reversal (related to the timing of certain developmental milestones associated with the Auris Health acquisition) and rounding
$ 23.5	Cash Flow from operations

Investing activities use of $20.8 billion of cash was primarily used for:

(Dollars In Billions)	
$ (7.3)	primarily related to the acquisitions of Momenta, bermekimab and related assets from XBiotech Inc. as well as the acquisition of all outstanding shares in Verb Surgical Inc.
(3.3)	additions to property, plant and equipment
(9.0)	net purchases of investments
(1.0)	Credit support agreements activity, net
0.3	proceeds from the disposal of assets/businesses, net
(0.5)	other (primarily licenses and milestones)
$ (20.8)	Net cash used for investing activities

Financing activities use of $6.1 billion of cash was primarily used for:

(Dollars In Billions)	
$ (10.5)	dividends to shareholders
(3.2)	repurchase of common stock
7.1	net proceeds from short and long term debt
1.1	proceeds from stock options exercised/employee withholding tax on stock awards, net
(0.3)	Credit support agreements activity, net
(0.3)	other
$ (6.1)	Net cash used for financing activities

As of January 3, 2021, the Company's notes payable and long-term debt was in excess of cash, cash equivalents and marketable securities. As of January 3, 2021, the net debt position was $10.1 billion as compared to the prior year of $8.4 billion. There was an increase in the net debt position due to increased borrowings in the fiscal third quarter of 2020. The debt balance at the end of 2020 was $35.3 billion as compared to $27.7 billion in 2019. Considering recent market conditions and the on-going COVID-19 crisis, the Company has evaluated its operating cash flows and liquidity profile and does not foresee any significant incremental risk. The Company anticipates that operating cash flows, the ability to raise funds from external sources, borrowing capacity from existing committed credit facilities and access to the commercial paper markets will continue to provide sufficient resources to fund operating needs, including the talc litigation and agreement in principle to settle opioid litigation of which the majority may be paid over the next two to three years. In addition, the Company monitors the global capital markets on an ongoing basis and from time to time may raise capital when market conditions are favorable. In the fiscal

third quarter of 2020, the Company issued approximately $5.0 billion of commercial paper, with approximately $0.8 billion outstanding at year end. In the fiscal third quarter of 2020, the Company issued senior unsecured notes for a total of $7.5 billion. For additional details on borrowings, see Note 7 to the Consolidated Financial Statements. The net proceeds from this offering were used to fund the Momenta Pharmaceuticals, Inc. acquisition which closed on October 1, 2020 and for general corporate purposes. Additionally, as a result of the Tax Cuts and Jobs Act (TCJA), the Company has access to its cash outside the U.S. at a significantly reduced cost.

The following table summarizes the Company's material contractual obligations and their aggregate maturities as of January 3, 2021: To satisfy these obligations, the Company intends to use cash from operations.

(Dollars in Millions)	Tax Legislation (TCJA)	Debt Obligations	Interest on Debt Obligations	Total
2021	$ 812	1,799	949	3,560
2022	812	2,226	908	3,946
2023	1,522	1,552	880	3,954
2024	2,029	1,598	842	4,469
2025	2,536	1,744	789	5,069
After 2025	—	25,515	9,503	35,018
Total	**$ 7,711**	**34,434**	**13,871**	**56,016**

For tax matters, see Note 8 to the Consolidated Financial Statements. The table does not include activity related to business combinations or the Company's approximate $0.9 billion in contractual supply commitments associated with its development of a COVID-19 vaccine.

Financing and Market Risk

The Company uses financial instruments to manage the impact of foreign exchange rate changes on cash flows. Accordingly, the Company enters into forward foreign exchange contracts to protect the value of certain foreign currency assets and liabilities and to hedge future foreign currency transactions primarily related to product costs. Gains or losses on these contracts are offset by the gains or losses on the underlying transactions. A 10% appreciation of the U.S. Dollar from the January 3, 2021 market rates would increase the unrealized value of the Company's forward contracts by $121 million. Conversely, a 10% depreciation of the U.S. Dollar from the January 3, 2021 market rates would decrease the unrealized value of the Company's forward contracts by $148 million. In either scenario, the gain or loss on the forward contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated earnings and cash flows.

The Company hedges the exposure to fluctuations in currency exchange rates, and the effect on certain assets and liabilities in foreign currency, by entering into currency swap contracts. A 1% change in the spread between U.S. and foreign interest rates on the Company's interest rate sensitive financial instruments would either increase or decrease the unrealized value of the Company's swap contracts by approximately $1,667 million. In either scenario, at maturity, the gain or loss on the swap contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated cash flows.

The Company does not enter into financial instruments for trading or speculative purposes. Further, the Company has a policy of only entering into contracts with parties that have at least an investment grade credit rating. The counterparties to these contracts are major financial institutions and there is no significant concentration of exposure with any one counterparty. Management believes the risk of loss is remote. The Company entered into credit support agreements (CSA) with certain derivative counterparties establishing collateral thresholds based on respective credit ratings and netting agreements. See Note 6 to the Consolidated Financial Statements for additional details on credit support agreements.

The Company invests in both fixed rate and floating rate interest earning securities which carry a degree of interest rate risk. The fair market value of fixed rate securities may be adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than predicted if interest rates fall. A 1% (100 basis points) change in spread on the Company's interest rate sensitive investments would either increase or decrease the unrealized value of cash equivalents and current marketable securities by approximately $36 million.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2020, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 9, 2021. Interest charged on borrowings under the credit line agreement is based on either bids provided by banks, London Interbank Offered Rates (LIBOR), Secured Overnight Financing Rate (SOFR) Swap Curve or other applicable market rate as allowed plus applicable margins. Commitment fees under the agreement are not material.

Total borrowings at the end of 2020 and 2019 were $35.3 billion and $27.7 billion, respectively. The increase in borrowings was the issuance of notes in 2020 when market conditions were favorable. In 2020, net debt (cash and current marketable securities, net of debt) was $10.1 billion compared to net debt of $8.4 billion in 2019. Total debt represented 35.8% of total capital (shareholders' equity and total debt) in 2020 and 31.8% of total capital in 2019. Shareholders' equity per share at the end of 2020 was $24.04 compared to $22.59 at year-end 2019.

A summary of borrowings can be found in Note 7 to the Consolidated Financial Statements.

Dividends

The Company increased its dividend in 2020 for the 58th consecutive year. Cash dividends paid were $3.98 per share in 2020 and $3.75 per share in 2019.

On January 4, 2021, the Board of Directors declared a regular cash dividend of $1.01 per share, payable on March 9, 2021 to shareholders of record as of February 23, 2021.

Other Information

Critical Accounting Policies and Estimates

Management's discussion and analysis of results of operations and financial condition are based on the Company's consolidated financial statements that have been prepared in accordance with accounting principles generally accepted in the U.S. (GAAP). The preparation of these financial statements requires that management make estimates and assumptions that affect the amounts reported for revenues, expenses, assets, liabilities and other related disclosures. Actual results may or may not differ from these estimates. The Company believes that the understanding of certain key accounting policies and estimates are essential in achieving more insight into the Company's operating results and financial condition. These key accounting policies include revenue recognition, income taxes, legal and self-insurance contingencies, valuation of long-lived assets, assumptions used to determine the amounts recorded for pensions and other employee benefit plans and accounting for stock based awards.

The extent to which COVID-19 impacts the Company's business and financial results will depend on numerous evolving factors including, but not limited to, the magnitude and duration of COVID-19, the extent to which it will impact worldwide macroeconomic conditions including interest rates, employment rates and health insurance coverage, the speed of the anticipated recovery, and governmental and business reactions to the pandemic. The Company assessed certain accounting matters that generally require consideration of forecasted financial information in context with the information reasonably available to the Company and the unknown future impacts of COVID-19 as of January 3, 2021 and through the date of this report. The accounting matters assessed included, but were not limited to, the Company's allowance for doubtful accounts and credit losses, inventory and related reserves, accrued rebates and associated reserves, and the carrying value of the goodwill and other long-lived assets. While there was not a material impact to the Company's consolidated financial statements as of and for the year ended January 3, 2021, the Company's future assessment of the magnitude and duration of COVID-19, as well as other factors, could result in material impacts to the Company's consolidated financial statements in future reporting periods.

Revenue Recognition: The Company recognizes revenue from product sales when obligations under the terms of a contract with the customer are satisfied; generally, this occurs with the transfer of control of the goods to customers. The Company's global payment terms are typically between 30 to 90 days. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns and discounts to customers are accounted for as variable consideration and recorded as a reduction in sales.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including consideration of competitor pricing. Rebates are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns are estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales return accruals.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The sales returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer Health and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual net trade sales during the fiscal years 2020 and 2019.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the same period as related sales. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue. The Company also earns profit-share payments through collaborative arrangements of certain products, which are included in sales to customers. For all years presented, profit-share payments were less than 3.0% of the total revenues and are included in sales to customers.

In addition, the Company enters into collaboration arrangements that contain multiple revenue generating activities. Amounts due from collaborative partners for these arrangements are recognized as each activity is performed or delivered, based on the relative selling price. Upfront fees received as part of these arrangements are deferred and recognized over the performance period. See Note 1 to the Consolidated Financial Statements for additional disclosures on collaborations.

Reasonably likely changes to assumptions used to calculate the accruals for rebates, returns and promotions are not anticipated to have a material effect on the financial statements. The Company currently discloses the impact of changes to assumptions in the quarterly or annual filing in which there is a material financial statement impact.

Below are tables that show the progression of accrued rebates, returns, promotions, reserve for doubtful accounts and reserve for cash discounts by segment of business for the fiscal years ended January 3, 2021 and December 29, 2019.

Consumer Health Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits	Balance at End of Period
2020				
Accrued rebates [1]	$ 284	793	(788)	289
Accrued returns	63	138	(125)	76
Accrued promotions	487	1,988	(2,047)	428
Subtotal	$ 834	2,919	(2,960)	793
Reserve for doubtful accounts	35	7	(3)	39
Reserve for cash discounts	17	201	(206)	12
Total	$ 886	3,127	(3,169)	844
2019				
Accrued rebates[1]	$ 271	841	(828)	284
Accrued returns	57	128	(122)	63
Accrued promotions	497	2,119	(2,129)	487
Subtotal	$ 825	3,088	(3,079)	834
Reserve for doubtful accounts	32	21	(18)	35
Reserve for cash discounts	23	198	(204)	17
Total	$ 880	3,307	(3,301)	886

(1) Includes reserve for customer rebates of $66 million at January 3, 2021 and $54 million at December 29, 2019, recorded as a contra asset.

Pharmaceutical Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits[2]	Balance at End of Period
2020				
Accrued rebates [1]	$ 9,013	32,415	(31,591)	9,837
Accrued returns	500	233	(273)	460
Accrued promotions	5	10	(9)	6
Subtotal	$ 9,518	32,658	(31,873)	10,303
Reserve for doubtful accounts	36	24	(8)	52
Reserve for cash discounts	65	1,034	(1,029)	70
Total	$ 9,619	33,716	(32,910)	10,425
2019				
Accrued rebates [1]	$ 7,510	26,868	(25,365)	9,013
Accrued returns	436	354	(290)	500
Accrued promotions	13	17	(25)	5
Subtotal	$ 7,959	27,239	(25,680)	9,518
Reserve for doubtful accounts	47	2	(13)	36
Reserve for cash discounts	53	936	(924)	65
Total	$ 8,059	28,177	(26,617)	9,619

(1) Includes reserve for customer rebates of $174 million at January 3, 2021 and $93 million at December 29, 2019, recorded as a contra asset.

(2) Includes adjustments

Medical Devices Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits	Balance at End of Period
2020				
Accrued rebates[1]	$ 1,013	5,144	(4,983)	1,174
Accrued returns	118	578	(558)	138
Accrued promotions	46	118	(112)	52
Subtotal	$ 1,177	5,840	(5,653)	1,364
Reserve for doubtful accounts	155	95	(48)	202
Reserve for cash discounts	10	88	(89)	9
Total	$ 1,342	6,023	(5,790)	1,575
2019				
Accrued rebates[1]	$ 1,218	5,487	(5,692)	1,013
Accrued returns	114	673	(669)	118
Accrued promotions	42	106	(102)	46
Subtotal	$ 1,374	6,266	(6,463)	1,177
Reserve for doubtful accounts	169	30	(44)	155
Reserve for cash discounts	—	106	(96)	10
Total	$ 1,543	6,402	(6,603)	1,342

(1) Includes reserve for customer rebates of $707 million at January 3, 2021 and $499 million at December 29, 2019, recorded as a contra asset.

Income Taxes: Income taxes are recorded based on amounts refundable or payable for the current year and include the results of any difference between U.S. GAAP accounting and tax reporting, recorded as deferred tax assets or liabilities. The Company estimates deferred tax assets and liabilities based on enacted tax regulations and rates. Future changes in tax laws and rates may affect recorded deferred tax assets and liabilities.

The Company has unrecognized tax benefits for uncertain tax positions. The Company follows U.S. GAAP, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Management believes that changes in these estimates would not have a material effect on the Company's results of operations, cash flows or financial position.

The Company has recorded deferred tax liabilities on all undistributed earnings prior to December 31, 2017 from its international subsidiaries. The Company has not provided deferred taxes on the undistributed earnings subsequent to January 1, 2018 from certain international subsidiaries where the earnings are considered to be indefinitely reinvested. The Company intends to continue to reinvest these earnings in those international operations. If the Company decides at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company estimates that the total tax effect of this repatriation would be approximately $0.7 billion under current enacted tax laws and regulations and at current currency exchange rates.

During the fiscal first quarter of 2021, the Internal Revenue Service published final regulations addressing the requirements for tax deductibility of settlement payments. The Company recorded a pre-tax reserve for $4.0 billion in fiscal 2019 based on the agreement in principle to settle opioid litigation and recorded an additional pre-tax $1.0 billion in the fiscal third quarter of 2020 upon which an effective rate of 21.4% has been applied.

See Note 8 to the Consolidated Financial Statements for further information regarding income taxes.

Legal and Self Insurance Contingencies: The Company records accruals for various contingencies, including legal proceedings and product liability claims as these arise in the normal course of business. The accruals are based on management’s judgment as to the probability of losses and, where applicable, actuarially determined estimates. The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated.

The Company follows the provisions of U.S. GAAP when recording litigation related contingencies. A liability is recorded when a loss is probable and can be reasonably estimated.

See Notes 1 and 19 to the Consolidated Financial Statements for further information regarding product liability and legal proceedings.

Long-Lived and Intangible Assets: The Company assesses changes, both qualitatively and quantitatively, in economic conditions and makes assumptions regarding estimated future cash flows in evaluating the value of the Company’s property, plant and equipment, goodwill and intangible assets. As these assumptions and estimates may change over time, it may or may not be necessary for the Company to record impairment charges.

Employee Benefit Plans: The Company sponsors various retirement and pension plans, including defined benefit, defined contribution and termination indemnity plans, which cover most employees worldwide. These plans are based on assumptions for the discount rate, expected return on plan assets, mortality rates, expected salary increases, health care cost trend rates and attrition rates. See Note 10 to the Consolidated Financial Statements for further details on these rates.

Stock Based Compensation: The Company recognizes compensation expense associated with the issuance of equity instruments to employees for their services. Based on the type of equity instrument, the fair value is estimated on the date of grant using either the Black-Scholes option valuation model or a combination of both the Black-Scholes option valuation model and Monte Carlo valuation model, and is expensed in the financial statements over the service period. The input assumptions used in determining fair value are the expected life, expected volatility, risk-free rate and expected dividend yield. Prior to fiscal 2020, for performance share units, the fair market value was calculated for each of the three component goals at the date of grant: operational sales, adjusted operational earnings per share and relative total shareholder return. Beginning in fiscal 2020, for performance share units, the fair market value is calculated for the two component goals at the date of grant: adjusted operational earnings per share and relative total shareholder return. The fair values for the earnings per share goal of each performance share unit was estimated on the date of grant using the fair market value of the shares at the time of the award, discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. See Note 16 to the Consolidated Financial Statements for additional information.

New Accounting Pronouncements

Refer to Note 1 to the Consolidated Financial Statements for recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of January 3, 2021.

Economic and Market Factors

COVID-19 considerations and business continuity
The Company has considered various internal and external factors in assessing the potential impact of COVID-19 on its business and financial results based upon information available at this time, as follows:

- *Operating Model:* The Company has a diversified business model across the healthcare industry with flexibility designed into its manufacturing, research and development clinical operations and commercial capabilities.
- *Supply Chain:* The Company continues to leverage its global manufacturing footprint and dual-source capabilities while closely monitoring and maintaining critical inventory at major distribution centers away from high-risk areas to ensure adequate and effective distribution.
- *Business Continuity:* The robust, active business continuity plans across the Company's network have been instrumental in preparing the Company for events like COVID-19 and the ability to meet the majority of patient and consumer needs remains uninterrupted.
- *Workforce:* The Company has put procedures in place to protect its essential workforce in manufacturing, distribution, commercial and research operations while ensuring appropriate remote working protocols have been established for other employees.
- *Liquidity:* The Company's high-quality credit rating allows the Company superior access to the financial capital markets for the foreseeable future. In the fiscal third quarter of 2020, the Company issued approximately $5.0 billion of commercial paper, with approximately $0.8 billion outstanding at year end, for additional liquidity. Additionally, in the fiscal third quarter of 2020, the Company issued senior unsecured notes for a total of $7.5 billion. The net proceeds from this offering were used to fund the Momenta Pharmaceuticals, Inc. acquisition on October 1, 2020 and for general corporate purposes.
- *Domestic and Foreign Legislation:* The Company will continue to assess and evaluate the on-going global legislative efforts to combat the COVID-19 impact on economies and the sectors in which it participates. Currently, the recent legislative acts put in place are not expected to have a material impact on the Company’s operations.

In fiscal 2020, the Company entered into a series of contract manufacturing arrangements for vaccine production with third party contract manufacturing organizations. These arrangements provide the Company with future supplemental commercial capacity for vaccine production and potentially transferable rights to such production if capacity is not required. Amounts paid and contractually obligated to be paid to these contract manufacturing organizations of approximately $0.9 billion are reflected in the prepaid expenses and other, other assets, accrued liabilities and other liabilities accounts in the Company's consolidated balance sheet upon execution of each agreement. Additionally, the Company has entered into certain vaccine development cost sharing arrangements with government related organizations.

The Company is aware that its products are used in an environment where, for more than a decade, policymakers, consumers and businesses have expressed concerns about the rising cost of health care. In response to these concerns, the Company has a long-standing policy of pricing products responsibly. For the period 2010 - 2020, in the U.S., the weighted average compound annual growth rate of the Company’s net price increases for health care products (prescription and over-the-counter drugs, hospital and professional products) was below the U.S. Consumer Price Index (CPI).

The Company operates in certain countries where the economic conditions continue to present significant challenges. The Company continues to monitor these situations and take appropriate actions. Inflation rates continue to have an effect on worldwide economies and, consequently, on the way companies operate. The Company has accounted for operations in Argentina (beginning in the fiscal third quarter of 2018) and Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. This did not have a material impact to the Company's results in the period. In the face of increasing costs, the Company strives to maintain its profit margins through cost reduction programs, productivity improvements and periodic price increases.

In June 2016, the United Kingdom (U.K.) held a referendum in which voters approved an exit from the European Union (E.U.), commonly referred to as “Brexit”. The U.K. officially exited the E.U. on January 31, 2020, however, there was a transition period to allow time to agree the terms of a new trade deal. On December 30, 2020, the U.K., E.U. and the European Atomic Energy Community (Euratom) signed the EU–UK Trade and Cooperation Agreement (TCA). Over the last few years, Brexit has created global political and economic uncertainty and has led to volatility in exchange rates and interest rates, additional cost containment by third-party payors and changes in regulations. While the UK and EU have now agreed on a future trade and cooperation agreement, it is still unclear what the ultimate financial, trade, regulatory and legal implications the withdrawal of the U.K. from the E.U. will have. However, the Company currently does not believe that these and other related effects will have a material impact on the Company’s consolidated financial position or operating results. As of January 3, 2021, the business of the Company’s U.K. subsidiaries represented less than 6% of the Company’s consolidated assets and less than 3% of the Company's fiscal twelve months revenues.

The Company is exposed to fluctuations in currency exchange rates. A 1% change in the value of the U.S. Dollar as compared to all foreign currencies in which the Company had sales, income or expense in 2020 would have increased or decreased the translation of foreign sales by approximately $384 million and net income by approximately $115 million.

Governments around the world consider various proposals to make changes to tax laws, which may include increasing or decreasing existing statutory tax rates. A change in statutory tax rate in any country would result in the revaluation of the Company's deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is enacted. This change would result in an expense or benefit recorded to the Company's Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries where it operates. Changes to the statutory tax rate may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted.

The Company faces various worldwide health care changes that may continue to result in pricing pressures that include health care cost containment and government legislation relating to sales, promotions and reimbursement of health care products.

Changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing health care insurance coverage, as a result of the current global economic downturn, may continue to impact the Company's businesses.

The Company also operates in an environment increasingly hostile to intellectual property rights. Firms have filed Abbreviated New Drug Applications or Biosimilar Biological Product Applications with the FDA or otherwise challenged the coverage and/or validity of the Company's patents, seeking to market generic or biosimilar forms of many of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the event the Company is not successful in defending the patent claims challenged in the resulting lawsuits, generic or biosimilar versions of the products at issue will be introduced to the market, resulting in the potential for substantial market share and revenue losses for those products, and which may result in a non-cash impairment charge in any associated intangible asset. There is also a risk that one or more competitors could launch a generic or biosimilar version of the product at issue following regulatory approval even though one or more valid patents are in place.

Legal Proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability, intellectual property, commercial and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of business.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of January 3, 2021, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; ability to achieve comprehensive multi-party settlements; complexity of related cross-claims and counterclaims; and/or there are numerous parties involved. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution of, or increase in accruals for, one or more of these matters in any reporting period may have a material adverse effect on the Company's results of operations and cash flows for that period.

See Note 19 to the Consolidated Financial Statements for further information regarding legal proceedings.

Common Stock

The Company's Common Stock is listed on the New York Stock Exchange under the symbol JNJ. As of February 16, 2021, there were 132,376 record holders of Common Stock of the Company.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The information called for by this item is incorporated herein by reference to "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition - Liquidity and Capital Resources - Financing and Market Risk" of this Report; and Note 1 "Summary of Significant Accounting Policies - Financial Instruments" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Audited Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
At January 3, 2021 and December 29, 2019
(Dollars in Millions Except Share and Per Share Amounts) (Note 1)

		2020	2019
Assets			
Current assets			
Cash and cash equivalents (Notes 1 and 2)	$	13,985	17,305
Marketable securities (Notes 1 and 2)		11,200	1,982
Accounts receivable trade, less allowances for doubtful accounts $293 (2019, $226)		13,576	14,481
Inventories (Notes 1 and 3)		9,344	9,020
Prepaid expenses and other receivables		3,132	2,392
Assets held for sale (Note 18)		—	94
Total current assets		**51,237**	**45,274**
Property, plant and equipment, net (Notes 1 and 4)		18,766	17,658
Intangible assets, net (Notes 1 and 5)		53,402	47,643
Goodwill (Notes 1 and 5)		36,393	33,639
Deferred taxes on income (Note 8)		8,534	7,819
Other assets		6,562	5,695
Total assets	**$**	**174,894**	**157,728**
Liabilities and Shareholders' Equity			
Current liabilities			
Loans and notes payable (Note 7)	$	2,631	1,202
Accounts payable		9,505	8,544
Accrued liabilities		13,968	9,715
Accrued rebates, returns and promotions		11,513	10,883
Accrued compensation and employee related obligations		3,484	3,354
Accrued taxes on income (Note 8)		1,392	2,266
Total current liabilities		**42,493**	**35,964**
Long-term debt (Note 7)		32,635	26,494
Deferred taxes on income (Note 8)		7,214	5,958
Employee related obligations (Notes 9 and 10)		10,771	10,663
Long-term taxes payable (Note 1)		6,559	7,444
Other liabilities		11,944	11,734
Total liabilities		**111,616**	**98,257**
Commitments and Contingencies (Note 19)			
Shareholders' equity			
Preferred stock — without par value (authorized and unissued 2,000,000 shares)		—	—
Common stock — par value $1.00 per share (Note 12) (authorized 4,320,000,000 shares; issued 3,119,843,000 shares)		3,120	3,120
Accumulated other comprehensive income (loss) (Note 13)		(15,242)	(15,891)
Retained earnings		113,890	110,659
		101,768	97,888
Less: common stock held in treasury, at cost (Note 12) (487,331,000 shares and 487,336,000 shares)		38,490	38,417
Total shareholders' equity		**63,278**	**59,471**
Total liabilities and shareholders' equity	**$**	**174,894**	**157,728**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EARNINGS
(Dollars and Shares in Millions Except Per Share Amounts) (Note 1)

	2020	2019	2018
Sales to customers	$ 82,584	82,059	81,581
Cost of products sold	28,427	27,556	27,091
Gross profit	54,157	54,503	54,490
Selling, marketing and administrative expenses	22,084	22,178	22,540
Research and development expense	12,159	11,355	10,775
In-process research and development (Note 5)	181	890	1,126
Interest income	(111)	(357)	(611)
Interest expense, net of portion capitalized (Note 4)	201	318	1,005
Other (income) expense, net	2,899	2,525	1,405
Restructuring (Note 20)	247	266	251
Earnings before provision for taxes on income	16,497	17,328	17,999
Provision for taxes on income (Note 8)	1,783	2,209	2,702
Net earnings	**$ 14,714**	**15,119**	**15,297**
Net earnings per share (Notes 1 and 15)			
Basic	**$ 5.59**	**5.72**	**5.70**
Diluted	**$ 5.51**	**5.63**	**5.61**
Average shares outstanding (Notes 1 and 15)			
Basic	**2,632.8**	**2,645.1**	**2,681.5**
Diluted	**2,670.7**	**2,684.3**	**2,728.7**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Dollars in Millions) (Note 1)

	2020	2019	2018
Net earnings	$ 14,714	15,119	15,297
Other comprehensive income (loss), net of tax			
Foreign currency translation	(233)	164	(1,518)
Securities:			
Unrealized holding gain (loss) arising during period	1	—	(1)
Reclassifications to earnings	—	—	1
Net change	1	—	—
Employee benefit plans:			
Prior service credit (cost), net of amortization	1,298	(18)	(44)
Gain (loss), net of amortization	(1,135)	(714)	(56)
Effect of exchange rates	(229)	(1)	92
Net change	(66)	(733)	(8)
Derivatives & hedges:			
Unrealized gain (loss) arising during period	1,000	(107)	(73)
Reclassifications to earnings	(53)	7	(192)
Net change	947	(100)	(265)
Other comprehensive income (loss)	649	(669)	(1,791)
Comprehensive income	$ 15,363	14,450	13,506

The tax effects in other comprehensive income for the fiscal years 2020, 2019 and 2018 respectively: Foreign Currency Translation; $536 million, $19 million and $236 million; Employee Benefit Plans: $21 million, $222 million and $4 million, Derivatives & Hedges: $252 million, $27 million and $70 million.

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY
(Dollars in Millions) (Note 1)

	Total	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Common Stock Issued Amount	Treasury Stock Amount
Balance, December 31, 2017	**$ 60,160**	**101,793**	**(13,199)**	**3,120**	**(31,554)**
Cumulative adjustment[1]	(486)	(254)	(232)		
Net earnings	15,297	15,297			
Cash dividends paid ($3.54 per share)	(9,494)	(9,494)			
Employee compensation and stock option plans	1,949	(1,111)			3,060
Repurchase of common stock	(5,868)				(5,868)
Other	(15)	(15)			
Other comprehensive income (loss), net of tax	(1,791)		(1,791)		
Balance, December 30, 2018	**59,752**	**106,216**	**(15,222)**	**3,120**	**(34,362)**
Net earnings	15,119	15,119			
Cash dividends paid ($3.75 per share)	(9,917)	(9,917)			
Employee compensation and stock option plans	1,933	(758)			2,691
Repurchase of common stock	(6,746)				(6,746)
Other	(1)	(1)			
Other comprehensive income (loss), net of tax	(669)		(669)		
Balance, December 29, 2019	**59,471**	**110,659**	**(15,891)**	**3,120**	**(38,417)**
Net earnings	14,714	14,714			
Cash dividends paid ($3.98 per share)	(10,481)	(10,481)			
Employee compensation and stock option plans	2,217	(931)			3,148
Repurchase of common stock	(3,221)				(3,221)
Other	(71)	(71)			
Other comprehensive income (loss), net of tax	649		649		
Balance, January 3, 2021	**$ 63,278**	**113,890**	**(15,242)**	**3,120**	**(38,490)**

[1] See Note 1 to Consolidated Financial Statements for additional details on the effect of cumulative adjustments to retained earnings.

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Dollars in Millions) (Note 1)

	2020	2019	2018
Cash flows from operating activities			
Net earnings	$ 14,714	15,119	15,297
Adjustments to reconcile net earnings to cash flows from operating activities:			
Depreciation and amortization of property and intangibles	7,231	7,009	6,929
Stock based compensation	1,005	977	978
Asset write-downs	233	1,096	1,258
Contingent consideration reversal	(1,148)	—	—
Net gain on sale of assets/businesses	(111)	(2,154)	(1,217)
Deferred tax provision	(1,141)	(2,476)	(1,016)
Credit losses and accounts receivable allowances	63	(20)	(31)
Changes in assets and liabilities, net of effects from acquisitions and divestitures:			
Decrease/(Increase) in accounts receivable	774	(289)	(1,185)
Increase in inventories	(265)	(277)	(644)
Increase in accounts payable and accrued liabilities	5,141	4,060	3,951
Increase in other current and non-current assets	(3,704)	(1,054)	(275)
Increase/(Decrease) in other current and non-current liabilities	744	1,425	(1,844)
Net cash flows from operating activities	**23,536**	**23,416**	**22,201**
Cash flows from investing activities			
Additions to property, plant and equipment	(3,347)	(3,498)	(3,670)
Proceeds from the disposal of assets/businesses, net	305	3,265	3,203
Acquisitions, net of cash acquired (Note 18)	(7,323)	(5,810)	(899)
Purchases of investments	(21,089)	(3,920)	(5,626)
Sales of investments	12,137	3,387	4,289
Credit support agreements activity, net	(987)	338	—
Other (primarily licenses and milestones)	(521)	44	(464)
Net cash used by investing activities	**(20,825)**	**(6,194)**	**(3,167)**
Cash flows from financing activities			
Dividends to shareholders	(10,481)	(9,917)	(9,494)
Repurchase of common stock	(3,221)	(6,746)	(5,868)
Proceeds from short-term debt	3,391	39	80
Repayment of short-term debt	(2,663)	(100)	(2,479)
Proceeds from long-term debt, net of issuance costs	7,431	3	5
Repayment of long-term debt	(1,064)	(2,823)	(1,555)
Proceeds from the exercise of stock options/employee withholding tax on stock awards, net	1,114	954	949
Credit support agreements activity, net	(333)	100	25
Other	(294)	475	(173)
Net cash used by financing activities	**(6,120)**	**(18,015)**	**(18,510)**
Effect of exchange rate changes on cash and cash equivalents	89	(9)	(241)
(Decrease)/Increase in cash and cash equivalents	(3,320)	(802)	283
Cash and cash equivalents, beginning of year (Note 1)	17,305	18,107	17,824
Cash and cash equivalents, end of year (Note 1)	**$ 13,985**	**17,305**	**18,107**
Supplemental cash flow data			
Cash paid during the year for:			
Interest	$ 904	995	1,049
Interest, net of amount capitalized	841	925	963
Income taxes	4,619	4,191	4,570

Supplemental schedule of non-cash investing and financing activities				
Treasury stock issued for employee compensation and stock option plans, net of cash proceeds/ employee withholding tax on stock awards	$	1,937	1,736	2,095
Conversion of debt		27	1	6
Acquisitions				
Fair value of assets acquired	$	7,755	7,228	1,047
Fair value of liabilities assumed and noncontrolling interests		(432)	(1,418)	(148)
Net cash paid for acquisitions (Note 18)	**$**	**7,323**	**5,810**	**899**

See Notes to Consolidated Financial Statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Johnson & Johnson and its subsidiaries (the Company). Intercompany accounts and transactions are eliminated. Columns and rows within tables may not add due to rounding. Percentages have been calculated using actual, non-rounded figures.

Description of the Company and Business Segments

The Company has approximately 134,500 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world and its primary focus is on products related to human health and well-being.

The Company is organized into three business segments: Consumer Health (previously referred to as Consumer), Pharmaceutical and Medical Devices. The Consumer Health segment includes a broad range of products used in the baby care, oral care, skin health/beauty, over-the-counter pharmaceutical, women's health and wound care markets. These products are marketed to the general public and sold online (eCommerce) and to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on six therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, pulmonary hypertension, and cardiovascular and metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, interventional solutions (cardiovascular and neurovascular) and eye health fields, which are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

New Accounting Standards

Recently Adopted Accounting Standards

ASU 2018-18: Collaborative Arrangements

The Company adopted this standard as of the beginning of the fiscal year 2020. This update clarifies the interaction between ASC 808, Collaborative Arrangements and ASC 606, Revenue from Contracts with Customers. The update clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer. In addition, the update precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue if the counterparty is not a customer for that transaction. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

ASU 2016-13: Financial Instruments - Credit Losses

The Company adopted this standard as of the beginning of the fiscal year 2020. This update introduces the current expected credit loss (CECL) model, which requires an entity to measure credit losses for certain financial instruments and financial assets, including trade receivables. Under this update, on initial recognition and at each reporting period, an entity is required to recognize an allowance that reflects the entity's current estimate of credit losses expected to be incurred over the life of the financial instrument. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

ASU 2018-14: Compensation - Defined Benefit Plans

The Company adopted this standard in the fiscal year ended 2020. This standard revised the financial statement note disclosure requirements of ASC 715-20 for defined benefit plan sponsors. The adoption of this standard had no impact on the Company's consolidated financial statements. See Note 10 to the Consolidated Financial Statements for defined benefit plan disclosures.

Accounting Standards adopted in the fiscal 2018 with a cumulative effect to the 2018 opening balance of Retained Earnings
The following table summarizes the cumulative effect adjustments made to the 2018 opening balance of retained earnings upon adoption of these accounting standards in 2018:

(Dollars in Millions)	Cumulative Effect Adjustment Increase (Decrease) to Retained Earnings
ASU 2014-09 - Revenue from Contracts with Customers	$ (47)
ASU 2016-01 - Financial Instruments	232
ASU 2016-16 - Income Taxes: Intra-Entity Transfers	(439)
Total	$ (254)

Recently Issued Accounting Standards
Not Adopted as of January 3, 2021
The Company assesses the adoption impacts of recently issued accounting standards by the Financial Accounting Standards Board on the Company's financial statements as well as material updates to previous assessments, if any, from the Company's Annual Report on Form 10-K for the fiscal year ended December 29, 2019. There were no new material accounting standards issued in fiscal 2020 that impacted the Company.

Cash Equivalents
The Company classifies all highly liquid investments with stated maturities of three months or less from date of purchase as cash equivalents and all highly liquid investments with stated maturities of greater than three months from the date of purchase as current marketable securities. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating. The Company invests its cash primarily in government securities and obligations, corporate debt securities, money market funds and reverse repurchase agreements (RRAs).

RRAs are collateralized by deposits in the form of Government Securities and Obligations for an amount not less than 102% of their value. The Company does not record an asset or liability as the Company is not permitted to sell or repledge the associated collateral. The Company has a policy that the collateral has at least an A (or equivalent) credit rating. The Company utilizes a third party custodian to manage the exchange of funds and ensure that collateral received is maintained at 102% of the value of the RRAs on a daily basis. RRAs with stated maturities of greater than three months from the date of purchase are classified as marketable securities.

Investments
Investments classified as held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings. Investments classified as available-for-sale debt securities are carried at estimated fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income. Available-for-sale securities available for current operations are classified as current assets otherwise, they are classified as long term. Management determines the appropriate classification of its investment in debt and equity securities at the time of purchase and re-evaluates such determination at each balance sheet date. The Company reviews its investments for impairment and adjusts these investments to fair value through earnings, as required.

Property, Plant and Equipment and Depreciation
Property, plant and equipment are stated at cost. The Company utilizes the straight-line method of depreciation over the estimated useful lives of the assets:

Building and building equipment	20 - 30 years
Land and leasehold improvements	10 - 20 years
Machinery and equipment	2 - 13 years

The Company capitalizes certain computer software and development costs, included in machinery and equipment, when incurred in connection with developing or obtaining computer software for internal use. Capitalized software costs are amortized over the estimated useful lives of the software, which generally range from 3 to 8 years.

The Company reviews long-lived assets to assess recoverability using undiscounted cash flows. When certain events or changes in operating or economic conditions occur, an impairment assessment may be performed on the recoverability of the carrying value of these assets. If the asset is determined to be impaired, the loss is measured based on the difference between

the asset's fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows.

Revenue Recognition
The Company recognizes revenue from product sales when obligations under the terms of a contract with the customer are satisfied; generally, this occurs with the transfer of control of the goods to customers. The Company's global payment terms are typically between 30 to 90 days. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns and discounts to customers are accounted for as variable consideration and recorded as a reduction in sales. The liability is recognized within Accrued Rebates, Returns, and Promotions on the consolidated balance sheet.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including consideration of competitor pricing. Rebates are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. A significant portion of the liability related to rebates is from the sale of the Company's pharmaceutical products within the U.S., primarily the Managed Care, Medicare and Medicaid programs, which amounted to $7.2 billion and $7.0 billion as of January 3, 2021 and December 29, 2019, respectively. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns are estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales return accruals.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The sales returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer Health and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual net trade sales during each of the fiscal years 2020, 2019 and 2018.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the same period as related sales. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue. The Company also earns profit-share payments through collaborative arrangements for certain products, which are included in sales to customers. For all years presented, profit-share payments were less than 3.0% of the total revenues and are included in sales to customers.

See Note 17 to the Consolidated Financial Statements for further disaggregation of revenue.

Shipping and Handling
Shipping and handling costs incurred were $1.0 billion, $1.0 billion and $1.1 billion in fiscal years 2020, 2019 and 2018, respectively, and are included in selling, marketing and administrative expense. The amount of revenue received for shipping and handling is less than 0.5% of sales to customers for all periods presented.

Inventories
Inventories are stated at the lower of cost or net realizable value determined by the first-in, first-out method.

Intangible Assets and Goodwill
The authoritative literature on U.S. GAAP requires that goodwill and intangible assets with indefinite lives be assessed annually for impairment. The Company completed its annual impairment test for 2020 in the fiscal fourth quarter. Future impairment tests will be performed annually in the fiscal fourth quarter, or sooner if warranted. Purchased in-process research and development is accounted for as an indefinite lived intangible asset until the underlying project is completed, at which point the intangible asset will be accounted for as a definite lived intangible asset, or abandoned, at which point the intangible asset will be written off or partially impaired.

Intangible assets that have finite useful lives continue to be amortized over their useful lives, and are reviewed for impairment when warranted by economic conditions. See Note 5 for further details on Intangible Assets and Goodwill.

Financial Instruments
As required by U.S. GAAP, all derivative instruments are recorded on the balance sheet at fair value. Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value, with Level 1 having the highest priority and Level 3 having the lowest. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The Company documents all relationships between hedged items and derivatives. The overall risk management strategy includes reasons for undertaking hedge transactions and entering into derivatives. The objectives of this strategy are: (1) minimize foreign currency exposure's impact on the Company's financial performance; (2) protect the Company's cash flow from adverse movements in foreign exchange rates; (3) ensure the appropriateness of financial instruments; and (4) manage the enterprise risk associated with financial institutions. See Note 6 for additional information on Financial Instruments.

Leases
The Company determines whether an arrangement is a lease at contract inception by establishing if the contract conveys the right to control the use of identified property, plant, or equipment for a period of time in exchange for consideration. Right of Use (ROU) Assets and Lease Liabilities for operating leases are included in Other assets, Accrued liabilities, and Other liabilities on the consolidated balance sheet. The ROU Assets represent the right to use an underlying asset for the lease term and lease liabilities represent an obligation to make lease payments arising from the lease. Commitments under finance leases are not significant, and are included in Property, plant and equipment, Loans and notes payable, and Long-term debt on the consolidated balance sheet.

ROU Assets and Lease Liabilities are recognized at the lease commencement date based on the present value of all minimum lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments, when the implicit rate is not readily determinable. Lease terms may include options to extend or terminate the lease. These options are included in the lease term when it is reasonably certain that the Company will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term. The Company has elected the following policy elections on adoption: use of portfolio approach on leases of assets under master service agreements, exclusion of short term leases on the balance sheet, and not separating lease and non-lease components.

The Company primarily has operating lease for space, vehicles, manufacturing equipment and data processing equipment. The ROU asset pertaining to operating leases was $1.0 billion and $1.0 billion in 2020 and 2019, respectively. The lease liability was $1.1 billion and $1.0 billion in 2020 and 2019, respectively. The operating lease costs were $0.3 billion, $0.3 billion and $0.3 billion in 2020, 2019 and 2018, respectively. Cash paid for amounts included in the measurement of lease liabilities were $0.3 billion and $0.3 billion in 2020 and 2019, respectively.

Product Liability
Accruals for product liability claims are recorded, on an undiscounted basis, when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated based on existing information and actuarially determined estimates where applicable. The accruals are adjusted periodically as additional information becomes available. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated.

Research and Development
Research and development expenses are expensed as incurred in accordance with ASC 730, Research and Development. Upfront and milestone payments made to third parties in connection with research and development collaborations are expensed as incurred up to the point of regulatory approval. Payments made to third parties subsequent to regulatory approval are capitalized and amortized over the remaining useful life of the related product. Amounts capitalized for such payments are included in other intangibles, net of accumulated amortization.

The Company enters into collaborative arrangements, typically with other pharmaceutical or biotechnology companies, to develop and commercialize drug candidates or intellectual property. These arrangements typically involve two (or more) parties who are active participants in the collaboration and are exposed to significant risks and rewards dependent on the commercial success of the activities. These collaborations usually involve various activities by one or more parties, including research and development, marketing and selling and distribution. Often, these collaborations require upfront, milestone and royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development.

Amounts due from collaborative partners related to development activities are generally reflected as a reduction of research and development expense because the performance of contract development services is not central to the Company's operations. In general, the income statement presentation for these collaborations is as follows:

Nature/Type of Collaboration	Statement of Earnings Presentation
Third-party sale of product & profit share payments received	Sales to customers
Royalties/milestones paid to collaborative partner (post-regulatory approval)*	Cost of products sold
Royalties received from collaborative partner	Other income (expense), net
Upfront payments & milestones paid to collaborative partner (pre-regulatory approval)	Research and development expense
Research and development payments to collaborative partner	Research and development expense
Research and development payments received from collaborative partner or government entity	Reduction of Research and development expense

* Milestones are capitalized as intangible assets and amortized to cost of products sold over the useful life.

For all years presented, there was no individual project that represented greater than 5% of the total annual consolidated research and development expense.

The Company has a number of products and compounds developed in collaboration with strategic partners including XARELTO®, co-developed with Bayer HealthCare AG and IMBRUVICA®, developed in collaboration and co-marketed with Pharmacyclics LLC, an AbbVie company.

Separately, the Company has a number of licensing arrangements for products and compounds including DARZALEX®, licensed from Genmab A/S.

Advertising

Costs associated with advertising are expensed in the year incurred and are included in selling, marketing and administrative expenses. Advertising expenses worldwide, which comprised television, radio, print media and Internet advertising, were $2.1 billion, $2.2 billion and $2.6 billion in fiscal years 2020, 2019 and 2018, respectively.

Income Taxes

Income taxes are recorded based on amounts refundable or payable for the current year and include the results of any difference between U.S. GAAP accounting and tax reporting, recorded as deferred tax assets or liabilities. The Company estimates deferred tax assets and liabilities based on enacted tax regulations and rates. Future changes in tax laws and rates may affect recorded deferred tax assets and liabilities in the future.

The Company has unrecognized tax benefits for uncertain tax positions. The Company follows U.S. GAAP which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Management believes that changes in these estimates would not have a material effect on the Company's results of operations, cash flows or financial position.

In 2017, the United States enacted into law new U.S. tax legislation, the U.S. Tax Cuts and Jobs Act (TCJA). This law included provisions for a comprehensive overhaul of the corporate income tax code, including a reduction of the statutory corporate tax rate from 35% to 21%, effective on January 1, 2018. The TCJA included a provision for a tax on all previously undistributed earnings of U.S. companies located in foreign jurisdictions. Undistributed earnings in the form of cash and cash equivalents were taxed at a rate of 15.5% and all other earnings were taxed at a rate of 8.0%. This tax is payable over 8 years and will not accrue interest. These payments began in 2018 and will continue through 2025. The remaining balance at the end of the 2020 was approximately $7.7 billion, of which $6.9 billion is classified as noncurrent and reflected as "Long-term taxes payable" on the Company's balance sheet. The balance of this account is related to receivables from tax authorities not expected to be received in the next 12 months.

The TCJA also includes provisions for a tax on global intangible low-taxed income (GILTI). GILTI is described as the excess of a U.S. shareholder's total net foreign income over a deemed return on tangible assets, as provided by the TCJA. In January 2018, the FASB issued guidance that allows companies to elect as an accounting policy whether to record the tax effects of GILTI in the period the tax liability is generated (i.e., "period cost") or provide for deferred tax assets and liabilities related to basis differences that exist and are expected to effect the amount of GILTI inclusion in future years upon reversal (i.e., "deferred method"). In 2018, the Company elected to account for GILTI under the deferred method. The deferred tax amounts recorded are based on the evaluation of temporary differences that are expected to reverse as GILTI is incurred in future periods.

The Company has recorded deferred tax liabilities on all undistributed earnings prior to December 31, 2017 from its international subsidiaries. The Company has not provided deferred taxes on the undistributed earnings subsequent to January 1, 2018 from certain international subsidiaries where the earnings are considered to be indefinitely reinvested. The Company

intends to continue to reinvest these earnings in those international operations. If the Company decides at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company estimates that the total tax effect of this repatriation would be approximately $0.7 billion under current enacted tax laws and regulations and at current currency exchange rates.

See Note 8 to the Consolidated Financial Statements for further information regarding income taxes.

Net Earnings Per Share

Basic earnings per share is computed by dividing net earnings available to common shareholders by the weighted average number of common shares outstanding for the period. Diluted earnings per share reflects the potential dilution that could occur if securities were exercised or converted into common stock using the treasury stock method.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the amounts reported. Estimates are used when accounting for sales discounts, rebates, allowances and incentives, product liabilities, income taxes, withholding taxes, depreciation, amortization, employee benefits, contingencies and intangible asset and liability valuations. Actual results may or may not differ from those estimates.

The Company follows the provisions of U.S. GAAP when recording litigation related contingencies. A liability is recorded when a loss is probable and can be reasonably estimated. The best estimate of a loss within a range is accrued; however, if no estimate in the range is better than any other, the minimum amount is accrued.

The extent to which COVID-19 impacts the Company's business and financial results will depend on numerous evolving factors including, but not limited to: the magnitude and duration of COVID-19, the extent to which it will impact worldwide macroeconomic conditions including interest rates, employment rates and health insurance coverage, the speed of the anticipated recovery, and governmental and business reactions to the pandemic. The Company assessed certain accounting matters that generally require consideration of forecasted financial information in context with the information reasonably available to the Company and the unknown future impacts of COVID-19 as of January 3, 2021 and through the date of this report. The accounting matters assessed included, but were not limited to, the Company's allowance for doubtful accounts and credit losses, inventory and related reserves, accrued rebates and associated reserves, and the carrying value of the goodwill and other long-lived assets. While there was not a material impact to the Company's consolidated financial statements as of and for the fiscal year ended January 3, 2021, the Company's future assessment of the magnitude and duration of COVID-19, as well as other factors, could result in material impacts to the Company's consolidated financial statements in future reporting periods.

Annual Closing Date

The Company follows the concept of a fiscal year, which ends on the Sunday nearest to the end of the month of December. Normally each fiscal year consists of 52 weeks, but every five or six years the fiscal year consists of 53 weeks, and therefore includes additional shipping days, as was the case in fiscal year 2020, and will be the case again in fiscal year 2026.

Reclassification

Certain prior period amounts have been reclassified to conform to current year presentation.

2. Cash, Cash Equivalents and Current Marketable Securities

At the end of the fiscal year 2020 and 2019, cash, cash equivalents and current marketable securities were comprised of:

(Dollars in Millions)	2020				
	Carrying Amount	Unrecognized Gain	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	$ 2,863	—	2,863	2,863	—
Non-U.S. Sovereign Securities[1]	690	—	690	—	690
U.S. Reverse repurchase agreements	1,937	—	1,937	1,937	—
Corporate debt securities[1]	2,674	—	2,674	1,451	1,223
Money market funds	2,102	—	2,102	2,102	—
Time deposits[1]	877	—	877	877	—
Subtotal	$ 11,143	—	11,143	9,230	1,913
U.S. Gov't Securities	$ 13,777	1	13,778	4,731	9,047
Other Sovereign Securities	14	—	14	—	14
Corporate debt securities	250	—	250	24	226
Subtotal available for sale[2]	$ 14,041	1	14,042	4,755	9,287
Total cash, cash equivalents and current marketable securities				**$ 13,985**	**11,200**

(Dollars in Millions)	2019		
	Carrying Amount	Cash & Cash Equivalents	Current Marketable Securities
Cash	$ 2,637	2,637	—
Non-U.S. Sovereign Securities[1]	439	149	290
U.S. Reverse repurchase agreements	6,375	6,375	—
Other Reverse repurchase agreements	375	375	—
Corporate debt securities[1]	1,323	889	434
Money market funds	2,864	2,864	—
Time deposits[1]	906	906	—
Subtotal	$ 14,919	14,195	724
Gov't Securities	$ 4,102	3,095	1,007
Corporate debt securities	266	15	251
Subtotal available for sale[2]	$ 4,368	3,110	1,258
Total cash, cash equivalents and current marketable securities		**$ 17,305**	**1,982**

[1] Held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings.
[2] Available for sale debt securities are reported at fair value with unrealized gains and losses reported net of taxes in other comprehensive income.

At the end of fiscal year 2019, the carrying amount was the same as the estimated fair value.

Fair value of government securities and obligations and corporate debt securities were estimated using quoted broker prices and significant other observable inputs.

The contractual maturities of the available for sale debt securities at January 3, 2021 are as follows:

(Dollars in Millions)	Cost Basis	Fair Value
Due within one year	$ 14,026	14,027
Due after one year through five years	15	15
Due after five years through ten years	—	—
Total debt securities	$ 14,041	14,042

The Company invests its excess cash in both deposits with major banks throughout the world and other high-quality money market instruments. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating.

3. Inventories

At the end of fiscal years 2020 and 2019, inventories were comprised of:

(Dollars in Millions)	2020	2019
Raw materials and supplies	$ 1,410	1,117
Goods in process	2,040	1,832
Finished goods	5,894	6,071
Total inventories [1]	**$ 9,344**	**9,020**

[1] See Note 18 to the Consolidated Financial Statements for details on assets held for sale and the related divestitures for the fiscal year ended December 29, 2019. There were no assets held for sale at January 3, 2021.

4. Property, Plant and Equipment

At the end of fiscal years 2020 and 2019, property, plant and equipment at cost and accumulated depreciation were:

(Dollars in Millions)	2020	2019
Land and land improvements	$ 882	854
Buildings and building equipment	12,502	11,877
Machinery and equipment	29,104	26,964
Construction in progress	4,316	3,637
Total property, plant and equipment, gross	$ 46,804	43,332
Less accumulated depreciation	28,038	25,674
Total property, plant and equipment, net[1]	**$ 18,766**	**17,658**

[1] See Note 18 to the Consolidated Financial Statements for details on assets held for sale and the related divestitures for the fiscal year ended December 29, 2019. There were no assets held for sale at January 3, 2021.

The Company capitalizes interest expense as part of the cost of construction of facilities and equipment. Interest expense capitalized in fiscal years 2020, 2019 and 2018 was $63 million, $70 million and $86 million, respectively.

Depreciation expense, including the amortization of capitalized interest in fiscal years 2020, 2019 and 2018 was $2.6 billion, $2.5 billion and $2.6 billion, respectively.

Upon retirement or other disposal of property, plant and equipment, the costs and related amounts of accumulated depreciation or amortization are eliminated from the asset and accumulated depreciation accounts, respectively. The difference, if any, between the net asset value and the proceeds are recorded in earnings.

5. Intangible Assets and Goodwill

At the end of fiscal years 2020 and 2019, the gross and net amounts of intangible assets were:

(Dollars in Millions)		2020	2019
Intangible assets with definite lives:			
Patents and trademarks — gross	$	39,990	36,634
Less accumulated amortization		17,618	13,154
Patents and trademarks — net	**$**	**22,372**	**23,480**
Customer relationships and other intangibles — gross	$	22,898	22,056
Less accumulated amortization		10,912	9,462
Customer relationships and other intangibles — net*	**$**	**11,986**	**12,594**
Intangible assets with indefinite lives:			
Trademarks	$	7,195	6,922
Purchased in-process research and development[(1)]		11,849	4,647
Total intangible assets with indefinite lives	**$**	**19,044**	**11,569**
Total intangible assets — net	**$**	**53,402**	**47,643**

*The majority is comprised of customer relationships

[(1)] In fiscal year 2020, the Company completed multiple acquisitions and recorded in-process research and development intangible assets of $6.0 billion from Momenta Pharmaceuticals, Inc., $0.8 billion for bermekimab and certain related assets from XBiotech, Inc., and $0.4 billion from the acquisition of all outstanding shares in Verb Surgical, Inc.

Goodwill as of January 3, 2021 and December 29, 2019, as allocated by segment of business, was as follows:

(Dollars in Millions)	Consumer Health	Pharmaceutical	Medical Devices	Total
Goodwill at December 30, 2018	$ 8,670	9,063	12,720	30,453
Goodwill, related to acquisitions	1,188	75	2,018	3,281
Currency translation/other	(122)	31	(4)	(95)
Goodwill at December 29, 2019	$ 9,736	9,169	14,734	33,639
Goodwill, related to acquisitions	—	1,222	238	1,460
Currency translation/other	600	618	76	1,294
Goodwill at January 3, 2021	**$ 10,336**	**11,009**	**15,048**	**36,393**

The weighted average amortization period for patents and trademarks is 12 years. The weighted average amortization period for customer relationships and other intangible assets is 21 years. The amortization expense of amortizable assets included in cost of products sold was $4.7 billion, $4.5 billion and $4.4 billion before tax, for the fiscal years ended January 3, 2021, December 29, 2019 and December 30, 2018, respectively. Intangible asset write-downs are included in Other (income) expense, net.

The estimated amortization expense for approved products, before tax, for the five succeeding years is approximately:

(Dollars in Millions)				
2021	**2022**	**2023**	**2024**	**2025**
$4,600	4,200	4,100	3,900	3,200

See Note 18 to the Consolidated Financial Statements for additional details related to acquisitions and divestitures.

6. Fair Value Measurements

The Company uses forward foreign exchange contracts to manage its exposure to the variability of cash flows, primarily related to the foreign exchange rate changes of future intercompany products and third-party purchases of materials denominated in a foreign currency. The Company uses cross currency interest rate swaps to manage currency risk primarily related to borrowings. Both types of derivatives are designated as cash flow hedges.

Additionally, the Company uses interest rate swaps as an instrument to manage interest rate risk related to fixed rate borrowings. These derivatives are designated as fair value hedges. The Company uses cross currency interest rate swaps and forward foreign exchange contracts designated as net investment hedges. Additionally, the Company uses forward foreign exchange contracts to offset its exposure to certain foreign currency assets and liabilities. These forward foreign exchange contracts are not designated as hedges and therefore, changes in the fair values of these derivatives are recognized in earnings, thereby offsetting the current earnings effect of the related foreign currency assets and liabilities.

The Company does not enter into derivative financial instruments for trading or speculative purposes, or that contain credit risk related contingent features. The Company maintains credit support agreements (CSA) with certain derivative counterparties establishing collateral thresholds based on respective credit ratings and netting agreements. As of January 3, 2021, the total amount of cash collateral paid by the Company under the CSA amounted to $1.1 billion net, related to net investment and cash flow hedges. On an ongoing basis, the Company monitors counter-party credit ratings. The Company considers credit non-performance risk to be low, because the Company primarily enters into agreements with commercial institutions that have at least an investment grade credit rating. Refer to the table on significant financial assets and liabilities measured at fair value contained in this footnote for receivables and payables with these commercial institutions. As of January 3, 2021, the Company had notional amounts outstanding for forward foreign exchange contracts, and cross currency interest rate swaps of $37.8 billion and $30.6 billion, respectively. As of December 29, 2019, the Company had notional amounts outstanding for forward foreign exchange contracts and cross currency interest rate swaps of $45.3 billion and $20.1 billion, respectively.

All derivative instruments are recorded on the balance sheet at fair value. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The designation as a cash flow hedge is made at the entrance date of the derivative contract. At inception, all derivatives are expected to be highly effective. Foreign exchange contracts designated as cash flow hedges are accounted for under the forward method and all gains/losses associated with these contracts will be recognized in the income statement when the hedged item impacts earnings. Changes in the fair value of these derivatives are recorded in accumulated other comprehensive income until the underlying transaction affects earnings, and are then reclassified to earnings in the same account as the hedged transaction.

Gains and losses associated with interest rate swaps and changes in fair value of hedged debt attributable to changes in interest rates are recorded to interest expense in the period in which they occur. The effect of which are immaterial for the fiscal years ended January 3, 2021 and December 29, 2019. Gains and losses on net investment hedge are accounted through the currency translation account within accumulated other comprehensive income. The portion excluded from effectiveness testing is recorded through interest (income) expense using the spot method. On an ongoing basis, the Company assesses whether each derivative continues to be highly effective in offsetting changes of hedged items. If and when a derivative is no longer expected to be highly effective, hedge accounting is discontinued.

The Company designated its Euro denominated notes issued in May 2016 with due dates ranging from 2022 to 2035 as a net investment hedge of the Company's investments in certain of its international subsidiaries that use the Euro as their functional currency in order to reduce the volatility caused by changes in exchange rates.

As of January 3, 2021, the balance of deferred net gain on derivatives included in accumulated other comprehensive income was $652 million after-tax. For additional information, see the Consolidated Statements of Comprehensive Income and Note 13. The Company expects that substantially all of the amounts related to forward foreign exchange contracts will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months, excluding interest rate contracts, net investment hedges. The amount ultimately realized in earnings may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity of the derivative.

The following table is a summary of the activity related to derivatives and hedges for the fiscal years ended January 3, 2021 and December 29, 2019, net of tax:

	January 3, 2021					December 29, 2019				
(Dollars in Millions)	Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense	Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense
The effects of fair value, net investment and cash flow hedging:										
Gain (Loss) on net investment hedging relationship:										
Cross currency interest rate swaps contracts:										
Amount of gain or (loss) recognized in income on derivative amount excluded from effectiveness testing	$ —	—	—	153	—	—	—	—	159	—
Amount of gain or (loss) recognized in AOCI	—	—	—	153	—	—	—	—	159	—
Gain (Loss) on cash flow hedging relationship:										
Forward foreign exchange contracts:										
Amount of gain or (loss) reclassified from AOCI into income	12	(329)	(137)	—	(16)	(54)	(321)	(105)	—	22
Amount of gain or (loss) recognized in AOCI	44	298	(191)	—	(52)	(20)	(606)	(94)	—	39
Cross currency interest rate swaps contracts:										
Amount of gain or (loss) reclassified from AOCI into income	—	—	—	370	—	—	—	—	292	—
Amount of gain or (loss) recognized in AOCI	$ —	—	—	748	—	—	—	—	417	—

The following table is the effect of derivatives not designated as hedging instrument for the fiscal years ended January 3, 2021 and December 29, 2019:

(Dollars in Millions)	Location of Gain /(Loss) Recognized in Income on Derivative	Gain/(Loss) Recognized In Income on Derivative	
Derivatives Not Designated as Hedging Instruments		January 3, 2021	December 29, 2019
Foreign Exchange Contracts	Other (income) expense	$ 24	(144)

The following table is the effect of net investment hedges for the fiscal years ended January 3, 2021 and December 29, 2019:

	Gain/(Loss) Recognized In Accumulated OCI		Location of Gain or (Loss) Reclassified from Accumulated Other Comprehensive Income Into Income	Gain/(Loss) Reclassified From Accumulated OCI Into Income	
(Dollars in Millions)	January 3, 2021	December 29, 2019		January 3, 2021	December 29, 2019
Debt	$ (473)	121	Interest (income) expense	—	—
Cross Currency interest rate swaps	$ 65	488	Interest (income) expense	—	—

The Company holds equity investments with readily determinable fair values and equity investments without readily determinable fair values. The Company measures equity investments that do not have readily determinable fair values at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer.

The following table is a summary of the activity related to equity investments for the fiscal years ended January 3, 2021 and December 29, 2019:

	December 29, 2019			January 3, 2021	
(Dollars in Millions)	Carrying Value	Changes in Fair Value Reflected in Net Income[1]	Sales/ Purchases/Other[2]	Carrying Value	Non Current Other Assets
Equity Investments with readily determinable value	$ 1,148	527	(194)	1,481	1,481
Equity Investments without readily determinable value	$ 712	(55)	81	738	738

	December 30, 2018			December 29, 2019	
(Dollars in Millions)	Carrying Value	Changes in Fair Value Reflected in Net Income[1]	Sales/ Purchases/Other[2]	Carrying Value	Non Current Other Assets
Equity Investments with readily determinable value	$ 511	533	104	1,148	1,148
Equity Investments without readily determinable value	$ 681	(38)	69	712	712

[1] Recorded in Other Income/Expense
[2] Other includes impact of currency

For the fiscal years ended January 3, 2021 and December 29, 2019 for equity investments without readily determinable market values, $76 million and $57 million, respectively, of the changes in fair value reflected in net income were the result of impairments. There were $21 million and $19 million, respectively, of changes in fair value reflected in net income due to changes in observable prices.

Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. In accordance with ASC 820, a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described below with Level 1 having the highest priority and Level 3 having the lowest.

The fair value of a derivative financial instrument (i.e., forward foreign exchange contracts, interest rate contracts) is the aggregation by currency of all future cash flows discounted to its present value at the prevailing market interest rates and subsequently converted to the U.S. Dollar at the current spot foreign exchange rate. The Company does not believe that fair values of these derivative instruments materially differ from the amounts that could be realized upon settlement or maturity, or

that the changes in fair value will have a material effect on the Company's results of operations, cash flows or financial position. The Company also holds equity investments which are classified as Level 1 and debt securities which are classified as Level 2. The Company holds acquisition related contingent liabilities based upon certain regulatory and commercial events, which are classified as Level 3, whose values are determined using discounted cash flow methodologies or similar techniques for which the determination of fair value requires significant judgment or estimations.

The following three levels of inputs are used to measure fair value:

Level 1 — Quoted prices in active markets for identical assets and liabilities.

Level 2 — Significant other observable inputs.

Level 3 — Significant unobservable inputs.

The Company's significant financial assets and liabilities measured at fair value as of the fiscal year ended January 3, 2021 and December 29, 2019 were as follows:

	2020				2019
(Dollars in Millions)	**Level 1**	**Level 2**	**Level 3**	**Total**	**Total [1]**
Derivatives designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	$ —	849	—	849	209
Interest rate contracts [2][3]	—	240	—	240	693
Total	$ —	**1,089**	—	**1,089**	**902**
Liabilities:					
Forward foreign exchange contracts	—	702	—	702	426
Interest rate contracts [3]	—	1,569	—	1,569	193
Total	$ —	**2,271**	—	**2,271**	**619**
Derivatives not designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	$ —	49	—	49	23
Liabilities:					
Forward foreign exchange contracts	—	38	—	38	33
Available For Sale Other Investments:					
Equity investments[4]	1,481	—	—	1,481	1,148
Debt securities[5]	—	14,042	—	14,042	4,368
Other Liabilities					
Contingent Consideration[6]	$		633	633	1,715

Gross to Net Derivative Reconciliation	2020	2019
(Dollars in Millions)		
Total Gross Assets	$ 1,138	925
Credit Support Agreement (CSA)	(1,107)	(841)
Total Net Asset	31	84
Total Gross Liabilities	2,309	652
Credit Support Agreement (CSA)	(2,172)	(586)
Total Net Liabilities	$ 137	66

Summarized information about changes in liabilities for contingent consideration is as follows:

		2020	2019	2018
(Dollars in Millions)				
Beginning Balance	$	1,715	397	600
Changes in estimated fair value [7]		(1,089)	151	(156)
Additions		106	1,246	125
Payments		(99)	(79)	(172)
Ending Balance	$	633	1,715	397

(1) 2019 assets and liabilities are all classified as Level 2 with the exception of equity investments of $1,148 million, which are classified as Level 1 and contingent consideration of $1,715 million, classified as Level 3.
(2) Includes $1 million of non-current assets as of December 29, 2019.
(3) Includes cross currency interest rate swaps and interest rate swaps.
(4) Classified as non-current other assets.
(5) Classified as cash equivalents and current marketable securities.
(6) Includes $594 million, $1,631 million (primarily related to Auris Health) and $397 million, classified as non-current other liabilities as of January 3, 2021, December 29, 2019 and December 30, 2018, respectively. Includes $39 million and $84 million classified as current liabilities as of January 3, 2021 and December 29, 2019, respectively.
(7) Ongoing fair value adjustment amounts are recorded primarily in Research and Development expense. The Company recorded a contingent consideration reversal of $1,148 million in 2020 related to the timing of certain developmental milestones associated with the Auris Health acquisition. The reversal of the contingent consideration was recorded in Other income and expense

See Notes 2 and 7 for financial assets and liabilities held at carrying amount on the Consolidated Balance Sheet.

7. Borrowings

The components of long-term debt are as follows:

(Dollars in Millions)	2020	Effective Rate %	2019	Effective Rate %
3% Zero Coupon Convertible Subordinated Debentures due 2020	$ —	—	51	3.00
2.95% Debentures due 2020	—	—	549	3.15
1.950% Notes due 2020	—	—	500	1.99
3.55% Notes due 2021	450	3.67	449	3.67
2.45% Notes due 2021	350	2.48	349	2.48
1.65% Notes due 2021	999	1.65	999	1.65
0.250% Notes due 2022 (1B Euro 1.2281)[2]/(1B Euro 1.1096)[3]	1,227 [2]	0.26	1,108 [3]	0.26
2.25% Notes due 2022	999	2.31	998	2.31
6.73% Debentures due 2023	250	6.73	250	6.73
3.375% Notes due 2023	803	3.17	804	3.17
2.05% Notes due 2023	499	2.09	498	2.09
0.650% Notes due 2024 (750MM Euro 1.2281)[2]/(750MM Euro 1.1096)[3]	919 [2]	0.68	829 [3]	0.68
5.50% Notes due 2024 (500MM 1.3654 GBP)[2]/(500MM GBP 1.2987)[3]	679 [2]	6.75	645 [3]	6.75
2.625% Notes due 2025	748	2.63	748	2.63
0.55% Notes due 2025[5]	996	0.57	—	—
2.45% Notes due 2026	1,994	2.47	1,993	2.47
2.95% Notes due 2027	997	2.96	996	2.96
0.95% Notes due 2027[5]	1,494	0.96	—	—
1.150% Notes due 2028 (750MM Euro 1.2281)[2]/(750MM Euro 1.1096)[3]	915 [2]	1.21	825 [3]	1.21
2.90% Notes due 2028	1,495	2.91	1,494	2.91
6.95% Notes due 2029	297	7.14	297	7.14
1.30% Notes due 2030[5]	1,743	1.30	—	—
4.95% Debentures due 2033	498	4.95	498	4.95
4.375% Notes due 2033	855	4.24	855	4.24
1.650% Notes due 2035 (1.5B Euro 1.2281)[2]/(1.5B Euro 1.1096)[3]	1,827 [2]	1.68	1,649 [3]	1.68
3.55% Notes due 2036	989	3.59	989	3.59
5.95% Notes due 2037	992	5.99	992	5.99
3.625% Notes due 2037	1,488	3.64	1,487	3.64
5.85% Debentures due 2038	696	5.85	696	5.85
3.400% Notes due 2038	991	3.42	991	3.42
4.50% Debentures due 2040	539	4.63	539	4.63
2.10% Notes due 2040[5]	986	2.14	—	—
4.85% Notes due 2041	297	4.89	297	4.89
4.50% Notes due 2043	496	4.52	495	4.52
3.70% Notes due 2046	1,974	3.74	1,973	3.74
3.75% Notes due 2047	991	3.76	991	3.76
3.500% Notes due 2048	742	3.52	742	3.52
2.250% Notes due 2050[5]	984	2.29	—	—

2.450% Notes due 2060[5]	1,228	2.49	—	—
Other	7	—	18	—
Subtotal	**34,434** [4]	**2.85 %** [1]	**27,594** [4]	**3.19** [1]
Less current portion	1,799		1,100	
Total long-term debt	**$ 32,635**		**26,494**	

(1) Weighted average effective rate.
(2) Translation rate at January 3, 2021.
(3) Translation rate at December 29, 2019.
(4) The excess of the fair value over the carrying value of debt was $5.4 billion at the end of fiscal year 2020 and $3.0 billion at the end of fiscal year 2019.
(5) In the fiscal third quarter of 2020, the Company issued senior unsecured notes for a total of $7.5 billion.

Fair value of the long-term debt was estimated using market prices, which were corroborated by quoted broker prices and significant other observable inputs.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2020, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 9, 2021. Interest charged on borrowings under the credit line agreement is based on either bids provided by banks, London Interbank Offered Rates (LIBOR), Secured Overnight Financing Rate (SOFR) Swap Curve or other applicable market rate as allowed plus applicable margins. Commitment fees under the agreements are not material.

Throughout fiscal year 2020, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $2.6 billion at the end of fiscal year 2020, of which $1.8 billion is the current portion of the long-term debt, and the remainder is commercial paper and local borrowings by international subsidiaries.

Throughout fiscal year 2019, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $1.2 billion at the end of fiscal year 2019, of which $1.1 billion is the current portion of the long term debt, and the remainder principally represents local borrowing by international subsidiaries.

Aggregate maturities of long-term debt obligations commencing in 2021 are:

(Dollars in Millions) 2021	2022	2023	2024	2025	After 2025
$1,799	2,226	1,552	1,598	1,744	25,515

8. Income Taxes

The provision for taxes on income consists of:

(Dollars in Millions)	2020	2019	2018
Currently payable:			
U.S. taxes	$ 1,026	1,941	1,284
International taxes	1,898	2,744	2,434
Total currently payable	2,924	4,685	3,718
Deferred:			
U.S. taxes	(76)	(814)	1,210 [1]
International taxes	(1,065)	(1,662)	(2,226)
Total deferred	(1,141)	(2,476)	(1,016)
Provision for taxes on income	**$ 1,783**	**2,209**	**2,702**

(1) Includes $1.4 billion of deferred tax expense for the adoption of the deferred method to account for GILTI.

A comparison of income tax expense at the U.S. statutory rate of 21% in fiscal years 2020, 2019 and 2018, to the Company's effective tax rate is as follows:

(Dollars in Millions)	2020	2019	2018
U.S.	$ 4,312	3,543	5,575
International	12,185	13,785	12,424
Earnings before taxes on income:	$ 16,497	17,328	17,999
Tax rates:			
U.S. statutory rate	21.0 %	21.0	21.0
International operations (1)	(9.9)	(5.9)	(3.7)
U.S. taxes on international income (2)	2.7	1.8	1.4
Tax benefits on Capital Loss	(1.2)	(0.3) (4)	—
Tax benefits on share-based compensation	(1.5)	(0.5)	(1.5)
TCJA and related impacts	0.7	(3.9) (3)	(1.9) (3)
All other	(1.0)	0.5 (4)	(0.3)
Effective Rate	10.8 %	12.7	15.0

(1) For all periods presented the Company has subsidiaries operating in Puerto Rico under various tax incentives. International operations reflects the impacts of operations in jurisdictions with statutory tax rates different than the U.S., particularly Ireland, Switzerland and Puerto Rico, which is a favorable impact on the effective tax rate as compared with the U.S. statutory rate. The 2020 and 2019 amounts include the impact of the new tax legislation enactment in Switzerland, which is further described below.
(2) Includes the impact of the GILTI tax, the Foreign-Derived Intangible Income deduction and other foreign income that is taxable under the U.S. tax code.
(3) Represents impact of adjustments to balances originally recorded as part of the 2017 TCJA provisional tax charge. Further information provided below.
(4) Certain prior year amounts have been reclassified to conform to current year presentation.

The fiscal year 2020 tax rate decreased by 1.9% compared to the fiscal year 2019 tax rate, which was primarily driven by the following items. In fiscal year 2019, Switzerland enacted the Federal Act on Tax Reform and AHV Financing (TRAF) which became effective on January 1, 2020. The Federal transitional provisions of TRAF allow companies, under certain conditions, to adjust the tax basis in certain assets to fair value (i.e., "step-up") to be depreciated and amortized resulting in an incremental Swiss tax deduction over the transitional period.

TRAF also provides for parameters which enable the Swiss cantons to establish localized tax rates and regulations for companies. The new cantonal tax parameters include favorable tax benefits for patents and additional research and development tax deductions. The cantonal transitional provisions of TRAF allowed companies to elect either 1) tax basis step-up similar to the Federal transition benefit or 2) alternative statutory tax rate for a period not to exceed 5 years. The Company currently has operations located in various Swiss cantons. During the fiscal year 2019, as described in further detail below, the Company recorded the impacts of the TRAF that were enacted in that period.

During the fiscal year 2020, the final canton where the Company maintains significant operations enacted TRAF legislation. Additionally, the Company received rulings from the Swiss Federal and cantonal tax authorities in the remaining jurisdictions where it has significant operations. These rulings resulted in the Company revising its estimate on the tax basis adjustment (i.e., "step-up") for its assets and as a result, the Company recorded additional deferred tax benefits in 2020. The Company recognized a net benefit in the fiscal year 2020 for Swiss Tax Reform of approximately $0.4 billion or 2.6% benefit to the Company's annual effective tax rate, comprised of the following items:

- approximately $0.3 billion tax benefit relating to the remeasurement of Swiss deferred tax assets and liabilities for the change in the Federal and cantonal tax rates, where enactment occurred in the fiscal year 2020; this benefit has been reflected as "International Operations" on the Company's effective tax rate reconciliation.
- a $450 million deferred tax asset related to the estimated value of a Federal tax basis step-up of the Company's Swiss subsidiaries' assets as described above; this benefit has been reflected as "International Operations" on the Company's effective tax rate reconciliation.
- approximately $0.3 billion of U.S. deferred tax expense relating to the GILTI deferred tax liability resulting from the remeasurement of the Swiss deferred tax assets and liabilities in the fiscal year 2020. This benefit has been reflected as "U.S. tax on international income" on the Company's effective tax rate reconciliation.

The Company does not expect to receive future rulings regarding the transitional provisions of TRAF.

Also, in the fiscal fourth quarter of 2020, the Company recognized a capital loss on certain U.S. affiliates related to the previously impaired book value of certain intangibles, which reduced the 2020 tax rate by approximately 1.2% which is

reflected as a "Tax Benefits on Capital Loss" on the effective tax rate reconciliation. In addition in the fiscal year 2020, the Company had lower income in higher tax jurisdictions, primarily driven by:

- the impact of the accrual of litigation costs related to Talc for $4.0 billion which reduced the U.S. earnings before taxes at an effective tax rate of 23.5%;
- the accrual of additional legal costs, including an additional $1.0 billion associated with a revised agreement in principle to settle opioid litigation at an effective tax rate of 21.4%

The Company also generated additional tax benefits from stock-based compensation that were either exercised or vested; reduced the contingent consideration liability related to the Auris Health acquisition (see Note 18); and reversal of some of its unrecognized tax benefits due to the completion of several years of tax examinations in certain jurisdictions during the fiscal year 2020.

The fiscal year 2019 tax rate decreased by 2.3% compared to the fiscal year 2018 tax rate. In addition to the impact of TRAF discussed in more detail below, the primary drivers of the net decrease were as follows:

- The Company reorganized the ownership structure of certain wholly-owned international subsidiaries in the fiscal fourth quarter of 2019, which resulted in a reduction of certain withholding and local taxes that it had previously recognized as part of the provisional Tax Cuts and Jobs Act (TCJA) tax charge in the fiscal year 2017 and finalized in the fiscal year 2018. Following the completion of this restructuring and approval by the applicable local authorities, the Company reversed a deferred tax liability of $0.6 billion and a related deferred tax asset of $0.2 billion for U.S. foreign tax credits, for a net deferred tax benefit of $0.4 billion decreasing the annual effective tax rate by 2.2%. This benefit has been reflected as "TCJA and related impacts" on the Company's effective tax rate reconciliation.
- The impact of the agreement in principle to settle opioid litigation for $4 billion (see Note 19 to the Consolidated Financial Statements) which reduced the U.S. earnings before taxes at an effective tax rate of 23.5% and decreased the Company's annual effective tax rate by approximately 2.1%.
- In December of fiscal year 2019, the U.S. Treasury issued final foreign tax credit regulations, which resulted in the Company revising the amount of foreign tax credits that were initially recorded in the fiscal year 2017 as part of the provisional TCJA tax charge. As a result, the Company recorded an increased deferred tax asset related to these foreign tax credits of approximately $0.3 billion or 1.7% to the annual effective tax rate. This benefit has been reflected as "TCJA and related impacts" on the Company's effective tax rate reconciliation.
- The Company reassessed its uncertain tax positions related to the current IRS audit and increased its unrecognized tax benefit by $0.3 billion liability which increased the annual effective tax rate by approximately 1.5% (see section on Unrecognized Tax Benefits for additional information). As these positions were related to uncertain tax regarding international transfer pricing, this expense has been classified as "International Operations" on the Company's effective tax rate reconciliation. Subsequent to December 29, 2019, the Company received and agreed to Notices of Proposed Adjustments (NOPAs) from the IRS. The Company believes it is adequately reserved for potential exposures.
- There were several one-time tax impacts that resulted in a cumulative net tax benefit to the 2018 annual effective tax rate of 1.2%. These items included the LifeScan divestiture, the adjustment to the 2017 provisional TCJA tax charge and the acceleration of certain tax deductions as part of the 2017 tax return.
- More income in higher tax jurisdictions relative to lower tax jurisdictions as compared to 2018.

As described above for the Swiss tax legislation, in the fiscal year 2019, the Company recorded a net tax expense of $0.1 billion which increased the effective tax rate for the fiscal year 2019 by approximately 0.6%. This net tax expense related to federal and certain cantonal enactments in the fiscal year 2019 consisting of the following provisions:

- approximately $0.6 billion tax expense relating to the remeasurement of Swiss deferred tax assets and liabilities for the change in the Federal and cantonal tax rates, where enactment occurred by December 29, 2019; this expense has been reflected as "International Operations" on the Company's effective tax rate reconciliation.
- a $0.9 billion deferred tax asset related to the estimated value of a Federal tax basis step-up of the Company's Swiss subsidiaries' assets; this benefit has been reflected as "International Operations" on the Company's effective tax rate reconciliation.
- approximately $450 million of U.S. deferred tax expense relating to the GILTI deferred tax liability resulting from the remeasurement of the Swiss deferred tax assets and liabilities and the new deferred tax asset for the Federal step-up. This benefit has been reflected as "U.S. tax on international income" on the Company's effective tax rate reconciliation.

In the fiscal year 2018, the Company completed its full assessment and finalized the accounting for the impact of the TCJA. The Company recorded net adjustments to the above components of the provisional charge of approximately $0.2 billion. These revisions were based on updated estimates and additional analysis by management as well as applying interpretative guidance issued by the U.S. Department of Treasury to the facts and circumstances that existed as of the TCJA enactment date. This charge was primarily related to additional deferred tax liabilities for foreign local and withholding taxes for the remaining balance of undistributed foreign earnings as of December 31, 2017 that were not provided for in the 2017 provisional charge.

As described in Note 1, in the fiscal year 2018, the Company elected to treat GILTI as a period expense under the deferred method and recorded a deferred tax cost of approximately $1.4 billion in the fiscal year 2018 related to facts and circumstances that existed on the date of TCJA enactment. During 2018, the Company reorganized the ownership structure of certain foreign subsidiaries which resulted in a reduction of certain foreign withholding taxes that it had recognized as part of the provisional TCJA tax charge in the fourth quarter of 2017. Following the completion of this restructuring and as a result of clarification by Swiss tax authorities regarding the applicability of withholding tax to repatriation of certain earnings, the Company reversed a deferred tax liability of $2.8 billion and a related deferred tax asset of $0.9 billion for U.S. foreign tax credits, for a net deferred tax benefit of $1.9 billion. This benefit has been reflected as “TCJA and related impacts” on the Company’s effective tax rate reconciliation.

Temporary differences and carryforwards at the end of fiscal years 2020 and 2019 were as follows:

	2020 Deferred Tax		2019 Deferred Tax*	
(Dollars in Millions)	**Asset**	**Liability**	**Asset**	**Liability**
Employee related obligations	$ 2,434		2,473	
Stock based compensation	627		595	
Depreciation & amortization	721		1,122	
Non-deductible intangibles		(6,567)		(5,835)
International R&D capitalized for tax	1,517		1,189	
Reserves & liabilities	3,466		2,337	
Income reported for tax purposes	1,705		1,605	
Net operating loss carryforward international	990		838	
Undistributed foreign earnings	812	(1,435)	765	(1,289)
Global intangible low-taxed income		(3,606)		(2,965)
Miscellaneous international	854	(211)	696	(81)
Miscellaneous U.S.	12		411	
Total deferred income taxes	**$ 13,138**	**(11,819)**	**12,031**	**(10,170)**

*Certain prior year amounts have been reclassified to conform to current year presentation

The Company has wholly-owned international subsidiaries that have cumulative net losses. The Company believes that it is more likely than not that these subsidiaries will generate future taxable income sufficient to utilize these deferred tax assets.

The following table summarizes the activity related to unrecognized tax benefits:

(Dollars in Millions)	**2020**	**2019**	**2018**
Beginning of year	$ 3,853	3,326	3,151
Increases related to current year tax positions	265	249	242
Increases related to prior period tax positions	668	408	145
Decreases related to prior period tax positions	(551)	(105)	(137)
Settlements	(839)	(9)	(40)
Lapse of statute of limitations	(23)	(16)	(35)
End of year	**$ 3,373**	**3,853**	**3,326**

The unrecognized tax benefits of $3.4 billion at January 3, 2021, if recognized, would affect the Company’s annual effective tax rate. The Company conducts business and files tax returns in numerous countries and currently has tax audits in progress with a number of tax authorities. With respect to the United States, the Internal Revenue Service (IRS) has completed its audit for the tax years through 2012. As of December 29, 2019, the Company classified unrecognized tax benefits and related interest

of approximately $0.9 billion as a current liability on the "Accrued taxes on Income" line of the Consolidated Balance Sheet. In the fiscal year 2020, the Company made its final payments for approximately $0.7 billion to the U.S. Treasury related to the final settlement of 2010-2012 tax audit liability.

In other major jurisdictions where the Company conducts business, the years that remain open to tax audit go back to the year 2006. The Company believes it is possible that tax audits may be completed over the next twelve months by taxing authorities in some jurisdictions outside of the United States. However, the Company is not able to provide a reasonably reliable estimate of the timing of any other future tax payments relating to uncertain tax positions.

The Company classifies liabilities for unrecognized tax benefits and related interest and penalties as long-term liabilities, except as previously noted on amounts related to the current United States IRS audit. Interest expense and penalties related to unrecognized tax benefits are classified as income tax expense. The Company recognized after tax interest expense of $32 million, $50 million and $53 million in fiscal years 2020, 2019 and 2018, respectively. The total amount of accrued interest was $468 million and $559 million in fiscal years 2020 and 2019, respectively.

9. Employee Related Obligations

At the end of fiscal 2020 and fiscal 2019, employee related obligations recorded on the Consolidated Balance Sheets were:

(Dollars in Millions)	2020	2019
Pension benefits	$ 5,761	5,538
Postretirement benefits	2,229	2,297
Postemployment benefits	3,078	3,004
Deferred compensation	250	338
Total employee obligations	11,318	11,177
Less current benefits payable	547	514
Employee related obligations — non-current	**$ 10,771**	**10,663**

Prepaid employee related obligations of $656 million and $551 million for 2020 and 2019, respectively, are included in Other assets on the Consolidated Balance Sheets.

10. Pensions and Other Benefit Plans

The Company sponsors various retirement and pension plans, including defined benefit, defined contribution and termination indemnity plans, which cover most employees worldwide. The Company also provides post-retirement benefits, primarily health care, to all eligible U.S. retired employees and their dependents.

Many international employees are covered by government-sponsored programs and the cost to the Company is not significant.

In the U.S, non-union pension benefits for employees hired before January 1, 2015 are primarily based on the employee's compensation during the last five years before retirement and the number of years of service (the Final Average Pay formula). U.S. pension benefits for employees hired after 2014, are calculated using a different formula based on employee compensation over total years of service (the Retirement Value formula).

In January 2021, the Company announced that, effective on January 1, 2026, all eligible U.S. non-union employees, regardless of hire date, will earn benefits under the Retirement Value formula. This amendment does not affect the benefits accrued under the Final Average Pay formula for service before January 1, 2026. The impact of this change decreases the PBO as of January 3, 2021 by approximately $1.8 billion and is included in the "Amendments" line in the Change in Benefit Obligation.

International subsidiaries have plans under which funds are deposited with trustees, annuities are purchased under group contracts, or reserves are provided.

The Company does not fund retiree health care benefits in advance and has the right to modify these plans in the future.

In 2020 and 2019 the Company used December 31, 2020 and December 31, 2019, respectively, as the measurement date for all U.S. and international retirement and other benefit plans.

Net periodic benefit costs for the Company's defined benefit retirement plans and other benefit plans for 2020, 2019 and 2018 include the following components:

	Retirement Plans			Other Benefit Plans		
(Dollars in Millions)	**2020**	**2019**	**2018**	**2020**	**2019**	**2018**
Service cost	$ 1,380	1,163	1,283	287	274	269
Interest cost	955	1,096	996	133	185	148
Expected return on plan assets	(2,461)	(2,322)	(2,212)	(7)	(6)	(7)
Amortization of prior service cost	2	4	3	(31)	(31)	(31)
Recognized actuarial losses (gains)	891	579	852	142	129	123
Curtailments and settlements	23	73	1	—	—	—
Net periodic benefit cost	**$ 790**	**593**	**923**	**524**	**551**	**502**

Unrecognized gains and losses for the U.S. pension plans are amortized over the average remaining future service for each plan. For plans with no active employees, they are amortized over the average life expectancy. The amortization of gains and losses for the other U.S. benefit plans is determined by using a 10% corridor of the greater of the market value of assets or the accumulated postretirement benefit obligation. Total unamortized gains and losses in excess of the corridor are amortized over the average remaining future service.

Prior service costs/benefits for the U.S. pension plans are amortized over the average remaining future service of plan participants at the time of the plan amendment. Prior service cost/benefit for the other U.S. benefit plans is amortized over the average remaining service to full eligibility age of plan participants at the time of the plan amendment.

The following table represents the weighted-average actuarial assumptions:

	Retirement Plans			Other Benefit Plans		
Worldwide Benefit Plans	**2020**	**2019**	**2018**	**2020**	**2019**	**2018**
Net Periodic Benefit Cost						
Service cost discount rate	2.82 %	3.63	3.20	3.04	4.45	3.85
Interest cost discount rate	3.13 %	4.13	3.60	3.08	4.25	3.62
Rate of increase in compensation levels	4.00 %	3.99	3.98	4.25	4.29	4.29
Expected long-term rate of return on plan assets	8.12 %	8.31	8.46			
Benefit Obligation						
Discount rate	2.14 %	2.91	3.76	2.23	3.39	4.40
Rate of increase in compensation levels	4.00 %	4.01	3.97	4.27	4.29	4.29

The Company’s discount rates are determined by considering current yield curves representing high quality, long-term fixed income instruments. The resulting discount rates are consistent with the duration of plan liabilities. The Company's methodology in determining service and interest cost uses duration specific spot rates along that yield curve to the plans' liability cash flows.

The expected rates of return on plan asset assumptions represent the Company's assessment of long-term returns on diversified investment portfolios globally. The assessment is determined using projections from external financial sources, long-term historical averages, actual returns by asset class and the various asset class allocations by market.

The following table displays the assumed health care cost trend rates, for all individuals:

Health Care Plans	**2020**	**2019**
Health care cost trend rate assumed for next year	5.68 %	5.87 %
Rate to which the cost trend rate is assumed to decline (ultimate trend)	4.49 %	4.50 %
Year the rate reaches the ultimate trend rate	2040	2040

The following table sets forth information related to the benefit obligation and the fair value of plan assets at fiscal year-end 2020 and 2019 for the Company's defined benefit retirement plans and other post-retirement plans:

	Retirement Plans		Other Benefit Plans	
(Dollars in Millions)	**2020**	**2019**	**2020**	**2019**
Change in Benefit Obligation				
Projected benefit obligation — beginning of year	$ 37,188	31,670	5,076	4,480
Service cost	1,380	1,163	287	274
Interest cost	955	1,096	133	185
Plan participant contributions	61	63	—	—
Amendments[1]	(1,780)	—	—	—
Actuarial (gains) losses[2]	5,716	5,178	(75)	562
Divestitures & acquisitions	(88)	(278)	—	—
Curtailments, settlements & restructuring	(24)	(172)	—	—
Benefits paid from plan	(1,111)	(1,555)[3]	(396)	(431)
Effect of exchange rates	1,003	23	3	6
Projected benefit obligation — end of year	**$ 43,300**	**37,188**	**5,028**	**5,076**
Change in Plan Assets				
Plan assets at fair value — beginning of year	$ 32,201	26,818	115	180
Actual return on plan assets	5,524	6,185	14	19
Company contributions	870	908	357	347
Plan participant contributions	61	63	—	—
Settlements	(13)	(16)	—	—
Divestitures & acquisitions	(84)	(274)	—	—
Benefits paid from plan assets	(1,111)	(1,555)[3]	(396)	(431)
Effect of exchange rates	747	72	—	—
Plan assets at fair value — end of year	**$ 38,195**	**32,201**	**90**	**115**
Funded status — end of year	**$ (5,105)**	**(4,987)**	**(4,938)**	**(4,961)**
Amounts Recognized in the Company's Balance Sheet consist of the following:				
Non-current assets	$ 656	551	—	—
Current liabilities	(125)	(113)	(418)	(397)
Non-current liabilities	(5,636)	(5,425)	(4,520)	(4,564)
Total recognized in the consolidated balance sheet — end of year	**$ (5,105)**	**(4,987)**	**(4,938)**	**(4,961)**
Amounts Recognized in Accumulated Other Comprehensive Income consist of the following:				
Net actuarial loss	$ 10,860	8,835	1,463	1,685
Prior service cost (credit)[1]	(1,797)	(8)	(44)	(75)
Unrecognized net transition obligation	—	—	—	—
Total before tax effects	**$ 9,063**	**8,827**	**1,419**	**1,610**
Accumulated Benefit Obligations — end of year	**$ 40,356**	**33,416**		

[1]In January 2021, the Company announced that, effective on January 1, 2026, all eligible U.S. non-union employees, regardless of hire date, will earn benefits under the Retirement Value formula. This amendment does not affect the benefits accrued under the Final Average Pay formula for service before January 1, 2026.
[2]The actuarial losses for retirement plans in 2020 and 2019 was primarily related to decreases in discount rates.
[3]In 2019, the Company offered a voluntary lump-sum payment option for certain eligible former employees who are vested participants of the U.S. Qualified Defined Benefit Pension Plan. The distribution of the lump-sums was completed by the end of fiscal 2019. The amount distributed in 2019 was approximately $514 million.

(Dollars in Millions)	Retirement Plans 2020	Retirement Plans 2019	Other Benefit Plans 2020	Other Benefit Plans 2019
Amounts Recognized in Net Periodic Benefit Cost and Other Comprehensive Income				
Net periodic benefit cost	**$ 790**	**593**	**524**	**551**
Net actuarial (gain) loss	2,616	1,084	(81)	550
Amortization of net actuarial loss	(891)	(579)	(142)	(129)
Prior service cost (credit)	(1,780)	—	—	—
Amortization of prior service (cost) credit	(2)	(4)	31	31
Effect of exchange rates	293	1	1	1
Total loss/(income) recognized in other comprehensive income, before tax	**$ 236**	**502**	**(191)**	**453**
Total recognized in net periodic benefit cost and other comprehensive income	**$ 1,026**	**1,095**	**333**	**1,004**

The Company plans to continue to fund its U.S. Qualified Plans to comply with the Pension Protection Act of 2006. International Plans are funded in accordance with local regulations. Additional discretionary contributions are made when deemed appropriate to meet the long-term obligations of the plans. For certain plans, funding is not a common practice, as funding provides no economic benefit. Consequently, the Company has several pension plans that are not funded.

In 2020, the Company contributed $441 million and $429 million to its U.S. and international pension plans, respectively.

The following table displays the funded status of the Company's U.S. Qualified & Non-Qualified pension plans and international funded and unfunded pension plans at December 31, 2020 and December 31, 2019, respectively:

	U.S. Plans				International Plans			
	Qualified Plans		Non-Qualified Plans		Funded Plans		Unfunded Plans	
(Dollars in Millions)	2020	2019	2020	2019	2020	2019	2020	2019
Plan Assets	$ 25,554	21,398	—	—	12,641	10,803	—	—
Projected Benefit Obligation	25,466	22,034	2,748	2,544	14,541	12,132	545	478
Accumulated Benefit Obligation	24,158	19,831	2,495	2,115	13,210	11,040	493	430
Over (Under) Funded Status								
Projected Benefit Obligation	$ 88	(636)	(2,748)	(2,544)	(1,900)	(1,329)	(545)	(478)
Accumulated Benefit Obligation	1,396	1,567	(2,495)	(2,115)	(569)	(237)	(493)	(430)

Plans with accumulated benefit obligations in excess of plan assets have an accumulated benefit obligation, projected benefit obligation and plan assets of $8.8 billion, $9.8 billion and $4.4 billion, respectively, at the end of 2020, and $4.3 billion, $5.2 billion and $0.9 billion, respectively, at the end of 2019.

The following table displays the projected future benefit payments from the Company's retirement and other benefit plans:

(Dollars in Millions)	2021	2022	2023	2024	2025	2026-2030
Projected future benefit payments						
Retirement plans	$ 1,257	1,292	1,388	1,424	1,494	8,795
Other benefit plans	$ 427	440	453	465	417	2,273

The following table displays the projected future minimum contributions to the unfunded retirement plans. These amounts do not include any discretionary contributions that the Company may elect to make in the future.

(Dollars in Millions)	2021	2022	2023	2024	2025	2026-2030
Projected future contributions	$ 110	116	121	130	136	787

Each pension plan is overseen by a local committee or board that is responsible for the overall administration and investment of the pension plans. In determining investment policies, strategies and goals, each committee or board considers factors including, local pension rules and regulations; local tax regulations; availability of investment vehicles (separate accounts, commingled accounts, insurance funds, etc.); funded status of the plans; ratio of actives to retirees; duration of liabilities; and other relevant factors including: diversification, liquidity of local markets and liquidity of base currency. A majority of the Company's pension funds are open to new entrants and are expected to be on-going plans. Permitted investments are primarily liquid and/or listed, with little reliance on illiquid and non-traditional investments such as hedge funds.

The Company's retirement plan asset allocation at the end of 2020 and 2019 and target allocations for 2021 are as follows:

	Percent of Plan Assets		Target Allocation
	2020	2019	2021
Worldwide Retirement Plans			
Equity securities	66 %	74 %	67 %
Debt securities	34	26	33
Total plan assets	**100 %**	**100 %**	**100 %**

Determination of Fair Value of Plan Assets

The Plan has an established and well-documented process for determining fair values. Fair value is based upon quoted market prices, where available. If listed prices or quotes are not available, fair value is based upon models that primarily use, as inputs, market-based or independently sourced market parameters, including yield curves, interest rates, volatilities, equity or debt prices, foreign exchange rates and credit curves.

While the Plan believes its valuation methods are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

Valuation Hierarchy

The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described in the table below with Level 1 having the highest priority and Level 3 having the lowest.

The Net Asset Value (NAV) is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Following is a description of the valuation methodologies used for the investments measured at fair value.

- *Short-term investment funds* — Cash and quoted short-term instruments are valued at the closing price or the amount held on deposit by the custodian bank. Other investments are through investment vehicles valued using the NAV provided by the administrator of the fund. The NAV is a quoted price in a market that is not active and classified as Level 2.
- *Government and agency securities* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified within Level 1 of the valuation hierarchy. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows. When quoted market prices for a security are not available in an active market, they are classified as Level 2.
- *Debt instruments* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified as Level 1. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows and are classified as Level 2. Level 3 debt instruments are priced based on unobservable inputs.
- *Equity securities* — Equity securities are valued at the closing price reported on the major market on which the individual securities are traded. Substantially all equity securities are classified within Level 1 of the valuation hierarchy.
- *Commingled funds* — These investment vehicles are valued using the NAV provided by the fund administrator. Assets in the Level 2 category have a quoted market price.

- *Other assets* — Other assets are represented primarily by limited partnerships. These investment vehicles are valued using the NAV provided by the fund administrator. Other assets that are exchange listed and actively traded are classified as Level 1, while inactively traded assets are classified as Level 2.

The following table sets forth the Retirement Plans' investments measured at fair value as of December 31, 2020 and December 31, 2019:

	Quoted Prices in Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs[1] (Level 3)		Investments Measured at Net Asset Value		Total Assets	
(Dollars in Millions)	**2020**	**2019**	**2020**	**2019**	**2020**	**2019**	**2020**	**2019**	**2020**	**2019**
Short-term investment funds	$ 127	119	763	405	—	—	—	—	890	524
Government and agency securities	—	—	5,023	4,140	—	—	—	—	5,023	4,140
Debt instruments	—	—	3,931	3,452	—	—	—	—	3,931	3,452
Equity securities	14,375	12,483	2	2	—	—	—	—	14,377	12,485
Commingled funds	—	—	4,690	3,338	160	181	8,236	7,580	13,086	11,099
Other assets	—	—	11	9	21	19	856	473	888	501
Investments at fair value	**$ 14,502**	**12,602**	**14,420**	**11,346**	**181**	**200**	**9,092**	**8,053**	**38,195**	**32,201**

[1] The activity for the Level 3 assets is not significant for all years presented.

The Company's Other Benefit Plans are unfunded except for U.S. commingled funds (Level 2) of $90 million and $84 million at December 31, 2020 and December 31, 2019, respectively and U.S. short-term investment funds (Level 2) of $31 million at December 31, 2019.

The fair value of Johnson & Johnson Common Stock directly held in plan assets was $946 million (2.5% of total plan assets) at December 31, 2020 and $984 million (3.1% of total plan assets) at December 31, 2019.

11. Savings Plan

The Company has voluntary 401(k) savings plans designed to enhance the existing retirement programs covering eligible employees. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which he/she is eligible. Total Company matching contributions to the plans were $243 million, $235 million and $242 million in fiscal years 2020, 2019 and 2018, respectively.

12. Capital and Treasury Stock

Changes in treasury stock were:

(Amounts in Millions Except Treasury Stock Shares in Thousands)	Treasury Stock Shares	Treasury Stock Amount
Balance at December 31, 2017	437,318	$ 31,554
Employee compensation and stock option plans	(22,082)	(3,060)
Repurchase of common stock	42,283	5,868
Balance at December 30, 2018	457,519	34,362
Employee compensation and stock option plans	(20,053)	(2,691)
Repurchase of common stock	49,870	6,746
Balance at December 29, 2019	487,336	38,417
Employee compensation and stock option plans	(21,765)	(3,148)
Repurchase of common stock	21,760	3,221
Balance at January 3, 2021	487,331	$ 38,490

Aggregate shares of common stock issued were approximately 3,119,843,000 shares at the end of fiscal years 2020, 2019 and 2018.

Cash dividends paid were $3.98 per share in fiscal year 2020, compared with dividends of $3.75 per share in fiscal year 2019, and $3.54 per share in fiscal year 2018.

On January 4, 2021, the Board of Directors declared a regular cash dividend of $1.01 per share, payable on March 9, 2021 to shareholders of record as of February 23, 2021.

On December 17, 2018, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's shares of common stock. This share repurchase program was completed as of September 29, 2019.

13. Accumulated Other Comprehensive Income (Loss)

Components of other comprehensive income (loss) consist of the following:

(Dollars in Millions)	Foreign Currency Translation	Gain/(Loss) On Securities	Employee Benefit Plans	Gain/ (Loss) On Derivatives & Hedges	Total Accumulated Other Comprehensive Income (Loss)
December 31, 2017	$ (7,351)	232	(6,150)	70	(13,199)
Cumulative adjustment to retained earnings		(232) [1]			(232)
Net 2018 changes	(1,518)	—	(8)	(265)	(1,791)
December 30, 2018	(8,869)	—	(6,158)	(195)	(15,222)
Net 2019 changes	164	—	(733)	(100)	(669)
December 29, 2019	(8,705)	—	(6,891)	(295)	(15,891)
Net 2020 changes	(233)	1	(66)	947	649
January 3, 2021	$ (8,938)	1	(6,957)	652	(15,242)

[1] Per the adoption of ASU 2016-01- Financial Instruments

Amounts in accumulated other comprehensive income are presented net of the related tax impact. Foreign currency translation is not adjusted for income taxes where it relates to permanent investments in international subsidiaries. For additional details on comprehensive income see the Consolidated Statements of Comprehensive Income.

Details on reclassifications out of Accumulated Other Comprehensive Income:

Gain/(Loss) On Securities - reclassifications released to Other (income) expense, net.

Employee Benefit Plans - reclassifications are included in net periodic benefit cost. See Note 10 for additional details.

Gain/(Loss) On Derivatives & Hedges - reclassifications to earnings are recorded in the same account as the hedged transaction. See Note 6 for additional details.

14. International Currency Translation

For translation of its subsidiaries operating in non-U.S. Dollar currencies, the Company has determined that the local currencies of its international subsidiaries are the functional currencies except those in highly inflationary economies, which are defined as those which have had compound cumulative rates of inflation of 100% or more during the past three years, or where a substantial portion of its cash flows are not in the local currency. For the majority of the Company's subsidiaries the local currency is the functional currency.

In consolidating international subsidiaries, balance sheet currency effects are recorded as a component of accumulated other comprehensive income. The other current and non current assets line within the Statement of Cash flows includes the impact of foreign currency translation. This equity account includes the results of translating certain balance sheet assets and liabilities at current exchange rates and some accounts at historical rates, except for those located in highly inflationary economies, (Argentina and Venezuela). The translation of balance sheet accounts for highly inflationary economies are reflected in the operating results.

A rollforward of the changes during fiscal years 2020, 2019 and 2018 for foreign currency translation adjustments is included in Note 13.

Net currency transaction gains and losses included in Other (income) expense were losses of $209 million, $267 million and $265 million in fiscal years 2020, 2019 and 2018, respectively.

15. Earnings Per Share

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal years ended January 3, 2021, December 29, 2019 and December 30, 2018:

(In Millions Except Per Share Amounts)	2020	2019	2018
Basic net earnings per share	$ 5.59	5.72	5.70
Average shares outstanding — basic	2,632.8	2,645.1	2,681.5
Potential shares exercisable under stock option plans	118.3	136.3	139.0
Less: shares repurchased under treasury stock method	(80.4)	(97.8)	(92.5)
Convertible debt shares	—	0.7	0.7
Adjusted average shares outstanding — diluted	2,670.7	2,684.3	2,728.7
Diluted net earnings per share	$ 5.51	5.63	5.61

The diluted net earnings per share calculation for fiscal year 2020 excluded 18 million shares related to stock options, as the exercise price of these options was greater than their average market value. As of January 3, 2021, the Company did not have convertible debt.

The diluted net earnings per share calculation for fiscal year 2019 excluded an insignificant number of shares related to stock options, as the exercise price of these options was greater than the average market value of the Company’s stock. The diluted net earnings per share calculation for fiscal year 2019 included the dilutive effect of convertible debt that was offset by the related reduction in interest expense of $1 million after-tax.

The diluted net earnings per share calculation for fiscal year 2018 included all shares related to stock options, as the exercise price of all options was less than the average market value of the Company's stock. The diluted net earnings per share calculation for fiscal year 2018 included the dilutive effect of convertible debt that was offset by the related reduction in interest expense of $1 million after-tax.

16. Common Stock, Stock Option Plans and Stock Compensation Agreements

At January 3, 2021, the Company had 2 stock-based compensation plans. The shares outstanding are for contracts under the Company's 2005 Long-Term Incentive Plan and the 2012 Long-Term Incentive Plan. The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan. Under the 2012 Long-Term Incentive Plan, the Company may issue up to 650 million shares of common stock, plus any shares canceled, expired, forfeited, or not issued from the 2005 Long-Term Incentive Plan subsequent to April 26, 2012. Shares available for future grants under the 2012 Long-Term Incentive Plan were 277 million at the end of fiscal year 2020.

The compensation cost that has been charged against income for these plans was $1,005 million, $977 million and $978 million for fiscal years 2020, 2019 and 2018, respectively. The total income tax benefit recognized in the income statement for share-based compensation costs was $210 million, $227 million and $192 million for fiscal years 2020, 2019 and 2018, respectively. The Company also recognized additional income tax benefits of $248 million, $209 million and $264 million for fiscal years 2020, 2019 and 2018, respectively, for which options were exercised or restricted shares were vested. The total

unrecognized compensation cost was $804 million, $823 million and $827 million for fiscal years 2020, 2019 and 2018, respectively. The weighted average period for this cost to be recognized was 1.76 years, 1.71 years and 1.73 years for fiscal years 2020, 2019, and 2018, respectively. Share-based compensation costs capitalized as part of inventory were insignificant in all periods.

The Company settles employee benefit equity issuances with treasury shares. Treasury shares are replenished through market purchases throughout the year for the number of shares used to settle employee benefit equity issuances.

Stock Options

Stock options expire 10 years from the date of grant and vest over service periods that range from 6 months to 4 years. All options are granted at the average of the high and low prices of the Company's Common Stock on the New York Stock Exchange on the date of grant.

The fair value of each option award was estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the following table. For 2020, 2019 and 2018 grants, expected volatility represents a blended rate of 10-year weekly historical overall volatility rate, and a 5-week average implied volatility rate based on at-the-money traded Johnson & Johnson options with a life of 2 years. For all grants, historical data is used to determine the expected life of the option. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant.

The average fair value of options granted was $16.42, $17.80 and $17.98, in fiscal years 2020, 2019 and 2018, respectively. The fair value was estimated based on the weighted average assumptions of:

	2020	2019	2018
Risk-free rate	1.47 %	2.56 %	2.77 %
Expected volatility	15.33 %	16.27 %	15.77 %
Expected life (in years)	7.0	7.0	7.0
Expected dividend yield	2.60 %	2.80 %	2.70 %

A summary of option activity under the Plan as of January 3, 2021, December 29, 2019 and December 30, 2018, and changes during the years ending on those dates is presented below:

(Shares in Thousands)	Outstanding Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (Dollars in Millions)
Shares at December 31, 2017	111,306	$ 90.48	$ 5,480
Options granted	17,115	129.51	
Options exercised	(16,228)	75.44	
Options canceled/forfeited	(2,541)	112.90	
Shares at December 30, 2018	109,652	98.29	3,214
Options granted	19,745	131.94	
Options exercised	(14,785)	82.43	
Options canceled/forfeited	(2,975)	125.11	
Shares at December 29, 2019	111,637	105.63	4,478
Options granted	20,723	151.41	
Options exercised	(16,275)	86.05	
Options canceled/forfeited	(1,835)	137.62	
Shares at January 3, 2021	**114,250**	**$ 116.22**	**$ 4,703**

The total intrinsic value of options exercised was $1,021 million, $807 million and $1,028 million in fiscal years 2020, 2019 and 2018, respectively.

The following table summarizes stock options outstanding and exercisable at January 3, 2021:

(Shares in Thousands)	Outstanding			Exercisable	
Exercise Price Range	Options	Average Life[1]	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
$62.20-$72.54	11,111	1.8	$70.79	11,111	$70.79
$90.44-$100.06	22,304	3.6	$95.36	22,304	$95.36
$100.48-$115.67	28,180	5.6	$108.64	27,695	$108.51
$129.51-$131.94	32,553	7.6	$130.85	145	$130.53
$141.06-$151.41	20,102	9.1	$151.41	34	$151.41
	114,250	**6.0**	**$116.22**	**61,289**	**$96.97**

[1] Average contractual life remaining in years.

Stock options outstanding at December 29, 2019 and December 30, 2018 were 111,637 and an average life of 6.0 years and 109,652 and an average life of 6.2 years, respectively. Stock options exercisable at December 29, 2019 and December 30, 2018 were 60,761 at an average price of $88.88 and 54,862 at an average price of $82.03, respectively.

Restricted Share Units and Performance Share Units

The Company grants restricted share units which vest over service periods that range from 6 months to 3 years. The Company also grants performance share units, which are paid in shares of Johnson & Johnson Common Stock after the end of a three-year performance period. Whether any performance share units vest, and the amount that does vest, is tied to the completion of service periods that range from 6 months to 3 years and the achievement, over a three-year period, of three equally-weighted goals that directly align with or help drive long-term total shareholder return: operational sales, adjusted operational earnings per share, and relative total shareholder return. Beginning in fiscal 2020, performance shares were granted with two equally-weighted goals that directly align with or help drive long-term total shareholder return: adjusted operational earnings per share and relative total shareholder return. The number of shares actually earned at the end of the three-year period will vary, based only on actual performance, from 0% to 200% of the target number of performance share units granted.

A summary of the restricted share units and performance share units activity under the Plans as of January 3, 2021 is presented below:

(Shares in Thousands)	Outstanding Restricted Share Units	Outstanding Performance Share Units
Shares at December 29, 2019	16,769	2,174
Granted	5,051	816
Issued	(6,042)	(702)
Canceled/forfeited/adjusted	(780)	(52)
Shares at January 3, 2021	14,998	2,236

The average fair value of the restricted share units granted was $139.58, $121.31 and $119.67 in fiscal years 2020, 2019 and 2018, respectively, using the fair market value at the date of grant. The fair value of restricted share units was discounted for dividends, which are not paid on the restricted share units during the vesting period. The fair value of restricted share units issued was $650 million, $586 million and $614 million in 2020, 2019 and 2018, respectively.

The weighted average fair value of the performance share units granted was $160.54, $124.67 and $120.64 in fiscal years 2020, 2019 and 2018, calculated using the weighted average fair market value for each of the component goals at the date of grant.

The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. The fair value of performance share units issued was $91 million, $119 million and $129 million in fiscal years 2020, 2019 and 2018, respectively.

17. Segments of Business* and Geographic Areas

(Dollars in Millions)	Sales to Customers			% Change	
	2020	2019	2018	'20 vs. '19	'19 vs. '18
Consumer Health)[1]					
OTC					
U.S.	$ 2,460	2,010	1,850	22.4 %	8.6
International	2,364	2,434	2,484	(2.9)	(2.0)
Worldwide	4,824	4,444	4,334	8.5	2.5
Skin Health/Beauty[2]					
U.S.	2,350	2,392	2,403	(1.7)	(0.4)
International	2,100	2,201	1,979	(4.6)	11.2
Worldwide	4,450	4,593	4,382	(3.1)	4.8
Oral Care					
U.S.	683	621	637	9.9	(2.5)
International	958	906	918	5.7	(1.2)
Worldwide	1,641	1,528	1,555	7.4	(1.7)
Baby Care					
U.S.	376	362	422	3.7	(14.2)
International	1,141	1,313	1,436	(13.1)	(8.6)
Worldwide	1,517	1,675	1,858	(9.4)	(9.9)
Women's Health					
U.S.	13	12	13	8.2	(5.5)
International	888	974	1,036	(8.8)	(6.0)
Worldwide	901	986	1,049	(8.6)	(6.0)
Wound Care/Other					
U.S.	480	441	436	8.9	1.2
International	240	230	239	4.1	(3.9)
Worldwide	720	671	675	7.2	(0.6)
TOTAL CONSUMER HEALTH					
U.S.	6,362	5,839	5,761	9.0	1.4
International	7,691	8,059	8,092	(4.6)	(0.4)
Worldwide	14,053	13,898	13,853	1.1	0.3

[1]Previously referred to as Consumer
[2]Previously referred to as Beauty

PHARMACEUTICAL					
Immunology					
U.S.	10,175	9,641	9,073	5.5	6.3
International	4,880	4,309	4,047	13.2	6.5
Worldwide	15,055	13,950	13,120	7.9	6.3
REMICADE®					
U.S.	2,508	3,079	3,664	(18.5)	(16.0)
U.S. Exports	346	294	436	18.0	(32.7)
International	893	1,007	1,226	(11.4)	(17.8)
Worldwide	3,747	4,380	5,326	(14.4)	(17.8)
SIMPONI / SIMPONI ARIA®					
U.S.	1,155	1,159	1,051	(0.3)	10.2
International	1,088	1,029	1,033	5.8	(0.4)
Worldwide	2,243	2,188	2,084	2.6	5.0
STELARA®					
U.S.	5,240	4,346	3,469	20.6	25.3
International	2,467	2,015	1,687	22.4	19.4
Worldwide	7,707	6,361	5,156	21.1	23.4
TREMFYA®					
U.S.	926	764	453	21.3	68.5
International	421	248	91	69.9	**
Worldwide	1,347	1,012	544	33.2	85.9
OTHER IMMUNOLOGY					
U.S.	—	—	—	—	—
International	11	10	10	6.4	4.5
Worldwide	11	10	10	6.4	4.5
Infectious Diseases					
U.S.	1,735	1,597	1,378	8.6	15.9
International	1,839	1,815	1,926	1.3	(5.7)
Worldwide	3,574	3,413	3,304	4.7	3.3
EDURANT® / rilpivirine					
U.S.	44	50	58	(11.2)	(13.7)
International	920	812	758	13.3	7.1
Worldwide	964	861	816	11.9	5.6
PREZISTA® / PREZCOBIX® / REZOLSTA® / SYMTUZA®					
U.S.	1,587	1,422	1,169	11.6	21.6
International	597	689	786	(13.4)	(12.3)
Worldwide	2,184	2,110	1,955	3.5	8.0
OTHER INFECTIOUS DISEASES					
U.S.	104	126	151	(17.6)	(16.5)
International	323	315	382	2.6	(17.6)
Worldwide	427	441	533	(3.2)	(17.3)

Neuroscience					
U.S.	3,091	2,919	2,574	5.9	13.4
International	3,457	3,409	3,503	1.4	(2.7)
Worldwide	6,548	6,328	6,077	3.5	4.1
CONCERTA® / methylphenidate					
U.S.	183	233	229	(21.4)	1.7
International	439	463	434	(5.1)	6.6
Worldwide	622	696	663	(10.6)	4.9
INVEGA SUSTENNA® / XEPLION® / INVEGA TRINZA® / TREVICTA®					
U.S.	2,314	2,107	1,791	9.8	17.6
International	1,339	1,224	1,137	9.4	7.7
Worldwide	3,653	3,330	2,928	9.7	13.7
RISPERDAL CONSTA®					
U.S.	296	314	315	(5.9)	(0.3)
International	346	374	422	(7.5)	(11.4)
Worldwide	642	688	737	(6.8)	(6.7)
OTHER NEUROSCIENCE					
U.S.	298	266	239	12.4	11.4
International	1,334	1,349	1,510	(1.1)	(10.7)
Worldwide	1,632	1,614	1,749	1.1	(7.7)
Oncology					
U.S.	5,092	4,299	4,331	18.5	(0.7)
International	7,275	6,393	5,513	13.8	16.0
Worldwide	12,367	10,692	9,844	15.7	8.6
DARZALEX®					
U.S.	2,232	1,567	1,203	42.4	30.3
International	1,958	1,430	822	36.9	73.9
Worldwide	4,190	2,998	2,025	39.8	48.0
ERLEADA®					
U.S.	583	297	124	96.1	**
International	176	35	—	* *	**
Worldwide	760	332	124	* *	**
IMBRUVICA®					
U.S.	1,821	1,555	1,129	17.1	37.7
International	2,307	1,856	1,486	24.3	24.9
Worldwide	4,128	3,411	2,615	21.0	30.4
VELCADE®					
U.S.	—	—	—	—	—
International	408	751	1,116	(45.7)	(32.7)
Worldwide	408	751	1,116	(45.7)	(32.7)
ZYTIGA® /abiraterone acetate					
U.S.	373	810	1,771	(54.0)	(54.3)
International	2,097	1,985	1,727	5.6	15.0
Worldwide	2,470	2,795	3,498	(11.6)	(20.1)

OTHER ONCOLOGY					
U.S.	83	70	104	19.2	(32.7)
International	330	336	362	(1.9)	(7.2)
Worldwide	413	407	466	1.7	(12.7)
Pulmonary Hypertension					
U.S.	2,133	1,684	1,651	26.6	2.0
International	1,015	939	922	8.2	1.9
Worldwide	3,148	2,623	2,573	20.0	1.9
OPSUMIT®					
U.S.	1,008	766	700	31.7	9.4
International	631	562	515	12.3	9.0
Worldwide	1,639	1,327	1,215	23.5	9.2
UPTRAVI®					
U.S.	955	714	598	33.8	19.3
International	138	105	65	30.9	62.4
Worldwide	1,093	819	663	33.5	23.5
OTHER					
U.S.	169	205	353	(17.6)	(41.9)
International	247	272	342	(9.2)	(20.5)
Worldwide	416	476	695	(12.8)	(31.5)
Cardiovascular / Metabolism / Other					
U.S.	3,509	3,734	4,279	(6.0)	(12.7)
International	1,369	1,458	1,537	(6.1)	(5.2)
Worldwide	4,878	5,192	5,816	(6.0)	(10.7)
XARELTO®					
U.S.	2,345	2,313	2,477	1.4	(6.6)
International	—	—	—	—	—
Worldwide	2,345	2,313	2,477	1.4	(6.6)
INVOKANA® / INVOKAMET®					
U.S.	564	536	711	5.2	(24.6)
International	231	199	170	16.3	17.3
Worldwide	795	735	881	8.2	(16.5)
PROCRIT® / EPREX®					
U.S.	277	505	674	(45.1)	(25.1)
International	274	285	314	(3.8)	(9.2)
Worldwide	552	790	988	(30.2)	(20.0)
OTHER					
U.S.	323	380	417	(15.1)	(9.1)
International	864	974	1,053	(11.3)	(7.6)
Worldwide	1,186	1,353	1,470	(12.4)	(8.0)
TOTAL PHARMACEUTICAL					
U.S.	25,735	23,874	23,286	7.8	2.5
International	19,837	18,324	17,448	8.3	5.0
Worldwide	45,572	42,198	40,734	8.0	3.6

MEDICAL DEVICES					
Diabetes Care					
U.S.	—	—	371	—	**
International	—	—	638	—	**
Worldwide	—	—	1,009	—	**
Interventional Solutions					
U.S.	1,452	1,443	1,283	0.6	12.5
International	1,594	1,554	1,363	2.6	14.0
Worldwide	3,046	2,997	2,646	1.6	13.3
Orthopaedics					
U.S.	4,779	5,319	5,281	(10.2)	0.7
International	2,984	3,520	3,604	(15.2)	(2.3)
Worldwide	7,763	8,839	8,885	(12.2)	(0.5)
HIPS					
U.S.	793	863	841	(8.2)	2.6
International	487	575	577	(15.3)	(0.3)
Worldwide	1,280	1,438	1,418	(11.0)	1.4
KNEES					
U.S.	743	889	911	(16.4)	(2.4)
International	427	591	591	(27.8)	0.0
Worldwide	1,170	1,480	1,502	(21.0)	(1.4)
TRAUMA					
U.S.	1,648	1,652	1,599	(0.2)	3.3
International	966	1,068	1,100	(9.6)	(2.9)
Worldwide	2,614	2,720	2,699	(3.9)	0.8
SPINE, SPORTS & OTHER[3]					
U.S.	1,595	1,915	1,930	(16.7)	(0.8)
International	1,104	1,286	1,336	(14.1)	(3.8)
Worldwide	2,699	3,201	3,266	(15.7)	(2.0)
Surgery					
U.S.	3,249	3,828	4,125	(15.1)	(7.2)
International	4,983	5,673	5,776	(12.2)	(1.8)
Worldwide	8,232	9,501	9,901	(13.4)	(4.0)
ADVANCED					
U.S.	1,535	1,637	1,657	(6.2)	(1.2)
International	2,304	2,458	2,345	(6.2)	4.8
Worldwide	3,839	4,095	4,002	(6.2)	2.3
GENERAL					
U.S.	1,714	2,192	2,468	(21.8)	(11.2)
International	2,679	3,215	3,431	(16.7)	(6.3)
Worldwide	4,392	5,406	5,899	(18.8)	(8.4)
Vision					
U.S.	1,557	1,794	1,777	(13.2)	0.9
International	2,362	2,830	2,776	(16.5)	2.0
Worldwide	3,919	4,624	4,553	(15.2)	1.6

CONTACT LENSES / OTHER					
U.S.	1,213	1,304	1,237	(7.0)	5.4
International	1,781	2,088	2,065	(14.7)	1.1
Worldwide	2,994	3,392	3,302	(11.7)	2.7
SURGICAL					
U.S.	344	490	540	(29.7)	(9.4)
International	581	742	711	(21.7)	4.4
Worldwide	925	1,232	1,251	(24.9)	(1.6)
TOTAL MEDICAL DEVICES					
U.S.	11,036	12,384	12,837	(10.9)	(3.5)
International	11,923	13,579	14,157	(12.2)	(4.1)
Worldwide	22,959	25,963	26,994	(11.6)	(3.8)
WORLDWIDE					
U.S.	43,133	42,097	41,884	2.5	0.5
International	39,451	39,962	39,697	(1.3)	0.7
Worldwide	$ 82,584	82,059	81,581	0.6 %	0.6

(3) Previously referred to as Spine & Other
*Certain prior year amounts have been reclassified to conform to current year presentation
**Percentage greater than 100% or not meaningful

	Income (Loss) Before Tax			Identifiable Assets	
(Dollars in Millions)	**2020 (3)**	**2019 (4)**	**2018 (5)**	**2020**	**2019**
Consumer Health	$ (1,064)	2,061	2,320	$ 27,355	26,618
Pharmaceutical	15,462	8,816	12,568	66,158	56,292
Medical Devices	3,044	7,286	4,397	49,578	49,462
Total	17,442	18,163	19,285	143,091	132,372
Less: Expense not allocated to segments (1)	945	835	1,286		
General corporate (2)				31,803	25,356
Worldwide total	**$ 16,497**	**17,328**	**17,999**	**$ 174,894**	**157,728**

	Additions to Property, Plant & Equipment			Depreciation and Amortization		
(Dollars in Millions)	**2020**	**2019**	**2018**	**2020**	**2019**	**2018**
Consumer Health	$ 248	328	438	$ 785	765	688
Pharmaceutical	863	950	1,012	4,006	3,910	3,802
Medical Devices	1,980	1,912	1,843	2,140	2,014	2,103
Segments total	3,091	3,190	3,293	6,931	6,689	6,593
General corporate	256	308	377	300	320	336
Worldwide total	**$ 3,347**	**3,498**	**3,670**	**$ 7,231**	**7,009**	**6,929**

(Dollars in Millions)	Sales to Customers 2020	2019	2018	Long-Lived Assets [6] 2020	2019
United States	$ 43,133	42,097	41,884	$ 49,951	41,528
Europe	18,980	18,466	18,753	49,363	48,015
Western Hemisphere excluding U.S.	5,335	5,941	6,113	2,734	2,862
Asia-Pacific, Africa	15,136	15,555	14,831	5,484	5,486
Segments total	82,584	82,059	81,581	107,532	97,891
General corporate				1,029	1,049
Other non long-lived assets				66,333	58,788
Worldwide total	**$ 82,584**	**82,059**	**81,581**	**$ 174,894**	**157,728**

See Note 1 for a description of the segments in which the Company operates.

Export sales are not significant. In fiscal year 2020, the Company utilized three wholesalers distributing products for all three segments that represented approximately 16.0%, 12.0% and 12.0% of the total consolidated revenues. In fiscal year 2019, the Company had three wholesalers distributing products for all three segments that represented approximately 15.0%, 12.0% and 11.0% of the total consolidated revenues. In fiscal year 2018, the Company had three wholesalers distributing products for all three segments that represented approximately 14.0%, 11.0%, and 11.0% of the total consolidated revenues.

(1) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.

(2) General corporate includes cash, cash equivalents and marketable securities.

(3) Consumer Health includes:

- Litigation expense of $3.9 billion, primarily talc related reserves and certain settlements.

Pharmaceutical includes:

- Litigation expense of $0.8 billion, primarily related to the agreement in principle to settle opioid litigation
- An unrealized gain on securities of $0.5 billion
- A restructuring related charge of $0.1 billion

Medical Devices includes:

- A contingent consideration reversal of $1.1 billion related to the timing of certain developmental milestones associated with the Auris Health acquisition.
- Litigation expense of $0.3 billion
- A restructuring related charge of $0.3 billion
- An in-process research and development expense of $0.2 billion
- A Medical Device Regulation charge of $0.1 billion

(4) Consumer Health includes:

- A gain of $0.3 billion related to the Company's previously held equity investment in DR. CI:LABO
- Litigation expense of $0.4 billion
- A restructuring related charge of $0.1 billion

Pharmaceutical includes:

- Litigation expense of $4.3 billion of which $4.0 billion is related to the agreement in principle to settle opioid litigation
- An in-process research and development expense of $0.9 billion related to the Alios asset
- A research and development expense of $0.3 billion for an upfront payment related to argenx
- An unrealized gain on securities of $0.6 billion
- Actelion acquisition and integration related costs of $0.2 billion
- A restructuring charge of $0.1 billion

Medical Devices includes:

- A gain of $2.0 billion from the divestiture of the ASP business

- A restructuring related charge of $0.4 billion
- Litigation expense of $0.4 billion
- Auris Health acquisition and integration related costs of $0.1 billion

(5) Consumer Health includes:

- A gain of $0.3 billion from the divestiture of NIZORAL®
- Litigation expense of $0.3 billion

Pharmaceutical includes:

- An in-process research and development charge of $1.1 billion related to the Alios and XO1 assets and the corresponding XO1 contingent liability reversal of $0.2 billion
- Actelion acquisition and integration related costs of $0.2 billion
- An unrealized loss on securities of $0.2 billion
- A gain of $0.2 billion from the divestiture of certain non-strategic Pharmaceutical products

Medical Devices includes:

- Litigation expense of $1.7 billion
- A restructuring related charge of $0.6 billion
- AMO acquisition and integration related costs of $0.1 billion
- A gain of $0.5 billion from the divestiture of the LifeScan business

(6) Long-lived assets include property, plant and equipment, net for fiscal years 2020, and 2019 of $18,766 and $17,658, respectively, and intangible assets and goodwill, net for fiscal years 2020 and 2019 of $89,795 and $81,282, respectively.

18. Acquisitions and Divestitures

Certain businesses were acquired for $7.3 billion in cash and $0.4 billion of liabilities assumed during fiscal year 2020. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $7.5 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

The fiscal year 2020 acquisitions primarily included: all rights to the investigational compound bermekimab, which has multiple dermatological indications, along with certain employees from XBiotech Inc. (XBiotech), Momenta Pharmaceuticals, Inc. (Momenta), a company that discovers and develops novel therapies for immune-mediated diseases and the outstanding shares in Verb Surgical Inc., a company with significant robotics and data science capabilities.

During the fiscal first quarter of 2020, the Company completed the acquisition of all rights to the investigational compound bermekimab, which has multiple dermatological indications, along with certain employees from XBiotech Inc., for a purchase price of $0.8 billion. The fair value of the acquisition was allocated primarily to non-amortizable intangible assets, primarily IPR&D, for $0.8 billion applying a probability of success factor that ranged from 20% to 60% to reflect inherent development, regulatory and commercial risk for the different indications. The discount rate applied was approximately 16%. XBiotech may be eligible to receive additional payments upon the receipt of certain commercialization authorizations. The transaction was accounted for as a business combination and included in the Pharmaceutical segment.

Additionally, in the fiscal first quarter of 2020, the Company completed the acquisition of all outstanding shares in Verb Surgical Inc., a company with significant robotics and data science capabilities, including those shares previously held by Verily. The transaction was accounted for as a business combination and included in the Medical Devices segment. The fair value of the acquisition was allocated primarily to non-amortizable intangible assets, primarily IPR&D, for $0.4 billion, goodwill for $0.2 billion, other assets of $0.2 billion and liabilities assumed of $0.3 billion. The fair value of the Company's previously held equity investment in Verb Surgical Inc. was $0.4 billion.

On October 1, 2020, the Company completed the acquisition of Momenta for a purchase price of approximately $6.1 billion, net of cash acquired. The fair value of the acquisition was allocated primarily to non-amortizable intangible assets (IPR&D) of $6.0 billion, goodwill of $1.2 billion, other assets of $0.5 billion and liabilities of $1.6 billion. The assets acquired are intended to address substantial unmet medical need in maternal-fetal disorders, neuro-inflammatory disorders, rheumatology, dermatology and autoimmune hematology. Depending on the asset, probability of success factors ranging from 20% to 77% were used in the fair value calculation to reflect inherent development and regulatory risk of the IPR&D. The discount rate applied was approximately 13%. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not expected to be deductible for tax purposes. The transaction was accounted for as a business combination and included in the Pharmaceutical segment.

During fiscal year 2019 certain businesses were acquired for $5.8 billion in cash and $1.4 billion of liabilities assumed. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $6.8 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

The fiscal year 2019 acquisitions primarily included DR. CI:LABO, a Japanese company focused on the marketing, development and distribution of a broad range of dermocosmetic, cosmetic and skincare products and Auris Health, Inc. a privately held developer of robotic technologies, initially focused in lung cancer, with an FDA-cleared platform currently used in bronchoscopic diagnostic and therapeutic procedures.

On January 17, 2019, the Company acquired DR. CI:LABO, a Japanese company focused on the marketing, development and distribution of a broad range of dermocosmetic, cosmetic and skincare products for a total purchase price of approximately ¥230 billion, which equates to approximately $2.1 billion, using the exchange rate of 109.06 Japanese Yen to each U.S. Dollar on January 16, 2019. Additionally, in the fiscal first quarter of 2019, the Company recognized a pre-tax gain recorded in Other (income) expense, net, of approximately $0.3 billion related to the Company's previously held equity investment in DR. CI:LABO.

The Company treated this transaction as a business combination and included it in the Consumer Health segment. During the fiscal first quarter of 2020, the Company finalized the purchase price allocation. The final fair value of the acquisition was allocated primarily to amortizable intangible assets for $1.5 billion, goodwill for $1.2 billion and liabilities of $0.4 billion. The amortizable intangible assets were comprised of brand/trademarks and customer relationships with a weighted average life of 15.3 years The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not expected to be deductible for tax purposes.

On April 1, 2019 the Company completed the acquisition of Auris Health, Inc. for approximately $3.4 billion, net of cash acquired. Additional contingent payments of up to $2.35 billion, in the aggregate, may be payable upon reaching certain predetermined milestones. Auris Health was a privately held developer of robotic technologies, initially focused in lung cancer, with an FDA-cleared platform currently used in bronchoscopic diagnostic and therapeutic procedures. The Company treated this transaction as a business combination and included it in the Medical Devices segment. The fair value of the acquisition was allocated primarily to amortizable and non-amortizable intangible assets, primarily IPR&D for $3.0 billion, goodwill for $2.0 billion, marketable securities of $0.2 billion and liabilities assumed of $1.8 billion, which includes the fair value of the contingent payments mentioned above. During the fiscal second quarter of 2020, the Company finalized the purchase price allocation. During fiscal 2020, the Company recorded Other income of approximately $1.1 billion for the reversal of all of the contingent consideration related to the timing of certain developmental and commercial milestones, which are not expected to be met based on the Company’s current timelines. During the fiscal third quarter of 2020, the Company recorded a partial IPR&D impairment charge of $0.1 billion related to timing and progression of the digital surgery platforms. A probability of success factor ranging from 55% to 95% was used in the fair value calculation to reflect inherent regulatory and commercial risk of the contingent payments and IPR&D. The discount rate applied was approximately 10%. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not expected to be deductible for tax purposes.

During fiscal year 2018 certain businesses were acquired for $0.9 billion in cash and $0.1 billion of liabilities assumed. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition. The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $1.0 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

In accordance with U.S. GAAP standards related to business combinations, and goodwill and other intangible assets, supplemental pro forma information for fiscal years 2020, 2019 and 2018 is not provided, as the impact of the aforementioned acquisitions did not have a material effect on the Company’s results of operations, cash flows or financial position.

Divestitures

Subsequent to fiscal 2020, in separate transactions, the Company divested two brands outside the U.S. within the Pharmaceutical segment and received combined proceeds of approximately $0.6 billion. The Company will reflect these brand divestitures in its 2021 financial results.

During fiscal year 2020, the Company sold 11.8 million shares of Idorsia LTD (Idorsia), or its 8.3% ownership in the company. The transaction resulted in gross proceeds of approximately CHF 337 million ($357 million) based on a sales price of CHF 28.55/share and an immaterial net loss. The Company currently has rights to at least an additional 38.7 million shares (or approximately 20% of Idorsia equity) through a convertible loan with a principal amount of CHF 445 million (due June 2027). Idorsia also has access to an approximate CHF 243 million credit facility with the Company. As of January 3, 2021, Idorsia has not made any draw-downs under the credit facility.

During fiscal year 2019, the Company divested its ASP business to Fortive Corporation for an aggregate value of approximately $2.8 billion, consisting of $2.7 billion of cash proceeds and $0.1 billion of retained net receivables. The Company recognized a pre-tax gain recorded in Other (income) expense, net, of approximately $2.0 billion.

During fiscal year 2018, the Company divested the LifeScan Inc business for approximately $2.1 billion and retained certain net liabilities. Other divestitures in fiscal year 2018 included: NIZORAL®, RoC® and certain non-strategic Pharmaceutical products. In 2018, the pre-tax gains on the divestitures were approximately $1.2 billion.

In fiscal year 2018, the Company accepted a binding offer to form a strategic collaboration with Jabil Inc., one of the world's leading manufacturing services providers for health care products and technology products. The Company is expanding a 12-year relationship with Jabil to produce a range of products within the Ethicon Endo-Surgery and DePuy Synthes businesses. This transaction includes the transfer of employees and manufacturing sites. The transfers were completed in fiscal year 2020. As of January 3, 2021, there were no assets held for sale on the Consolidated Balance Sheet. As of December 29, 2019, the assets held for sale on the Consolidated Balance Sheet were $0.1 billion of inventory and property, plant and equipment, net. For additional details on the global supply chain restructuring see Note 20 to the Consolidated Financial Statements.

19. Legal Proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability; intellectual property; commercial; supplier indemnification and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of their business. Due to the ongoing impacts of the COVID-19 pandemic, certain trials have been rescheduled or delayed. The Company continues to monitor its legal proceedings as the situation evolves.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of January 3, 2021, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; ability to achieve comprehensive multi-party settlements; complexity of related cross-claims and counterclaims; and/or there are numerous parties involved. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution of, or increase in accruals for, one or more of these matters in any reporting period may have a material adverse effect on the Company's results of operations and cash flows for that period.

PRODUCT LIABILITY

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While the Company believes it has substantial defenses, it is not feasible to predict the ultimate outcome of litigation. From time to time, even if it has substantial defenses, the Company considers isolated settlements based on a variety of circumstances. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

The most significant of these cases include: the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System; the PINNACLE® Acetabular Cup System; pelvic meshes; RISPERDAL®; XARELTO®; body powders containing talc, primarily JOHNSONS® Baby Powder; INVOKANA®; and ETHICON PHYSIOMESH® Flexible Composite Mesh. As of January 3, 2021, in the United States there were approximately 560 plaintiffs with direct claims in pending lawsuits regarding

injuries allegedly due to the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System; 7,800 with respect to the PINNACLE® Acetabular Cup System; 14,900 with respect to pelvic meshes; 9,300 with respect to RISPERDAL®; 12,600 with respect to XARELTO®; 25,000 with respect to body powders containing talc; 300 with respect to INVOKANA®; and 4,200 with respect to ETHICON PHYSIOMESH® Flexible Composite Mesh.

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System used in hip replacement surgery. Claims for personal injury have been made against DePuy and Johnson & Johnson. The number of pending lawsuits is expected to fluctuate as certain lawsuits are settled or dismissed and additional lawsuits are filed. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada, Australia, Ireland, Germany, India and Italy. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR Hip System plaintiffs to establish a program to settle claims with eligible ASR Hip patients in the United States who had surgery to replace their ASR Hips, known as revision surgery, as of August 31, 2013. DePuy reached additional agreements in February 2015 and March 2017, which further extended the settlement program to include ASR Hip patients who had revision surgeries after August 31, 2013 and prior to February 15, 2017. This settlement program has resolved more than 10,000 claims, therefore bringing to resolution significant ASR Hip litigation activity in the United States. However, lawsuits in the United States remain, and the settlement program does not address litigation outside of the United States. In Australia, a class action settlement was reached that resolved the claims of the majority of ASR Hip patients in that country. In Canada, the Company has reached agreements to settle the class actions filed in that country. The Company continues to receive information with respect to potential additional costs associated with this recall on a worldwide basis. The Company has established accruals for the costs associated with the United States settlement program and DePuy ASR™ Hip-related product liability litigation.

Claims for personal injury have also been made against DePuy Orthopaedics, Inc. and Johnson & Johnson (collectively, DePuy) relating to the PINNACLE® Acetabular Cup System used in hip replacement surgery. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Texas. Litigation has also been filed in some state courts and in countries outside of the United States. Several adverse verdicts have been rendered against DePuy, one of which was reversed on appeal and remanded for retrial. During the first quarter of 2019, DePuy established a United States settlement program to resolve these cases. As part of the settlement program, adverse verdicts have been settled. The Company has established an accrual for product liability litigation associated with the PINNACLE® Acetabular Cup System and the related settlement program.

Claims for personal injury have been made against Ethicon, Inc. (Ethicon) and Johnson & Johnson arising out of Ethicon's pelvic mesh devices used to treat stress urinary incontinence and pelvic organ prolapse. The Company continues to receive information with respect to potential costs and additional cases. Cases filed in federal courts in the United States had been organized as a multi-district litigation (MDL) in the United States District Court for the Southern District of West Virginia. The MDL Court is remanding cases for trial to the jurisdictions where the case was originally filed and additional pelvic mesh lawsuits have been filed, and remain, outside of the MDL. The Company has settled or otherwise resolved a majority of the United States cases and the estimated costs associated with these settlements and the remaining cases are reflected in the Company's accruals. In addition, class actions and individual personal injury cases or claims have been commenced in various countries outside of the United States, including claims and cases in the United Kingdom, the Netherlands, and class actions in Israel, Australia and Canada, seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices. In November 2019, the Federal Court of Australia issued a judgment regarding its findings with respect to liability in relation to the three Lead Applicants and generally in relation to the design, manufacture, pre and post-market assessments and testing, and supply and promotion of the devices in Australia used to treat stress urinary incontinence and pelvic organ prolapse. In March 2020, the Court entered damages awards to the three Lead Applicants. The Company is appealing the decision. With respect to other group members, there will be an individual case assessment process which will require proof of use and causally related loss. The form of the individual case assessment process has not yet been determined by the Court. The class actions in Canada were discontinued in 2020 as a result of a settlement of a group of cases. The Company has established accruals with respect to product liability litigation associated with Ethicon's pelvic mesh products.

Following a June 2016 worldwide market withdrawal of ETHICON PHYSIOMESH® Flexible Composite Mesh, claims for personal injury have been made against Ethicon, Inc. and Johnson & Johnson alleging personal injury arising out of the use of this hernia mesh device. Cases filed in federal courts in the United States have been organized as a multi-district litigation (MDL) in the United States District Court for the Northern District of Georgia. A multi-county litigation (MCL) has also been formed in New Jersey state court and assigned to Atlantic County for cases pending in New Jersey. In addition to the matters in the MDL and MCL, there are additional lawsuits pending in the United States District Court for the Southern District of Ohio, which are part of the MDL for polypropylene mesh devices manufactured by C.R. Bard, Inc., and lawsuits pending outside the United States. Discovery is proceeding in these cases and certain of the cases are in preparation for trials.

Claims have also been filed against Ethicon and Johnson & Johnson alleging personal injuries arising from the PROCEED® Mesh and PROCEED® Ventral Patch hernia mesh products. In March 2019, the New Jersey Supreme Court entered an order consolidating these cases pending in New Jersey as an MCL in Atlantic County Superior Court. Additional cases have been filed in various federal and state courts in the US, and in jurisdictions outside the US. Discovery is underway in these cases.

In September 2019, plaintiffs' attorney filed an application with the New Jersey Supreme Court seeking centralized management of 107 PROLENE™ Polypropylene Hernia System ("PHS") cases. The New Jersey Supreme Court granted plaintiffs application in January 2020 and those cases have also been transferred to an MCL in Atlantic County Superior Court. Discovery is underway in these cases.

The Company has established accruals with respect to product liability litigation associated with ETHICON PHYSIOMESH® Flexible Composite Mesh, PROCEED® Mesh and PROCEED® Ventral Patch, and PROLENE™ Polypropylene Hernia System products.

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and Johnson & Johnson arising out of the use of RISPERDAL®, and related compounds, indicated for the treatment of schizophrenia, acute manic or mixed episodes associated with bipolar I disorder and irritability associated with autism. Lawsuits have been primarily filed in state courts in Pennsylvania, California, and Missouri. Other actions are pending in various courts in the United States and Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has successfully defended a number of these cases but there have been verdicts against the Company, including a verdict in October 2019 of $8.0 billion of punitive damages related to one single plaintiff which was subsequently reduced in January 2020 to $6.8 million by the trial judge. The Company and plaintiff are each appealing this judgment. The Company has settled or otherwise resolved many of the United States cases and the costs associated with these settlements are reflected in the Company's accruals.

Claims for personal injury arising out of the use of XARELTO®, an oral anticoagulant, have been made against Janssen Pharmaceuticals, Inc. (JPI); Johnson & Johnson (J&J); and JPI's collaboration partner for XARELTO®, Bayer AG and certain of its affiliates. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Eastern District of Louisiana. In addition, cases have been filed in state courts across the United States. Many of these cases were consolidated into a state mass tort litigation in Philadelphia, Pennsylvania and in a coordinated proceeding in Los Angeles, California. Class action lawsuits also have been filed in Canada. In March 2019, JPI and J&J announced an agreement in principle to the settle the XARELTO® cases in the United States; the settlement agreement was executed in May 2019, the settlement became final in December 2019, and the settlement was funded in January 2020. This resolved the majority of cases pending in the United States. The Company has established accruals for its costs associated with the United States settlement program and XARELTO® related product liability litigation.

Personal injury claims alleging that talc causes cancer have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSON'S® Baby Powder. The number of pending personal injury lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California, and suits have also been filed outside the United States. The majority of cases are pending in federal court, organized into a multi-district litigation (MDL) in the United States District Court for the District of New Jersey. In the MDL, the parties sought to exclude experts through Daubert motions. In April 2020, the Court issued rulings that limit the scope of testimony, including some theories and testing methods, for certain plaintiff expert witnesses and denied plaintiffs' attempt to limit the scope of testimony of certain of the Company's witnesses. With this ruling made, case-specific discovery has begun per the Court's directive.

In talc cases that have previously gone to trial, the Company has obtained defense verdicts in a number of them, but there have also been verdicts against the Company, many of which have been reversed on appeal. In June 2020, the Missouri Court of Appeals reversed in part and affirmed in part a July 2018 verdict of $4.7 billion in *Ingham v. Johnson & Johnson, et al.,* No. ED 207476 (Mo. App.), reducing the overall award to $2.1 billion and, with additional interest as of January 3, 2021, as the Company pursues further appeal, is currently $2.5 billion (the *Ingham* decision). An application for transfer of the case to the Missouri Supreme Court was subsequently denied, and the Company is currently seeking review by the United States Supreme Court. The Company continues to believe that it has strong legal grounds for the appeal of this verdict, as well as other verdicts that it has appealed. Notwithstanding the Company's confidence in the safety of its talc products, in certain circumstances the Company has and may settle cases. The Company has established an accrual for defense costs and reserves for the resolution of certain cases and claims, including the *Ingham* decision currently on appeal, in connection with product liability litigation associated with body powders containing talc.

In February 2019, the Company's talc supplier, Imerys Talc America, Inc. and two of its affiliates, Imerys Talc Vermont, Inc. and Imerys Talc Canada, Inc. (collectively, Imerys) filed a voluntary chapter 11 petition commencing a reorganization under

the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware (Imerys Bankruptcy). The Imerys Bankruptcy relates to Imerys' potential liability for personal injury from exposure to talcum powder sold by Imerys (Talc Claims). In its bankruptcy filing, Imerys noted certain claims it alleges it has against the Company for indemnification and rights to joint insurance proceeds. The Company previously proposed to resolve Imerys' (and the Company's) obligations arising out of the Talc Claims by agreeing to assume the defense of litigation of all Talc Claims involving the Company's products, waiving the Company's indemnification claims against Imerys, and lifting the automatic stay to enable the Talc Claims to proceed outside the bankruptcy forum with the Company agreeing to settle or pay any judgment against Imerys. In May 2020, Imerys and the asbestos claimants' committee (Plan Proponents) filed their Plan of Reorganization (the Plan) and the Disclosure Statement related thereto agreeing to put its North American operations up for auction which was subsequently amended. The Company has objected to the Disclosure Statement and intends to object to the Plan of Reorganization as currently structured. Additionally, in June 2020, Cyprus Mines Corporation and its parent (Cyprus) filed an adversary proceeding against the Company as well as Imerys seeking a declaration of indemnity under certain contractual agreements. The Company denies such indemnification is owed and filed a motion to dismiss the adversary complaint arguing, among other things, that the Court does not have subject matter jurisdiction over Cyprus's claims against the Company. The Plan Proponents filed numerous amendments to the Plan and Disclosure Statement to which the Company objected. A hearing on the Plan Proponent's Disclosure Statement was held in January 2021, and the Court entered an order approving the Disclosure Statement for the Ninth Amended Joint Chapter 11 Plan of Reorganization of Imerys Talc America, Inc. and its Debtor Affiliates allowing Debtors to proceed with soliciting votes on the Plan. The Company intends to continue to object to the Plan. A hearing to consider confirmation of the Plan has been scheduled for June 2021.

In February 2018, a securities class action lawsuit was filed against Johnson & Johnson and certain named officers in the United States District Court for the District of New Jersey, alleging that Johnson & Johnson violated the federal securities laws by failing to disclose alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S® Baby Powder, and that purchasers of Johnson & Johnson's shares suffered losses as a result. Plaintiff is seeking damages. In April 2019, the Company moved to dismiss the complaint and briefing on the motion was complete as of August 2019. In December 2019, the Court denied, in part, the motion to dismiss. In March 2020, Defendants answered the complaint. Discovery is underway.

In June 2019, a shareholder filed a complaint initiating a summary proceeding in New Jersey state court for a books and records inspection. In August 2019, Johnson & Johnson responded to the books and records complaint and filed a cross motion to dismiss. In September 2019, Plaintiff replied and the Court heard oral argument. The Court has not yet ruled in the books and records action. In October 2019, December 2019, and January 2020, four shareholders filed four separate derivative lawsuits against Johnson & Johnson as the nominal defendant and its current directors and certain officers as defendants in the United States District Court for the District of New Jersey, alleging a breach of fiduciary duties related to the alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S® Baby Powder, and that Johnson & Johnson has suffered damages as a result of those alleged breaches. In February 2020, the four cases were consolidated into a single action under the caption *In re Johnson & Johnson Talc Stockholder Derivative Litigation*.

In July 2020, a report was delivered to the Company's Board of Directors by independent counsel retained by the Board to investigate the allegations in the derivative lawsuits and in a series of shareholder letters that the Board received raising similar issues. Four of the shareholders who sent demands are plaintiffs in the *In re Johnson & Johnson Talc Stockholder Derivative Litigation*. The independent counsel recommended that the Company reject the shareholder demands and take the steps that are necessary or appropriate to secure dismissal of the derivative lawsuits. The Board unanimously adopted the recommendations of the independent counsel's report. In October 2020, the shareholders filed a consolidated complaint, and in January 2021, Johnson & Johnson moved to dismiss the consolidated complaint.

In January 2019, two ERISA class action lawsuits were filed by participants in the Johnson & Johnson Savings Plan against Johnson & Johnson, its Pension and Benefits Committee, and certain named officers in the United States District Court for the District of New Jersey, alleging that the defendants breached their fiduciary duties by offering Johnson & Johnson stock as a Johnson & Johnson Savings Plan investment option when it was imprudent to do so because of failures to disclose alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S® Baby Powder. Plaintiffs are seeking damages and injunctive relief. In September 2019, Defendants filed a motion to dismiss. In April 2020, the Court granted Defendants' motion but granted leave to amend. In June 2020, Plaintiffs filed an amended complaint, and in July 2020, Defendants moved to dismiss the amended complaint. As of October 2020, briefing on Defendants' motion was complete. A lawsuit pending in the Superior Court of California for the County of San Diego alleging violations of California's Consumer Legal Remedies Act relating to JOHNSON'S® Baby Powder has been resolved in the Company's favor. In that lawsuit, the plaintiffs allege that Johnson & Johnson violated the CLRA by failing to provide required Proposition 65 warnings. In July 2019, the Company filed a notice of removal to the United States District Court for the Southern District of California and plaintiffs filed a second amended complaint shortly thereafter. In October 2019, the Company moved to dismiss the second amended complaint for failure to state a claim upon which relief may be granted. In response to those motions, plaintiffs filed a third amended complaint. In December 2019, the Company moved to dismiss the third amended complaint for failure to state a claim upon which relief may be granted. In April 2020, the Court granted the motion to dismiss but granted leave to amend. In May 2020, plaintiffs filed a Fourth Amended Complaint but indicated that they would be filing a motion for leave to file a fifth amended complaint. Plaintiffs filed a Fifth Amended Complaint in August 2020. The Company moved to dismiss the Fifth Amended Complaint for failure to state a claim upon which relief may be granted. In January 2021, the Court issued an Order and opinion ruling in the Company's favor and granting the motion to dismiss with prejudice.

In January 2020, the Abtahi Law Group filed an action under Proposition 65 against Johnson & Johnson and Johnson & Johnson Consumer Inc. as well as a number of other alleged talcum powder manufacturers and distributors, including one California company. In that action, the plaintiff alleges contamination of talcum powder products with unsafe levels of arsenic, hexavalent chromium and lead. The plaintiff seeks civil penalties and injunctive relief. Defendants filed a motion for summary judgment in January 2021, and a hearing has been scheduled for April 2021. Limited informal discovery is continuing.

In addition, the Company has received preliminary inquiries and subpoenas to produce documents regarding these matters from Senator Murray, a member of the Senate Committee on Health, Education, Labor and Pensions, the Department of Justice, the Securities and Exchange Commission (SEC) and the U.S. Congressional Subcommittee on Economic and Consumer Policy. The Company produced documents as required in response and will continue to cooperate with government inquiries. In November 2020, the SEC terminated its investigation.

Claims for personal injury have been made against a number of Johnson & Johnson companies, including Janssen Pharmaceuticals, Inc. and Johnson & Johnson, arising out of the use of INVOKANA®, a prescription medication indicated to improve glycemic control in adults with Type 2 diabetes. In December 2016, lawsuits filed in federal courts in the United States were organized as a multi-district litigation in the United States District Court for the District of New Jersey. Cases have also been filed in state courts. Class action lawsuits have been filed in Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has settled or otherwise resolved many of the cases and claims in the United States and the costs associated with these settlements are reflected in the Company's accruals.

Claims for personal injury have been made against a number of Johnson & Johnson companies, including Janssen Pharmaceuticals, Inc. and Johnson & Johnson, arising out of the use of ELMIRON®, a prescription medication indicated for the relief of bladder pain or discomfort associated with interstitial cystitis. These lawsuits, which allege that ELMIRON® contributes to the development of permanent retinal injury and vision loss, have been filed in both state and federal courts across the United States. In December 2020, the federal cases, including two putative class action cases seeking medical monitoring, were organized as a multi-district litigation in the United States District Court for the District of New Jersey. In addition, three class action lawsuits have been filed in Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has established accruals for defense costs associated with ELMIRON® related product liability litigation.

INTELLECTUAL PROPERTY

Certain subsidiaries of Johnson & Johnson are subject, from time to time, to legal proceedings and claims related to patent, trademark and other intellectual property matters arising out of their businesses. Many of these matters involve challenges to the coverage and/or validity of the patents on various products and allegations that certain of the Company’s products infringe the patents of third parties. Although these subsidiaries believe that they have substantial defenses to these challenges and allegations with respect to all significant patents, there can be no assurance as to the outcome of these matters. A loss in any of these cases could adversely affect the ability of these subsidiaries to sell their products, result in loss of sales due to loss of market exclusivity, require the payment of past damages and future royalties, and may result in a non-cash impairment charge for any associated intangible asset. Significant matters are described below.

Medical Devices

In November 2016, MedIdea, L.L.C. (MedIdea) filed a patent infringement lawsuit against DePuy Orthopaedics, Inc. in the United States District Court for the Northern District of Illinois alleging infringement by the ATTUNE® Knee System. In April 2017, MedIdea filed an amended complaint adding DePuy Synthes Products, Inc. and DePuy Synthes Sales, Inc. as named defendants (collectively, DePuy). MedIdea alleged infringement of United States Patent Nos. 6,558,426 (’426); 8,273,132 (’132); 8,721,730 (’730) and 9,492,280 (’280) relating to posterior stabilized knee systems. Specifically, MedIdea alleges that the SOFCAM™ Contact feature of the ATTUNE® posterior stabilized knee products infringes the patents-in-suit. MedIdea is seeking monetary damages and injunctive relief. In June 2017, the case was transferred to the United States District Court for the District of Massachusetts. In November 2019, judgment was entered in favor of DePuy. In January 2021, the U.S. Court of Appeals for the Federal Circuit affirmed.

In December 2016, Dr. Ford Albritton sued Acclarent, Inc. (Acclarent) in United States District Court for the Northern District of Texas alleging that Acclarent’s RELIEVA® Spin and RELIEVEA SpinPlus® products infringe U.S. Patent No. 9,011,412. Dr. Albritton also alleges breach of contract, fraud and that he is the true owner of Acclarent’s U.S. Patent No. 8,414,473. Trial is scheduled to begin in October 2021.

In November 2017, Board of Regents, The University of Texas System and TissueGen, Inc. (collectively, UT) filed a lawsuit in the United States District Court for the Western District of Texas against Ethicon, Inc. and Ethicon US, LLC (collectively, Ethicon) alleging the manufacture and sale of VICRYL® Plus Antibacterial Sutures, MONOCRYL® Plus Antibacterial Sutures, PDS® Plus Antibacterial Sutures, STRATAFIX® PDS® Antibacterial Sutures and STRATAFIX® MONOCRYL® Plus Antibacterial Sutures infringe plaintiffs' United States Patent Nos. 6,596,296 ('296) and 7,033,603 ('603) directed to implantable polymer drug releasing biodegradable fibers containing a therapeutic agent. UT is seeking damages and an injunction. In December 2018, Ethicon filed petitions with the United States Patent and Trademark Office (USPTO), seeking Inter Partes Review (IPR) of both asserted patents. In June 2020, the USPTO denied institution of the '296 patent IPR and granted institution of the '603 patent IPR. UT dismissed the '603 patent from the suit and no longer accuses PDS® Plus Antibacterial Sutures or STRATAFIX® PDS® Plus Antibacterial Sutures of infringement. The previously scheduled district court trial has been postponed.

In August 2018, Intuitive Surgical, Inc. and Intuitive Surgical Operations, Inc. (collectively, Intuitive) filed a patent infringement suit against Auris Health, Inc. (Auris) in United States District Court for the District of Delaware. In the suit, Intuitive alleges willful infringement of U.S. Patent Nos. 6,246,200 ('200); 6,491,701 ('701); 6,522,906 ('906); 6,800,056 ('056); 8,142,447 ('447); 8,620,473 ('473); 8,801,601 ('601); and 9,452,276 ('276) based on Auris' Monarch™ Platform. Auris filed IPR Petitions with the USPTO regarding the '200, '056, '601 '701, '447, '276 and '906 patents. Intuitive subsequently dropped the '200, '473 and '701 patents from the suit. In December 2019, the USPTO instituted review of the '601 patent and denied review of the '056 patent. In February and March 2020, the USPTO instituted review of the '200, '447, '701 and '906 patents and denied review of the '276 patent. In December 2020, the USPTO declared all of the challenged claims in the '601 patent to be invalid. Intuitive has appealed that decision. The district court trial is scheduled to begin in June 2021.

In August 2019, RSB Spine LLC (RSB Spine) filed a patent infringement suit against DePuy Synthes, Inc. in United States District Court for the District of Delaware. In October 2019, RSB Spine amended the complaint to change the named defendants to DePuy Synthes Sales, Inc. and DePuy Synthes Products, Inc. In the suit, RSB Spine alleges willful infringement of United States Patent Nos. 6,984,234 and 9,713,537 by one or more of the following products: ZERO-P-VA™ Spacer, ZERO-P® Spacer, ZERO-P NATURAL™ Plate, SYNFIX® LR Spacer and SYNFIX® Evolution System. RSB Spine seeks monetary damages and injunctive relief. In November 2019, the suit was consolidated for pre-trial purposes with other patent infringement suits brought by RSB Spine in the United States District Court for the District of Delaware against Life Spine, Inc., Medacta USA, Inc., and Precision Spine, Inc. In June 2020, the case was stayed pending IPR proceedings filed by the Consolidated Defendants involving the asserted patents.

In March 2020, Osteoplastics, LLC filed a patent infringement suit against DePuy Synthes, Inc., DePuy Synthes Products, Inc., Medical Device Business Services, Inc., and Synthes, Inc. (collectively, DePuy Synthes) in the United States District Court for the District of Delaware. In the suit, Osteoplastics alleges willful infringement of U.S. Patent Nos. 8,781,557; 9,929,920; 9,330,206; 9,626,756; 9,672,617; 9,672,302; and 9,275,191 based on the PROPLAN CMF® Virtual Surgical Planning Services and the TruMatch® CMF Personalize Solutions. In April 2020, Osteoplastics filed an amended complaint to substitute U.S. Patent No. 9,292,920 for U.S. Patent No. 9,929,920. Osteoplastics seeks monetary damages and injunctive relief. In June 2020, DePuy Synthes filed a motion to dismiss the complaint. In October 2020, the Court dismissed Medical Device Business Services, Inc. from the case but otherwise denied the motion. Trial is scheduled for October 2022.

Pharmaceutical

Litigation Against Filers of Abbreviated New Drug Applications (ANDAs)

The following summarizes lawsuits pending against generic companies that have filed ANDAs with the FDA or undertaken similar regulatory processes outside of the United States, seeking to market generic forms of products sold by various subsidiaries of Johnson & Johnson prior to expiration of the applicable patents covering those products. These ANDAs typically include allegations of non-infringement and invalidity of the applicable patents. In the event the subsidiaries are not successful in an action, or the automatic statutory stay of the ANDAs expires before the United States District Court rulings are obtained, the third-party companies involved would have the ability, upon approval of the FDA, to introduce generic versions of their products to the market, resulting in the potential for substantial market share and revenue losses for the applicable products, and which may result in a non-cash impairment charge in any associated intangible asset. In addition, from time to time, subsidiaries may settle these types of actions and such settlements can involve the introduction of generic versions of the products at issue to the market prior to the expiration of the relevant patents. The Inter Partes Review (IPR) process with the

USPTO, created under the 2011 America Invents Act, is also being used at times by generic companies in conjunction with ANDAs and lawsuits, to challenge the applicable patents.

ZYTIGA®

In November 2017, Janssen Inc. and Janssen Oncology Inc. (collectively, Janssen) initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex Inc. (Apotex) and the Minister of Health in Canada in response to Apotex's filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of ZYTIGA® before the expiration of Canadian Patent No. 2,661,422 ('422). The final hearing concluded in May 2019. In October 2019, the Court issued an order prohibiting the Canadian Minister of Health from approving Apotex's ANDS until the expiration of the '422 patent. In November 2019, Apotex filed an appeal.

Beginning in January 2019, Janssen initiated Statements of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations in Canada against Apotex, Pharmascience Inc. (Pharmascience) and Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, DRL) in response to those parties' filing of Abbreviated New Drug Submissions (ANDS) seeking approval to market generic versions of ZYTIGA® before the expiration of the '422 patent. The final hearing in these actions concluded in November 2020, and the Court issued a decision holding the '422 patent invalid in January 2021. In February 2021, Janssen appealed the decision.

In August 2020, Janssen initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against JAMP Pharma Corporation (Jamp) in Canada in response to Jamp's filing of an ANDS seeking approval to market a generic version of ZYTIGA® before the expiration of the '422 patent. The final hearing is scheduled to begin in May 2022.

In each of these Canadian actions, Janssen is seeking an order enjoining the defendants from marketing their generic versions of ZYTIGA® before the expiration of the '422 patent.

XARELTO®

In August 2020, Janssen Pharmaceuticals, Inc. (JPI) and Bayer Intellectual Property GmbH and Bayer AG (collectively, Bayer) filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, DRL) which filed an ANDA seeking approval to market a generic version of XARELTO® before expiration of U.S. Patent No. 9,539,218 ('218). In this lawsuit, JPI and Bayer were seeking an order enjoining DRL from marketing their generic versions of XARELTO® before the expiration of the relevant patents. In November 2020, JPI and Bayer entered into a confidential settlement agreement with DRL, and the case was voluntarily dismissed.

INVOKANA®/INVOKAMET®/INVOKAMET XR®

Beginning in July 2017, Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Cilag GmbH International and Janssen Pharmaceutica NV (collectively, Janssen) and Mitsubishi Tanabe Pharma Corporation (MTPC) filed patent infringement lawsuits in the United States District Court for the District of New Jersey against a number of generic companies that filed ANDAs seeking approval to market generic versions of INVOKANA®, INVOKAMET® and/or INVOKAMET® XR before expiration of MTPC's United States Patent Nos. 7,943,582 ('582) and/or 8,513,202 ('202) relating to INVOKANA®, INVOKAMET® and/or INVOKAMET® XR. Janssen is the exclusive licensee of the asserted patents. Named defendants include MSN Laboratories Private Ltd. and MSN Pharmaceuticals, Inc. (MSN); Zydus Pharmaceuticals (USA) Inc. (Zydus); Sandoz, Inc. (Sandoz); and Lupin Ltd. and Lupin Pharmaceuticals, Inc. (Lupin). These cases were consolidated into one action (Polymorph Main Action), which has been scheduled for trial starting in April 2021. In December 2020, Janssen and MTPC entered into a confidential settlement with Sandoz and in January 2021, Janssen and MTPC entered into a confidential settlement with Lupin. The cases against Sandoz and Lupin were voluntarily dismissed.

In July 2017, Janssen and MTPC filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Zydus which filed ANDAs seeking approval to market generic versions of INVOKANA® and IVOKAMET® before expiration of MTPC's United States Patent No. 7,943,788 ('788), 8,222,219 ('219) and/or 8,785,403 ('403) relating to INVOKANA®, INVOKAMET® and/or INVOKAMET® XR (Compounds Main Action). Janssen is the exclusive licensee of the asserted patents. Trial concluded in October 2020.

In July 2019, Janssen and MTPC filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against MSN, which filed an ANDA seeking approval to market a generic version of INVOKAMET XR® before expiration of the '582 patent and '202 patent relating to INVOKAMET XR®. In October 2019, Janssen and MTPC initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against MSN, which filed ANDAs seeking approval to market generic versions of INVOKANA® and INVOKAMET XR® before expiration of the '788 patent. In

October 2019, Janssen and MTPC initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories Ltd (DRL), who filed an ANDA seeking approval to market a generic version of INVOKAMET® before expiration of the '788 patent. In January 2021, Janssen and MTPC filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Macleods Pharmaceuticals, Ltd. and Macleods Pharma USA, Inc. (Macleods), which filed an ANDA seeking approval to market a generic version of INVOKAMET XR® before expiration of the '582 patent and '202 patent relating to INVOKAMET XR®. In February 2021, Janssen filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Macleods Pharmaceuticals, Ltd. and Macleods Pharma USA, Inc. (Macleods), which filed an ANDA seeking approval to market a generic version of INVOKANA® before expiration of United States Patent No. 10,617,668 relating to INVOKANA®. These lawsuits have not been consolidated with the Main Actions.

In each of these U.S. lawsuits, Janssen and MTPC are seeking an order enjoining the defendant from marketing their generic versions of INVOKANA®, INVOKAMET® and/or, INVOKAMET XR® before the expiration of the relevant patents.

In October 2020, Janssen Inc., Janssen Pharmaceutica NV and MTPC initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Sandoz Canada Inc. (Sandoz) in Canada in response to Sandoz's filing of an ANDS seeking approval to market a generic version of INVOKANA® before the expiration of the Canadian Patent Nos. 2,534,024 and 2,671,357. The final hearing is scheduled to begin in August 2022.

Janssen Inc., Janssen Pharmaceutica NV and MTPC are seeking an order enjoining Sandoz from marketing its generic version of INVOKANA® before the expiration of the relevant patents.

OPSUMIT®

In October 2020, Actelion Pharmaceuticals Ltd (Actelion) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Laurus Labs Limited and PharmaQ, Inc. (collectively, Laurus), which filed an ANDA seeking approval to market generic versions of OPSUMIT® before the expiration of U.S. Patent No. 7,094,781 ('781). Actelion was seeking an order enjoining Laurus from marketing generic versions of OPSUMIT® before the expiration of the '781 patent. In January 2021, Actelion entered into a settlement agreement with Laurus.

In May 2020, Janssen Inc. (Janssen) and Actelion initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Sandoz Canada Inc. (Sandoz) in Canada in response to Sandoz's filing of an ANDS seeking approval to market a generic version of OPSUMIT® 10 mg, before the expiration of Canadian Patent No. 2,659,770 ('770). Trial is scheduled to begin in January 2022.

In May 2020, Janssen and Actelion initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex Inc. (Apotex) in Canada in response to Apotex's filing of an ANDS seeking approval to market a generic version of OPSUMIT® 10 mg, before the expiration of the '770 patent. Trial is scheduled to begin in February 2022.

In July 2020, Janssen and Actelion initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against JAMP Pharma Corporation (JAMP) in Canada in response to JAMP's filing of an ANDS seeking approval to market a generic version of OPSUMIT® 10 mg before the expiration of the '770 patent and Canadian Patent No. 2,621,273 ('273). Trial is scheduled to begin in April 2022.

In each of these Canadian actions, Janssen and Actelion are seeking an order enjoining the defendants from marketing their generic versions of OPSUMIT® before the expiration of the relevant patents.

INVEGA SUSTENNA®

In January 2018, Janssen Pharmaceutica NV and Janssen Pharmaceuticals, Inc. (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva Pharmaceuticals USA, Inc. (Teva), which filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of United States Patent No. 9,439,906 ('906). Trial concluded in October 2020.

In August 2019, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Mylan Laboratories Limited (Mylan), which filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of the '906 patent. In February 2020, Mylan filed a Petition for Inter Partes Review with the USPTO seeking to invalidate the '906 patent. The USPTO denied the Petition in September 2020, and Mylan appealed.

In December 2019, Janssen initiated a patent infringement lawsuit in the United States District Courts for the Districts of New Jersey and Delaware against Pharmascience Inc., Mallinckrodt PLC and Specgx LLC (collectively, Pharmascience), which filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of the '906 patent.

In each of these U.S. lawsuits, Janssen is seeking an order enjoining the defendant from marketing a generic version of INVEGA SUSTENNA® before the expiration of the relevant patents.

In February 2018, Janssen Inc. and Janssen Pharmaceutica NV (collectively, Janssen Canada) initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Teva Canada Limited (Teva Canada) in response to Teva's filing of an ANDS seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of Canadian Patent Nos. 2,309,629 ('629) and 2,655,335 ('335). Janssen subsequently discontinued the portion of the lawsuit relating to the '629 patent. In May 2020, the Canadian Federal Court issued a Public Judgment and Reasons declaring that Teva Canada's generic version of INVEGA SUSTENNA®, if approved, would infringe claims of the '335 patent and that the claims of the '335 patent are not invalid for obviousness. Teva Canada appealed.

In November 2020, Janssen Canada initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Pharmascience Inc. in response to Pharmascience Inc.'s filing of an ANDS seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of the '335 patent. The Final Hearing is scheduled to begin in July 2022.

In January 2021, Janssen Canada initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex Inc. (Apotex) in response to Apotex's filing of an ANDS seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of the '335 patent. The Final Hearing is scheduled to begin in September 2022.

In each of these Canadian lawsuits, Janssen Canada is seeking an order enjoining the defendant from marketing a generic version of INVEGA SUSTENNA® before the expiration of the relevant patents.

IMBRUVICA®

Beginning in January 2018, Pharmacyclics LLC (Pharmacyclics) and Janssen Biotech, Inc. (JBI) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies that filed ANDAs seeking approval to market generic versions of IMBRUVICA® 140 mg capsules before expiration of Pharmacyclics' United States Patent Nos. 8,008,309, 7,514,444, 8,697,711, 8,735,403, 8,957,079, 9,181,257, 8,754,091, 8,497,277, 8,925,015, 8,476,284, 8,754,090, 8,999,999, 9,125,889, 9,801,881, 9,801,883, 9,814,721, 9,795,604, 9,296,753, 9,540,382, 9,713,617 and/or 9,725,455 relating to IMBRUVICA®. JBI is the exclusive licensee of the asserted patents. The named defendants include the following generic companies: Cipla Limited and Cipla USA Inc. (collectively, Cipla); Sandoz Inc. and Lek Pharmaceuticals d.d. (collectively, Sandoz).

In January 2019, Pharmacyclics and JBI amended their complaint against Sandoz to allege infringement of United States Patent Nos. 10,125,140 and 10,106,548.

In February 2019, Pharmacyclics and JBI amended their complaint against Cipla to allege infringement of United States Patent Nos. 10,106,548, and 10,125,140.

In March 2019, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Alvogen Pine Brook LLC and Natco Pharma Ltd. (collectively, Alvogen), which filed an ANDA seeking approval to market generic versions of IMBRUVICA® tablets, asserting infringement of United States Patent Nos. 7,514,444, 8,003,309, 8,476,284, 8,497,277, 8,697,711, 8,753,403, 8,754,090, 8,754,091, 8,952,015, 8,957,079, 9,181,257, 9,296,753, 9,655,857, 9,725,455, 10,010,507, 10,106,548, and 10,125,140.

In May 2019, Pharmacyclics and JBI amended their complaint against Cipla to further allege infringement of United States Patent No. 10,016,435. In June 2019, Pharmacyclics and JBI amended their complaint against Alvogen to further allege infringement of United States Patent No. 10,213,386.

In August 2019, Pharmacyclics and JBI amended their complaints against Cipla and Sandoz to further allege infringement of U.S. Patent Nos. 10,294,231 and 10,294,232. In August 2019, the Court granted a joint stipulation to stay the litigation against Cipla.

Trial in the actions against Sandoz and Alvogen took place in October 2020.

In March 2019, Sandoz filed an IPR Petition with the USPTO, seeking to invalidate United States Patent No. 9,795,604. In September 2020, the USPTO issued a final decision in the IPR invalidating certain claims of the '604 patent and upholding the validity of certain claims in the '604 patent. The final decision was not appealed by the parties.

In March 2020, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Alvogen and Sandoz asserting infringement of United States Patent No. 10,478,439. In April 2020, Pharmacyclics and JBI amended their complaint against Sandoz to further allege infringement of U.S. Patent No. 10,463,668. In October 2020, Pharmacyclics and JBI amended their complaint against Sandoz to further allege infringement of U.S. Patent Nos. 10,752,634 and 10,695,350 and amended their complaint against Alvogen to further allege infringement of U.S. Patent No. 10,653,696. In December 2020 the Court entered a joint stipulation dismissing the complaint against Sandoz.

In April 2020, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Zydus Worldwide DMCC and Cadila Healthcare Limited (collectively, Zydus), which filed an ANDA seeking approval to market generic versions of IMBRUVICA® tablets, asserting infringement of United States Patent Nos. 7,514,444, 8,008,309, 8,476,284, 8,497,277, 8,697,711, 8,753,403, 8,754,090, 8,754,091, 8,952,015, 8,957,079, 9,181,257, 9,296,753, 9,655,857, 9,725,455, 10,010,507, 10,106,548, 10,125,140, 10,213,386 and 10,478,439.

Trials in the actions against Alvogen and Zydus are scheduled to begin in March 2022.

In each of the lawsuits, Pharmacyclics and JBI are seeking an order enjoining the defendants from marketing generic versions of IMBRUVICA® before the expiration of the relevant patents.

UPTRAVI®

In April 2020, Actelion Pharmaceuticals Ltd (Actelion) and Nippon Shinyaku Co., Ltd. (Nippon Shinyaku) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against a number of generic companies that filed ANDAs seeking approval to market generic versions of UPTRAVI® before expiration of Nippon Shinyaku's United States Patent Nos. 7,205,302; 8,791,122; and 9,284,280 relating to UPTRAVI® . Actelion is the exclusive licensee of the asserted patents. The defendants include Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals Inc. (collectively, Alembic); MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. (collectively, MSN);); VGYAAN Pharmaceuticals LLC (VGYAAN); and Zydus Pharmaceuticals (USA), Inc. and Zydus Worldwide DMCC (collectively, Zydus). In January 2021, the Court entered joint stipulations dismissing VGYAAN and MSN from suit.

Actelion and Nippon Shinyaku are seeking an order enjoining the defendants from marketing generic versions of UPTRAVI® before the expiration of the relevant patents.

INVEGA TRINZA®

In September 2020, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV, and Janssen Research & Development, LCC (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Mylan Laboratories Limited, Mylan Pharmaceuticals Inc., and Mylan Institutional LLC (collectively, Mylan). Mylan filed an ANDA seeking approval to market generic versions of INVEGA TRINZA® before expiration of United States Patent No. 10,143,693 relating to INVEGA TRINZA®. Janssen is seeking an order enjoining Mylan from marketing a generic version of INVEGA TRINZA® before the expiration of the relevant patent.

GOVERNMENT PROCEEDINGS

Like other companies in the pharmaceutical, consumer health and medical devices industries, Johnson & Johnson and certain of its subsidiaries are subject to extensive regulation by national, state and local government agencies in the United States and other countries in which they operate. Such regulation has been the basis of government investigations and litigations. The most significant litigation brought by, and investigations conducted by, government agencies are listed below. It is possible that criminal charges and substantial fines and/or civil penalties or damages could result from government investigations or litigation.

Average Wholesale Price (AWP) Litigation

Johnson & Johnson and several of its pharmaceutical subsidiaries (the J&J AWP Defendants), along with numerous other pharmaceutical companies, were named as defendants in a series of lawsuits in state and federal courts involving allegations

that the pricing and marketing of certain pharmaceutical products amounted to fraudulent and otherwise actionable conduct because, among other things, the companies allegedly reported an inflated Average Wholesale Price (AWP) for the drugs at issue. Payors alleged that they used those AWPs in calculating provider reimbursement levels. The plaintiffs in these cases included three classes of private persons or entities that paid for any portion of the purchase of the drugs at issue based on AWP, and state government entities that made Medicaid payments for the drugs at issue based on AWP. Many of these cases, both federal actions and state actions removed to federal court, were consolidated for pre-trial purposes in a multi-district litigation in the United States District Court for the District of Massachusetts, where all claims against the J&J AWP Defendants were ultimately dismissed. The J&J AWP Defendants also prevailed in a case brought by the Commonwealth of Pennsylvania. Other AWP cases have been resolved through court order or settlement. The case brought by Illinois was settled after trial. In New Jersey, a putative class action based upon AWP allegations is pending against Centocor, Inc. and Ortho Biotech Inc. (both now Janssen Biotech, Inc.), Johnson & Johnson and ALZA Corporation. All other cases have been resolved.

Opioid Litigation

Beginning in 2014 and continuing to the present, Johnson & Johnson and Janssen Pharmaceuticals, Inc. (JPI), along with other pharmaceutical companies, have been named in more than 3,100 lawsuits related to the marketing of opioids, including DURAGESIC®, NUCYNTA® and NUCYNTA® ER. The suits also raise allegations related to previously owned active pharmaceutical ingredient supplier subsidiaries, Tasmanian Alkaloids Pty, Ltd. and Noramco, Inc. (both subsidiaries were divested in 2016). The majority of the cases have been filed by state and local governments. Similar lawsuits have also been filed by private plaintiffs and organizations, including but not limited to the following: individual plaintiffs on behalf of children suffering from Neonatal Abstinence Syndrome; hospitals; and health insurers/payors. To date, complaints against pharmaceutical companies, including Johnson & Johnson and JPI, have been filed by the state Attorneys General in Arkansas, Florida, Idaho, Illinois, Kentucky, Louisiana, Mississippi, Missouri, New Hampshire, New Jersey, New Mexico, New York, Ohio, Oklahoma, South Dakota, Texas, Washington and West Virginia. Complaints against the manufacturers also have been filed in state or federal court by city, county and local government agencies in the following states: Alabama, Arizona, Arkansas, California, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Mississippi, Missouri, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina; Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia and Wisconsin. The Government of Puerto Rico filed suit in Superior Court of San Juan. There are more than 370 cases pending in various state courts. There are over 2,800 federal cases coordinated in a federal Multi-District Litigation (MDL) pending in the U.S. District Court for the Northern District of Ohio (MDL No. 2804). In addition, the Province of British Columbia filed suit in Canada. In October 2019, an anti-trust complaint was filed by private plaintiffs in federal court in Tennessee and is pending transfer to the MDL. These actions allege a variety of claims related to opioid marketing practices, including false advertising, unfair competition, public nuisance, consumer fraud violations, deceptive acts and practices, false claims and unjust enrichment. The suits generally seek penalties and/or injunctive and monetary relief and, in some of the suits, the plaintiffs are seeking joint and several liability among the defendants. An adverse judgment in any of these lawsuits could result in the imposition of large monetary penalties and significant damages including, punitive damages, cost of abatement, substantial fines, equitable remedies and other sanctions.

The trial in the matter filed by the Oklahoma Attorney General resulted in a judgment against Johnson & Johnson and JPI in the amount of $572 million, subject to a final order to be issued by the Court. The Court issued a final judgment reducing the amount to $465 million. Johnson & Johnson and JPI have appealed the judgment. The Company believes that it has strong grounds to overturn this judgment. In October 2019 Johnson & Johnson and JPI announced a settlement of the first case set for trial in the MDL with two counties in Ohio.

Johnson & Johnson, JPI and other pharmaceutical companies have also received subpoenas or requests for information related to opioids marketing practices from the following state Attorneys General: Alaska, Indiana, Montana, New Hampshire, South Carolina, Tennessee, Texas and Washington. In September 2017, Johnson & Johnson and JPI were contacted by the Texas and Colorado Attorney General's Offices on behalf of approximately 38 states regarding a multi-state Attorney General investigation. In October 2019, the Company announced a proposed agreement in principle that would include the Company paying $4 billion as settlement of these matters. In October 2020, the Company agreed to contribute up to an additional $1 billion to an all-in settlement amount that would resolve opioid lawsuits filed and future claims by states, cities, counties and tribal governments, for a total of $5 billion which has been accrued, subject to various conditions and an agreement being finalized. This agreement in principle is not an admission of liability or wrong-doing and would resolve opioid lawsuits filed and future claims by states, cities and counties. The Company cannot predict if or when the agreement will be finalized and individual cases are ongoing.
In August 2019, Johnson & Johnson received a grand jury subpoena from the United States Attorney's Office for the Eastern District of New York for documents related to the Company's anti-diversion policies and procedures and distribution of its

opioid medications, in what the Company understands to be part of a broader investigation into manufacturers' and distributors' monitoring programs and reporting under the Controlled Substances Act. In September 2019, Johnson & Johnson received subpoenas from the New York State Department of Financial Services (NYDFS) as part of an industry-wide inquiry into the effect of opioid prescriptions on New York health insurance premiums. In September 2020, the Company learned that NYDFS filed a statement of charges related to this investigation.

From June 2017 through December 2019, the Company's Board of Directors received a series of shareholder demand letters alleging breaches of fiduciary duties related to the marketing of opioids. The Board retained independent counsel to investigate the allegations in the demands, and in April 2020, independent counsel delivered a report to the Board recommending that the Company reject the shareholder demands and take the steps that are necessary or appropriate to secure dismissal of related derivative litigation. The Board unanimously adopted the recommendations of the independent counsel's report.

In November 2019, one of the shareholders who sent a demand filed a derivative complaint against Johnson & Johnson as the nominal defendant and certain current and former directors and officers as defendants in the Superior Court of New Jersey. The complaint alleges breaches of fiduciary duties related to the marketing of opioids, and that Johnson & Johnson has suffered damages as a result of those alleged breaches. In May 2020, the shareholder filed an amended complaint challenging the Board's rejection of his demand. In August 2020, Johnson & Johnson moved to dismiss the amended complaint, and as of December 2020, that motion was fully briefed. In August 2020, another shareholder who sent a demand filed a separate derivative complaint in the same court making similar allegations. In October 2020, the Court granted defendants' request to reassign the second-filed case to the division where the first-filed case is pending.

In December 2019, two additional shareholders who sent demands filed two separate derivative complaints making similar allegations against Johnson & Johnson as the nominal defendant and certain current and former directors and officers as defendants in the United States District for the District of New Jersey. In April 2020, the two federal cases were consolidated into a single action captioned *In re Johnson & Johnson Opioid Stockholder Derivative Litigation*. In July 2020, the shareholders filed a consolidated complaint. In September 2020, Johnson & Johnson moved to dismiss the consolidated complaint, and in December 2020, the shareholders opposed Johnson & Johnson's motion. Johnson & Johnson filed its reply in February 2021. In July 2020, an additional shareholder who sent a demand filed a derivative complaint in the same federal court making similar allegations against the same defendants named in the consolidated action. In January 2021, pursuant to an order in the consolidated action, the third case was consolidated into the consolidated action. In February 2021, the shareholders in the consolidated action filed a motion for voluntary dismissal.

Other

In August 2012, DePuy Orthopaedics, Inc., DePuy, Inc. (now known as DePuy Synthes, Inc.), and Johnson & Johnson Services, Inc. (collectively DePuy) received an informal request from the United States Attorney's Office for the District of Massachusetts and the Civil Division of the United States Department of Justice (the United States) for the production of materials relating to the DePuy ASR™ XL Hip device. In July 2014, the United States notified the United States District Court for the District of Massachusetts that it had declined to intervene in a *qui tam* case filed pursuant to the False Claims Act against the companies. In February 2016, the district court granted the companies' motion to dismiss with prejudice, unsealed the *qui tam* complaint, and denied the *qui tam* relators' request for leave to file a further amended complaint. The *qui tam* relators appealed the case to the United States Court of Appeals for the First Circuit. In July 2017, the First Circuit affirmed the district court's dismissal in part, reversed in part, and affirmed the decision to deny the relators' request to file a third amended complaint. The relators' remaining claims are now pending before the district court. In July 2020, the Court ordered the relators to complete discovery by August 2020; the Relators have requested an extension of the August 2020 deadline that DePuy opposed and additional discovery-related motions have been filed by both parties. Additionally, DePuy has requested a schedule for the filing of a motion to strike and to dismiss the relators' second amended complaint.

In October 2012, Johnson & Johnson was contacted by the California Attorney General's office regarding a multi-state Attorney General investigation of the marketing of surgical mesh products for hernia and urogynecological purposes by Johnson & Johnson's subsidiary, Ethicon, Inc. (Ethicon). In May 2016, California and Washington filed civil complaints against Johnson & Johnson, Ethicon and Ethicon US, LLC alleging violations of their consumer protection statutes. Similar complaints were filed against the companies by the following states: Kentucky, Mississippi, West Virginia and Oregon. In April 2019, Johnson & Johnson and Ethicon settled the Washington case. The California case started trial in July 2019 and concluded in September 2019. The trial date for the Kentucky case was scheduled for September 2019 but has been adjourned and no new trial date has been scheduled. In October 2019, Johnson & Johnson and Ethicon settled the multi-state investigation with 41 other states and the District of Columbia. In January 2020, the Court in California issued a statement of decision, finding in favor of the State of California, and awarded civil penalties in the amount of $344 million. In April 2020, the Court in California denied the Company's motion for a new trial. In August 2020, the Court entered judgment with respect to the penalties of $344 million, but denied the Attorney General's request for injunctive relief. The Company is appealing the penalty judgment. In April 2020, the

Company settled the West Virginia. In October 2020, the Company settled with the Attorney General of Oregon. In November 2020, the Company settled with the Attorney General of Mississippi.

In December 2012, Therakos, Inc. (Therakos), formerly a subsidiary of Johnson & Johnson and part of the Ortho-Clinical Diagnostics, Inc. (OCD) franchise, received a letter from the civil division of the United States Attorney's Office for the Eastern District of Pennsylvania informing Therakos that the United States Attorney's Office was investigating the sales and marketing of Uvadex® (methoxsalen) and the Uvar Xts® and Cellex® Systems during the period 2000 to the present. The United States Attorney's Office requested that OCD and Johnson & Johnson preserve documents that could relate to the investigation. Therakos was subsequently acquired by an affiliate of Gores Capital Partners III, L.P. in January 2013, and OCD was divested in June 2014. Following the divestiture of OCD, Johnson & Johnson retained OCD's portion of any liability resulting from the investigation for activity that occurred prior to the sale of Therakos. Following production of documents to and settlement discussions with the U.S. Attorney's Office, J&J affiliate Medical Device Business Services, Inc. agreed to resolve claims under the federal False Claims Act and analogous state laws in a settlement announced in November 2020. In the settlement agreement, Medical Device Business Services expressly denied any wrongful conduct. As a result of the settlement, a qui tam complaint filed by two relators pending in the U.S. District Court for the Eastern District of Pennsylvania will be dismissed. Separate settlement agreements with the states participating in the settlement are in the process of being finalized.

In June 2014, the Mississippi Attorney General filed a complaint in Chancery Court of The First Judicial District of Hinds County, Mississippi against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (now known as Johnson & Johnson Consumer Inc.) (JJCI). The complaint alleges that defendants violated the Mississippi Consumer Protection Act by
failing to disclose alleged health risks associated with female consumers' use of talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product divested in 2012) and seeks injunctive and monetary relief. The matter is stayed pending interlocutory appeal of a December 2018 denial of Johnson & Johnson and JJCI's motion for summary judgment. The Mississippi Supreme Court granted J&J and JJCI's request to file an interlocutory appeal of the denial of the motion for summary judgment in late 2019. Briefing is complete and oral argument was held in February 2021.

In January 2020, the State of New Mexico filed a consumer protection case alleging that the Company deceptively marketed and sold its talcum powder products by making misrepresentations about the safety of the products and the presence of carcinogens, including asbestos. The State of New Mexico filed an Amended Complaint in March 2020. The Company moved to dismiss certain of the claims in the Amended Complaint, which was granted. The Company then filed a motion for partial judgment on the pleadings in December 2020.

Forty-one states have commenced a joint investigation into the Company's marketing of its talcum powder products. At this time, the multi-state group has not asserted any claims against the Company. Several states have issued Civil Investigative Demands seeking documents and other information.

In March 2016, Janssen Pharmaceuticals, Inc. (JPI) received a Civil Investigative Demand from the United States Attorney's Office for the Southern District of New York related to JPI's contractual relationships with pharmacy benefit managers over the period from January 1, 2006 to the present with regard to certain of JPI's pharmaceutical products. The demand was issued in connection with an investigation under the False Claims Act. The Company has provided documents in response to the demand.

In July 2016, Johnson & Johnson and Janssen Products LP were served with a *qui tam* complaint pursuant to the False Claims Act filed in the United States District Court for the District of New Jersey alleging the off-label promotion of two HIV products, PREZISTA® and INTELENCE®, and anti-kickback violations in connection with the promotion of these products. The complaint was filed under seal in December 2012. The federal and state governments have declined to intervene, and the lawsuit is being prosecuted by the relators. In February 2021, the Court stayed the case and ordered mediation.

In March 2017, Janssen Biotech, Inc. received a Civil Investigative Demand from the United States Department of Justice regarding a False Claims Act investigation concerning management and advisory services provided to rheumatology and gastroenterology practices that purchased REMICADE® or SIMPONI ARIA®. In August 2019, the Unites States Department of Justice notified Janssen Biotech, Inc. that it was closing the investigation. Subsequently, the United States District Court for the District of Massachusetts unsealed a qui tam False Claims Act complaint, which was served on the Company. The Department of Justice had declined to intervene in the qui tam lawsuit in August 2019. The Company filed a motion to dismiss, which was granted in part and denied in part. Discovery is underway.

In April and September 2017, Johnson & Johnson received subpoenas from the United States Attorney for the District of Massachusetts seeking documents broadly relating to pharmaceutical copayment support programs for DARZALEX®, OLYSIO®, REMICADE®, SIMPONI®, STELARA® and ZYTIGA®. The subpoenas also seek documents relating to Average Manufacturer Price and Best Price reporting to the Center for Medicare and Medicaid Services related to those products, as well as rebate payments to state Medicaid agencies. The Company has provided documents in response to the subpoenas.

In June 2017, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts seeking information regarding practices pertaining to the sterilization of DePuy Synthes, Inc. spinal implants at three hospitals in Boston as well as interactions of employees of Company subsidiaries with physicians at these hospitals. Johnson & Johnson and DePuy Synthes, Inc. have produced documents in response to the subpoena and are fully cooperating with the government's investigation.

In July 2018 the Public Prosecution Service in Rio de Janeiro and representatives from the Brazilian antitrust authority CADE inspected the offices of more than 30 companies including Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda. The authorities appear to be investigating allegations of possible anti-competitive behavior and possible improper payments in the medical device industry. We continue to actively respond to inquiries regarding the Foreign Corrupt Practices Act from the United States Department of Justice and the United States Securities and Exchange Commission.

From time to time, the Company has received requests from a variety of United States Congressional Committees to produce information relevant to ongoing congressional inquiries. It is the policy of Johnson & Johnson to cooperate with these inquiries by producing the requested information.

GENERAL LITIGATION

In March 2018, a purported class action was filed in the Circuit Court Third Judicial District Madison County, Illinois against Johnson & Johnson Consumer, Inc. (JJCI), alleging violations of state consumer fraud statutes based on nondisclosure of alleged health risks associated with talc contained in JOHNSON'S® Baby Powder. The complaint seeks damages but does not allege personal injury. In October 2020, JJCI moved to dismiss the complaint.

In August 2014, United States Customs and Border Protection (US CBP) issued a Penalty Notice against Janssen Ortho LLC (Janssen Ortho), assessing penalties for the alleged improper classification of darunavir ethanolate (the active pharmaceutical ingredient in PREZISTA®) in connection with its importation into the United States. In August 2020, US CBP formally rejected Janssen's Supplemental Petition challenging the penalties assessment and demanded payment of the mitigated penalty. In October 2020, US CBP agreed to not refer the matter to the Office of Chief Counsel at this time, pending resolution of the related Classification Litigation. In December 2013, Janssen Ortho sued the United States in the United States Court of International Trade (the Classification Litigation) seeking a determination that darunavir ethanolate is exempt from duties upon importation into the United States. In February 2020, the Court ruled that darunavir ethanolate is eligible for duty free treatment. In April 2020, the United States appealed to the United States Court of Appeals for the Federal Circuit.

In September 2020, Genmab A/S brought an arbitration against Janssen Biotech, Inc. pursuant to a 2012 License Agreement between the parties. The arbitration relates to royalties for certain Janssen daratumumab products.

In March and April 2015, over 30 putative class action complaints were filed by contact lens patients in a number of courts around the United States against Johnson & Johnson Vision Care, Inc. (JJVCI) and other contact lens manufacturers, distributors, and retailers, alleging vertical and horizontal conspiracies to fix the retail prices of contact lenses. The complaints allege that the manufacturers reached agreements with each other and certain distributors and retailers concerning the prices at which some contact lenses could be sold to consumers. The plaintiffs are seeking damages and injunctive relief. All of the class action cases were transferred to the United States District Court for the Middle District of Florida in June 2015. The plaintiffs filed a consolidated class action complaint in November 2015. Discovery and pre-trial motion practice is complete. No trial date has been set.

In August 2015, two third-party payors filed a purported class action in the United States District Court for the Eastern District of Louisiana against Janssen Research & Development, LLC, Janssen Ortho LLC, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Johnson & Johnson (as well as certain Bayer entities), alleging that the defendants improperly marketed and promoted XARELTO® as safer and more effective than less expensive alternative medications while failing to fully disclose its risks. The complaint seeks damages. In November 2020, Defendants moved to dismiss the complaint.

In September 2017, Pfizer, Inc. (Pfizer) filed an antitrust complaint against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) in United States District Court for the Eastern District of Pennsylvania. Pfizer alleges that Janssen has violated federal antitrust laws through its contracting strategies for REMICADE®. The complaint seeks damages and injunctive relief. Discovery is ongoing.

Beginning in September 2017, multiple purported class actions were filed on behalf of indirect purchasers of REMICADE® against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) alleging that Janssen has violated federal antitrust laws through its contracting strategies for REMICADE®. The cases were consolidated for pre-trial purposes as *In re REMICADE® Antitrust Litigation* in United States District Court for the Eastern District of Pennsylvania. The consolidated complaint seeks damages and injunctive relief. Discovery is ongoing.

In June 2018, Walgreen Co. and Kroger Co, filed an antitrust complaint against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) in the United States District Court for the Eastern District of Pennsylvania. The complaint alleges that Janssen has violated federal antitrust laws through its contracting strategies for REMICADE®. The complaint seeks damages and injunctive relief. In March 2019, summary judgment was granted in favor of Janssen. In February 2020, the United States Court of Appeals for the Third Circuit reversed the District Court's decision. Discovery is ongoing.

In June 2019, the United States Federal Trade Commission (FTC) issued a Civil Investigative Demand to Johnson & Johnson in connection with its investigation of whether Janssen's REMICADE® contracting practices violate federal antitrust laws. The Company produced documents and information responsive to the Civil Investigative Demand.

In October 2017, certain United States service members and their families brought a complaint against a number of pharmaceutical and medical devices companies, including Johnson & Johnson and certain of its subsidiaries in United States District Court for the District of Columbia, alleging that the defendants violated the United States Anti-Terrorism Act. The complaint alleges that the defendants provided funding for terrorist organizations through their sales practices pursuant to pharmaceutical and medical device contracts with the Iraqi Ministry of Health. In July 2020, the District Court dismissed the complaint. In January 2021, plaintiffs appealed the District Court's decision to the United States Court of Appeals for the District of Columbia Circuit.

In October 2018, two separate putative class actions were filed against Actelion Pharmaceutical Ltd., Actelion Pharmaceuticals US, Inc., and Actelion Clinical Research, Inc. (collectively Actelion) in United States District Court for the District of Maryland and United States District Court for the District of Columbia. The complaints allege that Actelion violated state and federal antitrust and unfair competition laws by allegedly refusing to supply generic pharmaceutical manufacturers with samples of TRACLEER®. TRACLEER® is subject to a Risk Evaluation and Mitigation Strategy required by the Food and Drug Administration, which imposes restrictions on distribution of the product. In January 2019, the plaintiffs dismissed the District of Columbia case and filed a consolidated complaint in the United States District Court for the District of Maryland. In October 2019, the Court granted Actelion's motion to dismiss the amended complaint. Plaintiffs have appealed the decision to the United States Court of Appeals for the Fourth Circuit.

In December 2018, Janssen Biotech, Inc., Janssen Oncology, Inc, Janssen Research & Development, LLC, and Johnson & Johnson (collectively, Janssen) were served with a *qui tam* complaint filed on behalf of the United States, 28 states, and the District of Columbia. The complaint, which was filed in December 2017 in United States District Court for the Northern District of California, alleges that Janssen violated the federal False Claims Act and state law when providing pricing information for ZYTIGA® to the government in connection with direct government sales and government-funded drug reimbursement programs. At this time, the federal and state governments have declined to intervene. The case has been transferred to United States District Court for the District of New Jersey. In September 2019, Janssen moved to dismiss the complaint.

In April 2019, Blue Cross & Blue Shield of Louisiana and HMO Louisiana, Inc. filed a class action complaint against Janssen Biotech, Inc, Janssen Oncology, Inc, Janssen Research & Development, LLC and BTG International Limited in the United States District Court for the Eastern District of Virginia on behalf of indirect purchasers of ZYTIGA®. Several additional complaints were filed thereafter in Virginia and New Jersey. The indirect purchaser complaints generally allege that the defendants violated the antitrust and consumer protections laws of several states and the Sherman Act by pursuing patent litigation relating to ZYTIGA® in order to delay generic entry and seek damages. The Virginia cases have been transferred to the United States District Court for the District of New Jersey and consolidated with the New Jersey case for pretrial purposes. In May 2020, a class action complaint was filed against Janssen Biotech Inc., Janssen Oncology, Inc., Janssen Research & Development LLC and BTG International Limited in the United States District Court for the District of New Jersey, on behalf of direct purchasers of ZYTIGA®. The direct purchaser complaint alleges that defendants violated the Sherman Act by pursuing patent litigation relating to ZYTIGA® in order to delay generic entry, and seek damages and injunctive relief.

In May 2019, a class action antitrust complaint was filed against Janssen R&D Ireland (Janssen) and Johnson & Johnson in the United States District Court for the Northern District of California. The complaint alleges that Janssen violated federal and state antitrust and consumer protection laws by agreeing to exclusivity provisions in its agreements with Gilead concerning the

development and marketing of combination antiretroviral therapies (cART) to treat HIV. The complaint also alleges that Gilead entered into similar agreements with Bristol-Myers Squibb and Japan Tobacco. In March 2020, the Court granted in part and denied in part defendants' motions to dismiss. Plaintiffs filed an amended complaint in April 2020. Defendants moved to dismiss the amended complaint. In July 2020, the Court granted in part and denied in part the renewed motion to dismiss. Discovery is ongoing.

In October 2019, Innovative Health, LLC filed a complaint against Biosense Webster, Inc. (BWI) in the United States District Court for the Middle District of California. The complaint alleges that certain of BWI's business practices and contractual terms violate the antitrust laws of the United States and the State of California by restricting competition in the sale of High Density Mapping Catheters and Ultrasound Catheters. In January 2020, BWI filed a motion to dismiss the complaint. In August 2020, the Court granted in part and denied in part BWI's motion to dismiss. Discovery is ongoing.

In November 2019, Johnson & Johnson received a demand for indemnification from Pfizer Inc., pursuant to the 2006 Stock and Asset Purchase Agreement between the Company and Pfizer. Also in November 2019, Johnson & Johnson, Inc. received a demand for indemnification from Sanofi Consumer Health, Inc., pursuant to the 2016 Asset Purchase Agreement between J&J, Inc. and Sanofi. In January 2020, Johnson & Johnson received a demand for indemnification from Boehringer Ingelheim Pharmaceuticals, Inc., pursuant to the 2006 Asset Purchase Agreement among the Company, Pfizer, and Boehringer Ingelheim. The notices seek indemnification for legal claims related to over-the-counter Zantac (ranitidine) products. Plaintiffs in the underlying actions allege that Zantac and other over-the-counter ranitidine medications contain unsafe levels of NDMA (N-nitrosodimethylamine) and can cause and/or have caused various cancers in patients using the products, and seek injunctive and monetary relief.

In October 2020, Fortis Advisors LLC (Fortis), in its capacity as representative of the former stockholders of Auris Health Inc. (Auris), filed a complaint against Johnson & Johnson, Ethicon Inc., and certain named officers and employees (collectively, Ethicon) in the Court of Chancery of the State of Delaware. The complaint alleges breach of contract, fraud, and other causes of action against Ethicon in connection with Ethicon's acquisition of Auris in 2019. The complaint seeks damages and other relief. In December 2020, Ethicon moved to dismiss certain causes of action in the complaint.

Johnson & Johnson or its subsidiaries are also parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the cost of past and/or future remediation.

20. Restructuring

In the fiscal second quarter of 2018, the Company announced plans to implement a series of actions across its Global Supply Chain that are intended to focus resources and increase investments in the critical capabilities, technologies and solutions necessary to manufacture and supply its product portfolio, enhance agility and drive growth. The Global Supply Chain actions include expanding the use of strategic collaborations and bolstering initiatives to reduce complexity, improve cost-competitiveness, enhance capabilities and optimize the Supply Chain network. For additional details on the Global Supply Chain restructuring strategic collaborations see Note 18 to the Consolidated Financial Statements. In fiscal year 2020, the Company recorded a pre-tax charge of $0.4 billion, which is included on the following lines of the Consolidated Statement of Earnings, $0.2 billion in restructuring, $0.1 billion in other (income) expense and $0.1 billion in cost of products sold. Total project costs of approximately $1.3 billion have been recorded since the restructuring was announced. See the following table for additional details on the restructuring program.

In total, the Company expects the Global Supply Chain actions to generate approximately $0.6 billion to $0.8 billion in annual pre-tax cost savings that will be substantially delivered by 2022. The Company expects to record pre-tax restructuring charges of approximately $1.9 billion to $2.3 billion, over the 4 to 5 year period of this activity. These costs are associated with network optimizations, exit costs and accelerated depreciation and amortization.

The following table summarizes the severance charges and the associated spending under these initiatives through the fiscal year ended 2020:

(Dollars in Millions)	Severance	Asset Write-offs/Sales	Other[2]	Total
Reserve balance, December 30, 2018	$ 194	—	48	242
2019 activity	(30)	—	(32)	(62)
Reserve balance, December 29, 2019	164	—	16	180
Current year activity:				
Charges	—	43	405	448
Cash settlements	(29)	24 [4]	(399)	(404)
Settled non cash	—	(67)	(13) [3]	(80)
Reserve balance, January 3, 2021[1]	$ 135	—	9	144

[1] Cash outlays for severance are expected to be substantially paid out over the next 2 years in accordance with the Company's plans and local laws.
[2] Other includes project expense such as salaries for employees supporting these initiatives and consulting expenses.
[3] Relates to pension related net actuarial losses associated with the transfer of employees to Jabil Inc. as part of the strategic collaboration.
[4] Represents gain on sale of an asset

The Company continuously reevaluates its severance reserves related to restructuring and the timing of payments due to the planned release of associates regarding several longer-term projects. The Company believes that the existing severance reserves are sufficient to cover the Global Supply Chain plans given the period over which the actions will take place. The Company will continue to assess and make adjustments as necessary if additional amounts become probable and estimable.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Johnson & Johnson

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Johnson & Johnson and its subsidiaries (the "Company") as of January 3, 2021 and December 29, 2019, and the related consolidated statements of earnings, of comprehensive income, of equity and of cash flows for each of the three fiscal years in the period ended January 3, 2021, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of January 3, 2021, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of January 3, 2021 and December 29, 2019, and the results of its operations and its cash flows for each of the three fiscal years in the period ended January 3, 2021 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of January 3, 2021, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

U.S. Pharmaceutical Rebate Reserves – Managed Care, Medicare and Medicaid

As described in Note 1 to the consolidated financial statements, the Company recognizes revenue from product sales when obligations under the terms of a contract with the customer are satisfied. Rebates and discounts provided to customers are accounted for as variable consideration and recorded as a reduction in sales. The liability for such rebates and discounts is recognized within Accrued Rebates, Returns, and Promotions on the consolidated balance sheet. A significant portion of the liability related to rebates is from the sale of pharmaceutical goods within the U.S., primarily the Managed Care, Medicare and Medicaid programs, which amounted to $7.2 billion as of January 3, 2021. For significant rebate programs, which include the U.S. Managed Care, Medicare and Medicaid rebate programs, rebates and discounts estimated by management are based on contractual terms, historical experience, patient outcomes, trend analysis, and projected market conditions in the U.S. pharmaceutical market.

The principal considerations for our determination that performing procedures relating to U.S. pharmaceutical rebate reserves - Managed Care, Medicare and Medicaid is a critical audit matter are the significant judgment by management due to the significant measurement uncertainty involved in developing these reserves and the high degree of auditor judgment, subjectivity and audit effort in performing procedures and evaluating the assumptions related to contractual terms, historical experience, patient outcomes, trend analysis, and projected market conditions in the U.S. pharmaceutical market.
Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to U.S. pharmaceutical rebate reserves - Managed Care, Medicare and Medicaid, including controls over the assumptions used to estimate these rebates. These procedures also included, among others, (i) developing an independent estimate of the rebates by utilizing third party information on price and market conditions in the U.S. pharmaceutical market, the terms of the specific rebate programs, and the historical experience and trend analysis of actual rebate claims paid; (ii) testing rebate claims processed by the Company, including evaluating those claims for consistency with the contractual and mandated terms of the Company's rebate arrangements; and (iii) comparing the independent estimates to management's estimates.

Litigation Contingencies – Talc

As described in Notes 1 and 19 to the consolidated financial statements, the Company records accruals for loss contingencies associated with legal matters, including talc, when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. To the extent adverse verdicts have been rendered against the Company, management does not record an accrual until a loss is determined to be probable and can be reasonably estimated. For these matters, management is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors, including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; ability to achieve comprehensive multi-party settlements; complexity of related cross-claims and counterclaims; and/or there are numerous parties involved. There have been verdicts against the Company for this matter, including a verdict in July 2018 of $4.7 billion, which was reversed in part and affirmed in part by the Missouri Court of Appeals in June 2020, reducing the overall award to $2.1 billion and, with additional interest as of January 3, 2021, as the Company pursues further appeal, is currently $2.5 billion. An application for transfer of the case to the Missouri Supreme Court was subsequently denied, and the Company is currently seeking review by the United States Supreme Court. As described by management, the Company continues to believe that it has strong legal grounds for the appeal of this verdict, as well as other verdicts it has appealed. Notwithstanding the Company's confidence in the safety of its talc products, in certain circumstances the Company has and may settle cases. The Company has established an accrual for defense costs and reserves for settlement of certain cases and claims, as well as one case currently on appeal, in connection with product liability litigation associated with body powders containing talc.

The principal considerations for our determination that performing procedures relating to the talc litigation is a critical audit matter are the significant judgment by management when assessing the likelihood of a loss being incurred and when

determining whether a reasonable estimate of the loss or range of loss for each claim can be made, which in turn led to a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating management's assessment of the loss contingencies associated with this litigation.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's evaluation of the talc litigation, including controls over determining whether a loss is probable and whether the amount of loss can be reasonably estimated, as well as financial statement disclosures. These procedures also included, among others, (i) gaining an understanding of the Company's process around the accounting and reporting for the talc litigation; (ii) discussing the status of significant known actual and potential litigation with the Company's in-house legal counsel, as well as external counsel when deemed necessary; (iii) obtaining and evaluating the letters of audit inquiry with internal and external legal counsel for significant litigation; (iv) evaluating the reasonableness of management's assessment regarding whether an unfavorable outcome is reasonably possible or probable and reasonably estimable; and (v) evaluating the sufficiency of the Company's litigation contingencies disclosures.

Litigation – Opioids

As described in Notes 1 and 19 to the consolidated financial statements, the Company records accruals for loss contingencies associated with legal matters, including opioids, when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. To the extent adverse verdicts have been rendered against the Company, management does not record an accrual until a loss is determined to be probable and can be reasonably estimated. For these matters, management is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors, including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; ability to achieve comprehensive multi-party settlements; complexity of related cross-claims and counterclaims; and/or there are numerous parties involved. The Company has been named in numerous lawsuits brought by certain state and local governments related to opioids matters. The trial in the matter filed by the Oklahoma Attorney General resulted in a judgment against the Company in the amount of $572 million which was subsequently reduced to $465 million. The Company has appealed the judgment and, as described by management, believes that it has strong grounds to overturn this judgment. Separately in October 2019, the Company announced a proposed agreement in principle that would include the Company paying $4 billion as settlement of the lawsuits. In October 2020, the Company agreed to contribute up to an additional $1 billion to an all-in settlement amount that would resolve opioid lawsuits filed and future claims by states, cities, counties and tribal governments, for a total of $5 billion which has been accrued, subject to various conditions and an agreement being finalized. As described by management, this agreement in principle is not an admission of liability or wrong-doing and would resolve opioid lawsuits filed and future claims by states, cities and counties.

The principal considerations for our determination that performing procedures relating to the opioids litigation is a critical audit matter are the significant judgment by management when assessing the likelihood of a loss being incurred for the judgment against the Company in Oklahoma and when determining whether a reasonable estimate of the range of loss for the proposed agreement in principle to settle opioids litigation can be made, which in turn led to a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating management's assessment of the loss contingencies associated with this litigation.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's evaluation of the opioid litigation, including controls over determining whether a loss is probable and whether the amount of loss can be reasonably estimated, as well as financial statement disclosures. These procedures also included, among others, (i) gaining an understanding of the Company's process around the accounting and reporting for the opioids litigation; (ii) discussing the status of significant known actual and potential litigation and ongoing settlement negotiations with the Company's in-house legal counsel, as well as external counsel when deemed necessary; (iii) obtaining and evaluating the letters of audit inquiry with internal and external legal counsel for significant litigation; (iv) evaluating the reasonableness of management's assessment regarding whether an unfavorable outcome is reasonably possible or probable and reasonably estimable; and (v) evaluating the sufficiency of the Company's litigation contingencies disclosures.

/s/ PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 22, 2021
We have served as the Company's auditor since at least 1920. We have not been able to determine the specific year we began serving as auditor of the Company.

Management's Report on Internal Control Over Financial Reporting

Under Section 404 of the Sarbanes-Oxley Act of 2002, management is required to assess the effectiveness of the Company's internal control over financial reporting as of the end of each fiscal year and report, based on that assessment, whether the Company's internal control over financial reporting is effective.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is designed to provide reasonable assurance as to the reliability of the Company's financial reporting and the preparation of external financial statements in accordance with generally accepted accounting principles.

Internal controls over financial reporting, no matter how well designed, have inherent limitations. Therefore, internal control over financial reporting determined to be effective can provide only reasonable assurance with respect to financial statement preparation and may not prevent or detect all misstatements. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management has assessed the effectiveness of the Company's internal control over financial reporting as of January 3, 2021. In making this assessment, the Company used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework (2013)." These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. The Company's assessment included extensive documenting, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

Based on the Company's processes and assessment, as described above, management has concluded that, as of January 3, 2021, the Company's internal control over financial reporting was effective.

The effectiveness of the Company's internal control over financial reporting as of January 3, 2021 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which appears herein.

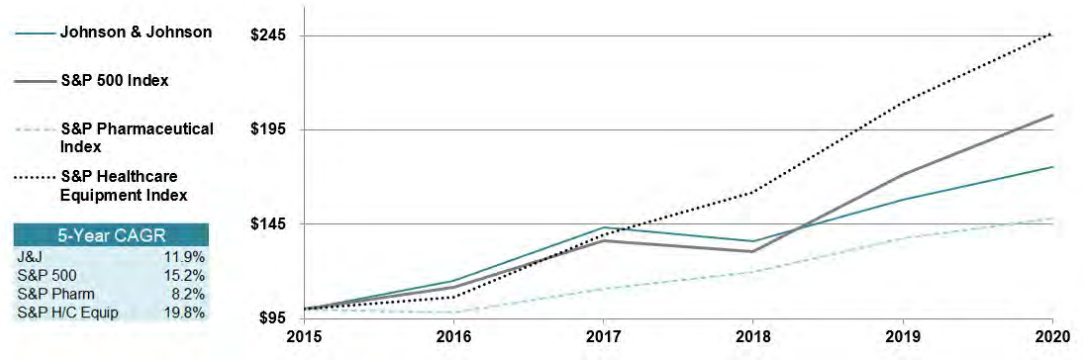
/s/ Alex Gorsky
Alex Gorsky
Chairman, Board of Directors
Chief Executive Officer

/s/ Joseph J. Wolk
Joseph J. Wolk
Executive Vice President, Chief Financial Officer

Shareholder Return Performance Graphs

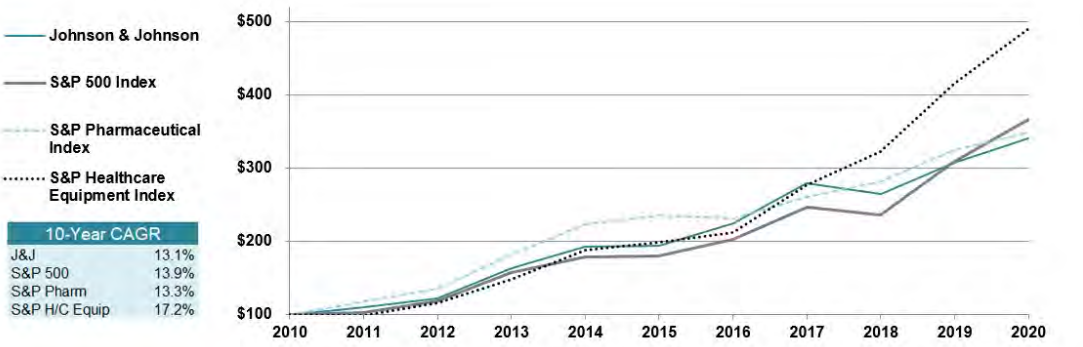
Set forth below are line graphs comparing the cumulative total shareholder return on the Company's Common Stock for periods of five years and ten years ending January 3, 2021, against the cumulative total return of the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index. The graphs and tables assume that $100 was invested on December 31, 2015 and December 31, 2010 in each of the Company's Common Stock, the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index and that all dividends were reinvested.

5 Year Shareholder Return Performance J&J vs. Indices



	2015	2016	2017	2018	2019	2020
Johnson & Johnson	$100.00	$115.32	$143.47	$136.10	$158.16	$175.32
S&P 500 Index	$100.00	$111.95	$136.38	$130.39	$171.44	$202.96
S&P Pharmaceutical Index	$100.00	$98.44	$110.81	$119.78	$137.85	$148.23
S&P Healthcare Equipment Index	$100.00	$106.48	$139.38	$162.02	$209.52	$246.47

10 Year Shareholder Return Performance J&J vs. Indices



	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Johnson & Johnson	$100.00	$109.89	$121.79	$163.95	$192.37	$194.59	$224.41	$279.18	$264.84	$307.77	$341.17
S&P 500 Index	$100.00	$102.11	$118.44	$156.78	$178.22	$180.67	$202.27	$246.41	$235.59	$309.74	$366.70
S&P Pharmaceutical Index	$100.00	$117.76	$134.75	$182.22	$222.70	$235.59	$231.91	$261.06	$282.19	$324.76	$349.21
S&P Healthcare Equipment Index	$100.00	$99.20	$116.33	$148.54	$187.58	$198.78	$211.67	$277.07	$322.07	$416.50	$489.94

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures. At the end of the period covered by this Report, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Alex Gorsky, Chairman and Chief Executive Officer, and Joseph J. Wolk, Executive Vice President, Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Gorsky and Wolk concluded that, as of the end of the period covered by this Report, the Company's disclosure controls and procedures were effective

Reports on Internal Control Over Financial Reporting. The information called for by this item is incorporated herein by reference to "Management's Report on Internal Control Over Financial Reporting", and the attestation regarding internal controls over financial reporting included in the "Report of Independent Registered Public Accounting Firm" included in Item 8 of this Report.

Changes in Internal Control Over Financial Reporting. During the fiscal quarter ended January 3, 2021, there were no changes in the Company's internal control over financial reporting identified in connection with the evaluation required under Rules 13a-15 and 15d-15 under the Exchange Act that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting. The Company has not experienced any material impact to its internal controls over financial reporting despite the fact that most of its employees are working remotely due to the COVID-19 pandemic. The Company proactively took actions to re-evaluate and refine its financial reporting process through additional monitoring controls to provide reasonable assurance that the financial results are reported accurately and timely. The Company continues to monitor and assess the effectiveness of the design and operation of its disclosure controls and procedures.

The Company is implementing a multi-year, enterprise-wide initiative to integrate, simplify and standardize processes and systems for the human resources, information technology, procurement, supply chain and finance functions. These are enhancements to support the growth of the Company's financial shared service capabilities and standardize financial systems. This initiative is not in response to any identified deficiency or weakness in the Company's internal control over financial reporting. In response to this initiative, the Company has and will continue to align and streamline the design and operation of its financial control environment.

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information called for by this item is incorporated herein by reference to the discussion of the Audit Committee under the caption "Item 1. Election of Directors - Board Committees"; and the material under the captions "Item 1. Election of Directors" and, if applicable, "Stock Ownership and Section 16 Compliance – Delinquent Section 16(a) Reports" in the Proxy Statement; and the material under the caption "Executive Officers of the Registrant" in Part I of this Report.

The Company's Code of Business Conduct, which covers all employees (including the Chief Executive Officer, Chief Financial Officer and Controller), meets the requirements of the SEC rules promulgated under Section 406 of the Sarbanes-Oxley Act of 2002. The Code of Business Conduct is available on the Company's website at *www.jnj.com/code-of-business-conduct*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code of Business Conduct or any waiver of the Code granted to the Chief Executive Officer, the Chief Financial Officer or the Controller will be posted on the Company's website at *www.investor.jnj.com/gov.cfm* within five business days (and retained on the website for at least one year).

In addition, the Company has adopted a Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers. The Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers is available on the Company's website at *www.investor.jnj.com/gov/boardconduct.cfm*, and copies are available to shareholders

without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code or any waiver of the Code granted to any member of the Board of Directors or any executive officer will be posted on the Company's website at *www.investor.jnj.com/gov.cfm* within five business days (and retained on the website for at least one year).

Item 11. EXECUTIVE COMPENSATION

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1. Election of Directors – Director Compensation," and "Item 2. Compensation Committee Report," "Compensation Discussion and Analysis" and "Executive Compensation Tables" in the Proxy Statement.

The material incorporated herein by reference to the material under the caption "Compensation Committee Report" in the Proxy Statement shall be deemed furnished, and not filed, in this Report and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, as a result of this furnishing, except to the extent that the Company specifically incorporates it by reference.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information called for by this item is incorporated herein by reference to the material under the caption "Item 1. Stock Ownership and Section 16 Compliance" in the Proxy Statement; and Note 16 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements in Item 8 of this Report.

Equity Compensation Plan Information

The following table provides certain information as of January 3, 2021 concerning the shares of the Company's Common Stock that may be issued under existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights	Weighted Average Exercise Price of Outstanding Options and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans[2][3]
Equity Compensation Plans Approved by Security Holders[1]	131,483,837	$100.98	276,949,737
Equity Compensation Plans Not Approved by Security Holders	-	-	-
Total	131,483,837	$100.98	276,949,737

(1) Included in this category are the following equity compensation plans which have been approved by the Company's shareholders: 2005 Long-Term Incentive Plan and 2012 Long-Term Incentive Plan.

(2) This column excludes shares reflected under the column "Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights."

(3) The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1. Election of Directors - Director Independence" and "Related Person Transactions" in the Proxy Statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information called for by this item is incorporated herein by reference to the material under the caption "Item 3. Ratification of Appointment of Independent Registered Public Accounting Firm" in the Proxy Statement.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this report:

1. *Financial Statements*

   Consolidated Balance Sheets at end of Fiscal Years 2020 and 2019

   Consolidated Statements of Earnings for Fiscal Years 2020, 2019 and 2018

   Consolidated Statements of Comprehensive Income for Fiscal Years 2020, 2019 and 2018

   Consolidated Statements of Equity for Fiscal Years 2020, 2019 and 2018

   Consolidated Statements of Cash Flows for Fiscal Years 2020, 2019 and 2018

   Notes to Consolidated Financial Statements

   Report of Independent Registered Public Accounting Firm

   All schedules are omitted because they are not applicable or the required information is included in the financial statements or notes.

2. *Exhibits* Required *to be Filed by Item 601 of Regulation S-K*

   The information called for by this item is incorporated herein by reference to the Exhibit Index in this Report.

Item 16. FORM 10-K SUMMARY

Registrants may voluntarily include a summary of information required by Form 10-K under this Item 16. The Company has elected not to include such summary information.

SIGNATURES

Pursuant to the requirements of Section 13 of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 22, 2021

JOHNSON & JOHNSON
(Registrant)

By /s/ A. Gorsky
A. Gorsky, Chairman, Board of Directors,
and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ A. Gorsky A. Gorsky	Chairman, Board of Directors Chief Executive Officer (Principal Executive Officer)	February 22, 2021
/s/ J. J. Wolk J. J. Wolk	Chief Financial Officer (Principal Financial Officer)	February 22, 2021
/s/ R. J. Decker Jr. R. J. Decker Jr.	Controller and Chief Accounting Officer (Principal Accounting Officer)	February 22, 2021
/s/ M. C. Beckerle M. C. Beckerle	Director	February 22, 2021
/s/ D. S. Davis D. S. Davis	Director	February 22, 2021
/s/ I. E. L. Davis I. E. L. Davis	Director	February 22, 2021
/s/ J. A. Doudna J. A. Doudna	Director	February 22, 2021

Signature	Title	Date
/s/ M. A. Hewson M. A. Hewson	Director	February 22, 2021
/s/ H. Joly H. Joly	Director	February 22, 2021
/s/ M. B. McClellan M. B. McClellan	Director	February 22, 2021
/s/ A. M. Mulcahy A. M. Mulcahy	Director	February 22, 2021
/s/ C. Prince C. Prince	Director	February 22, 2021
/s/ A. E. Washington A. E. Washington	Director	February 22, 2021
/s/ M. A. Weinberger M. A. Weinberger	Director	February 22, 2021
/s/ N.Y. West N. Y. West	Director	February 22, 2021
/s/ R. A. Williams R. A. Williams	Director	February 22, 2021

EXHIBIT INDEX

Reg. S-K Exhibit Table Item No.	Description of Exhibit
3(i)	Restated Certificate of Incorporation effective February 19, 2016 — Incorporated herein by reference to Exhibit 3(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.
3(ii)	Certificate of Amendment to the Certificate of Incorporation of Johnson & Johnson effective April 30, 2020 — Incorporated herein by reference to Exhibit 3.1 of the Registrant's Form 8-K Current Report filed April 29, 2020.
3(iii)	By-Laws of the Company, as amended effective June 9, 2020 — Incorporated herein by reference to Exhibit 3.1 of the Registrant's Form 8-K Current Report filed June 10, 2020.
4(a)	Upon the request of the Securities and Exchange Commission, the Registrant will furnish a copy of all instruments defining the rights of holders of long-term debt of the Registrant.
4(b)	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 — Incorporated herein by reference to Exhibit 4.1 of the Registrant's Form 8-K Current Report filed August 12, 2020.
10(a)	2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 4 of the Registrant's S-8 Registration Statement filed on May 10, 2005 (file no. 333-124785).*
10(b)	Form of Stock Option Certificate under the 2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 8-K Current Report filed January 13, 2012.*
10(c)	2012 Long-Term Incentive Plan — Incorporated herein by reference to Appendix A of the Registrant's Proxy Statement filed on March 15, 2017.*
10(d)	Form of Stock Option Certificate, Restricted Share Unit Certificate and Performance Share Unit Certificate under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.2, 10.3 and 10.4 of the Registrant's Form 10-Q Quarterly Report for the quarter ended April 1, 2012.*
10(e)	Global NonQualified Stock Option Award Agreement, Global Restricted Share Unit Award Agreement and Global Performance Share Unit Award Agreement under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.1, 10.2 and 10.3 of the Registrant's Form 10-Q Quarterly Report for the quarter ended April 1, 2018.*
10(f)	Johnson & Johnson Executive Incentive Plan (Amended as of November 28, 2018) — Incorporated herein by reference to Exhibit 10(a) of the Registrant's Form 10-Q Quarterly Report for the quarter ended March 31, 2019.*
10(g)	Domestic Deferred Compensation (Certificate of Extra Compensation) Plan — Incorporated herein by reference to Exhibit 10(g) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2003.*
10(h)	Amendments to the Certificate of Extra Compensation Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(i)	2009 Certificates of Long-Term Performance Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 27, 2009.*
10(j)	Amended and Restated Deferred Fee Plan for Directors (Amended as of January 17, 2012) — Incorporated herein by reference to Exhibit 10(k) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 1, 2012.*
10(k)	The Johnson & Johnson Executive Income Deferral Plan Amended and Restated Effective January 1, 2010 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*
10(l)	Excess Savings Plan (Effective as of January 1, 1996) — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 29, 1996.*
10(m)	Amendments to the Johnson & Johnson Excess Savings Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(p) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2008.*
10(n)	Amended and Restated Excess Benefit Plan of Johnson & Johnson and Affiliated Companies (Amended and restated effective January 1, 2020, except as otherwise provided) — Filed with this document.*
10(o)**	Executive Life Plan Agreement — Incorporated herein by reference to Exhibit 10(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 1993.*
10(p)	Executive Life Plan Agreement Closure Letter — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended March 29, 2015.*
10(q)	Employment Agreement for Dr. Paulus Stoffels - Incorporated herein by reference to Exhibit 10.2 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*

Reg. S-K Exhibit Table Item No.	Description of Exhibit
10(r)	Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies, Amended and Restated as of October 1, 2014 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 28, 2014.*
10(s)	First Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended June 28, 2015.*
10(t)	Second Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10(x) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.*
21	Subsidiaries — Filed with this document.
23	Consent of Independent Registered Public Accounting Firm — Filed with this document.
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
32.1	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
32.2	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
Exhibit 101:	
EX-101.INS	Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
EX-101.SCH	Inline XBRL Taxonomy Extension Schema
EX-101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
EX-101.LAB	Inline XBRL Taxonomy Extension Label Linkbase
EX-101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
EX-101.DEF	Inline XBRL Taxonomy Extension Definition Document
Exhibit 104:	Cover Page Interactive Data File—the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

* Management contract or compensatory plan.

** Paper filing.

A copy of any of the Exhibits listed above will be provided without charge to any shareholder submitting a written request specifying the desired exhibit(s) to the Secretary at the principal executive offices of the Company. Pursuant to Item 601(b)(4)(iii)(A) of Regulation S-K, the Company has not filed as exhibits to this Form 10-K certain long-term debt instruments, including indentures, under which the total amount of securities authorized does not exceed 10% of the total assets of the Company and its subsidiaries on a consolidated basis. The Company hereby agrees to furnish a copy of any such instrument to the SEC upon request.

Exhibit “J19”

This is Exhibit “J19” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended January 1, 2023

or

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
for the transition period from to

Commission file number 1-3215

JOHNSON & JOHNSON

(Exact name of registrant as specified in its charter)

New Jersey	**22-1024240**
(State of incorporation)	(I.R.S. Employer Identification No.)
One Johnson & Johnson Plaza **New Brunswick, New Jersey**	**08933**
(Address of principal executive offices)	(Zip Code)

One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
(Address of principal executive offices)

Registrant's telephone number, including area code: **(732) 524-0400**

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, Par Value $1.00	JNJ	New York Stock Exchange
0.650% Notes Due May 2024	JNJ24C	New York Stock Exchange
5.50% Notes Due November 2024	JNJ24BP	New York Stock Exchange
1.150% Notes Due November 2028	JNJ28	New York Stock Exchange
1.650% Notes Due May 2035	JNJ35	New York Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☑ No ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $472 billion.

On February 10, 2023, there were 2,604,286,303 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Parts I and III: Portions of registrant's proxy statement for its 2023 annual meeting of shareholders filed within 120 days after the close of the registrant's fiscal year (the "Proxy Statement"), are incorporated by reference to this report on Form 10-K (this "Report").

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and Johnson & Johnson's other publicly available documents contain "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Management and representatives of Johnson & Johnson and its subsidiaries (the Company) also may from time to time make forward-looking statements. Forward-looking statements do not relate strictly to historical or current facts and reflect management's assumptions, views, plans, objectives and projections about the future. Forward-looking statements may be identified by the use of words such as "plans," "expects," "will," "anticipates," "estimates" and other words of similar meaning in conjunction with, among other things: discussions of future operations; expected operating results and financial performance; impact of planned acquisitions and dispositions; impact and timing of restructuring initiatives, including associated cost savings and other benefits; the planned separation of the Company's Consumer Health business; the Company's strategy for growth; product development activities; regulatory approvals; market position and expenditures.

Because forward-looking statements are based on current beliefs, expectations and assumptions regarding future events, they are subject to uncertainties, risks and changes that are difficult to predict and many of which are outside of the Company's control. Investors should realize that if underlying assumptions prove inaccurate, or known or unknown risks or uncertainties materialize, the Company's actual results and financial condition could vary materially from expectations and projections expressed or implied in its forward-looking statements. Investors are therefore cautioned not to rely on these forward-looking statements. Risks and uncertainties include, but are not limited to:

Risks Related to Product Development, Market Success and Competition

- Challenges and uncertainties inherent in innovation and development of new and improved products and technologies on which the Company's continued growth and success depend, including uncertainty of clinical outcomes, additional analysis of existing clinical data, obtaining regulatory approvals, health plan coverage and customer access, and initial and continued commercial success;
- Challenges to the Company's ability to obtain and protect adequate patent and other intellectual property rights for new and existing products and technologies in the United States and other important markets;
- The impact of patent expirations, typically followed by the introduction of competing generic, biosimilar or other products and resulting revenue and market share losses;
- Increasingly aggressive and frequent challenges to the Company's patents by competitors and others seeking to launch competing generic, biosimilar or other products and increased receptivity of courts, the United States Patent and Trademark Office and other decision makers to such challenges, potentially resulting in loss of market exclusivity and rapid decline in sales for the relevant product sooner than expected;
- Competition in research and development of new and improved products, processes and technologies, which can result in product and process obsolescence;
- Competition to reach agreement with third parties for collaboration, licensing, development and marketing agreements for products and technologies;
- Competition based on cost-effectiveness, product performance, technological advances and patents attained by competitors; and
- Allegations that the Company's products infringe the patents and other intellectual property rights of third parties, which could adversely affect the Company's ability to sell the products in question and require the payment of money damages and future royalties.

Risks Related to Product Liability, Litigation and Regulatory Activity

- Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the United States Food and Drug Administration (or international counterparts), declining sales, reputational damage, increased litigation expense and share price impact;
- The impact, including declining sales and reputational damage, of significant litigation or government action adverse to the Company, including product liability claims and allegations related to pharmaceutical marketing practices and contracting strategies;

- The impact of an adverse judgment or settlement and the adequacy of reserves related to legal proceedings, including patent litigation, product liability, personal injury claims, securities class actions, government investigations, employment and other legal proceedings;
- Increased scrutiny of the healthcare industry by government agencies and state attorneys general resulting in investigations and prosecutions, which carry the risk of significant civil and criminal penalties, including, but not limited to, debarment from government business;
- Failure to meet compliance obligations in compliance agreements with governments or government agencies, which could result in significant sanctions;
- Potential changes to applicable laws and regulations affecting United States and international operations, including relating to: approval of new products; licensing and patent rights; sales and promotion of healthcare products; access to, and reimbursement and pricing for, healthcare products and services; environmental protection; and sourcing of raw materials;
- Compliance with local regulations and laws that may restrict the Company's ability to manufacture or sell its products in relevant markets, including requirements to comply with medical device reporting regulations and other requirements such as the European Union's Medical Devices Regulation;
- Changes in domestic and international tax laws and regulations, increasing audit scrutiny by tax authorities around the world and exposures to additional tax liabilities potentially in excess of existing reserves; and
- The issuance of new or revised accounting standards by the Financial Accounting Standards Board and regulations by the Securities and Exchange Commission.

Risks Related to the Company's Strategic Initiatives, Healthcare Market Trends and the Planned Separation of the Company's Consumer Health Business

- Pricing pressures resulting from trends toward healthcare cost containment, including the continued consolidation among healthcare providers and other market participants, trends toward managed care, the shift toward governments increasingly becoming the primary payers of healthcare expenses, significant new entrants to the healthcare markets seeking to reduce costs and government pressure on companies to voluntarily reduce costs and price increases;
- Restricted spending patterns of individual, institutional and governmental purchasers of healthcare products and services due to economic hardship and budgetary constraints;
- Challenges to the Company's ability to realize its strategy for growth including through externally sourced innovations, such as development collaborations, strategic acquisitions, licensing and marketing agreements, and the potential heightened costs of any such external arrangements due to competitive pressures;
- The potential that the expected strategic benefits and opportunities from any planned or completed acquisition or divestiture by the Company may not be realized or may take longer to realize than expected;
- The potential that the expected benefits and opportunities related to past and ongoing restructuring actions may not be realized or may take longer to realize than expected;
- The Company's ability to consummate the planned separation of the Company's Consumer Health business on a timely basis or at all;
- The Company's ability to successfully separate the Company's Consumer Health business and realize the anticipated benefits from the planned separation; and
- The New Consumer Health Company's ability to succeed as a standalone publicly traded company.

Risks Related to Economic Conditions, Financial Markets and Operating Internationally

- The risks associated with global operations on the Company and its customers and suppliers, including foreign governments in countries in which the Company operates;
- The impact of inflation and fluctuations in interest rates and currency exchange rates and the potential effect of such fluctuations on revenues, expenses and resulting margins;
- Potential changes in export/import and trade laws, regulations and policies of the United States and other countries, including any increased trade restrictions or tariffs and potential drug reimportation legislation;
- The impact on international operations from financial instability in international economies, sovereign risk, possible imposition of governmental controls and restrictive economic policies, and unstable international governments and legal systems;
- The impact of global public health crises and pandemics, including the novel coronavirus (COVID-19) pandemic;

- Changes to global climate, extreme weather and natural disasters that could affect demand for the Company's products and services, cause disruptions in manufacturing and distribution networks, alter the availability of goods and services within the supply chain, and affect the overall design and integrity of the Company's products and operations; and
- The impact of armed conflicts and terrorist attacks in the United States and other parts of the world, including social and economic disruptions and instability of financial and other markets.

Risks Related to Supply Chain and Operations

- Difficulties and delays in manufacturing, internally, through third-party providers or otherwise within the supply chain, that may lead to voluntary or involuntary business interruptions or shutdowns, product shortages, withdrawals or suspensions of products from the market, and potential regulatory action;
- Interruptions and breaches of the Company's information technology systems or those of the Company's vendors, which could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action;
- Reliance on global supply chains and production and distribution processes that are complex and subject to increasing regulatory requirements that may adversely affect supply, sourcing and pricing of materials used in the Company's products; and
- The potential that the expected benefits and opportunities related to restructuring actions contemplated for the global supply chain may not be realized or may take longer to realize than expected, including due to any required approvals from applicable regulatory authorities.

Investors also should carefully read the Risk Factors described in Item 1A of this Annual Report on Form 10-K for a description of certain risks that could, among other things, cause the Company's actual results to differ materially from those expressed in its forward-looking statements. Investors should understand that it is not possible to predict or identify all such factors and should not consider the risks described above and in Item 1A to be a complete statement of all potential risks and uncertainties. The Company does not undertake to publicly update any forward-looking statement that may be made from time to time, whether as a result of new information or future events or developments.

PART I

Item 1. BUSINESS

General

Johnson & Johnson and its subsidiaries (the Company) have approximately 152,700 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the healthcare field. Johnson & Johnson is a holding company, with operating companies conducting business in virtually all countries of the world. The Company's primary focus is products related to human health and well-being. Johnson & Johnson was incorporated in the State of New Jersey in 1887.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Company's three business segments: Consumer Health, Pharmaceutical and MedTech (previously referred to as Medical Devices). Within the strategic parameters provided by the Committee, senior management groups at U.S. and international operating companies are each responsible for their own strategic plans and the day-to-day operations of those companies. Each subsidiary within the business segments is, with limited exceptions, managed by residents of the country where located.

Segments of Business

The Company is organized into three business segments: Consumer Health, Pharmaceutical and MedTech. Additional information required by this item is incorporated herein by reference to the narrative and tabular descriptions of segments and operating results under: "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition" of this Report; and Note 17 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Consumer Health

The Consumer Health segment includes a broad range of products focused on personal healthcare used in the Skin Health/Beauty, Over-the-Counter medicines, Baby Care, Oral Care, Women's Health and Wound Care markets. Major brands in Skin Health/Beauty include the AVEENO; CLEAN & CLEAR; DR. CI:LABO; NEUTROGENA and OGX product lines. Over-the-Counter (OTC) medicines include the broad family of TYLENOL acetaminophen products; SUDAFED cold, flu and allergy products; BENADRYL and ZYRTEC allergy products; MOTRIN IB ibuprofen products; NICORETTE smoking cessation products outside the U.S.; ZARBEE'S products, inspired by nature, and the PEPCID line of acid reflux products. Baby Care includes the JOHNSON'S and AVEENO Baby line of products. Oral Care includes the LISTERINE product line. Major brands in Women's Health outside of North America are STAYFREE and CAREFREE sanitary pads and o.b. tampon brands. Wound Care brands include the BAND-AID Brand Adhesive Bandages and NEOSPORIN First Aid product lines. These products are marketed to the general public and sold online (eCommerce) and to retail outlets and distributors throughout the world.
In November 2021, the Company announced its intention to separate the Company's Consumer Health business (Kenvue as the name for the planned New Consumer Health Company), with the intention to create a new, publicly traded company by the end of the fiscal year 2023.

Pharmaceutical

The Pharmaceutical segment is focused on the following therapeutic areas: Immunology (e.g., rheumatoid arthritis, psoriatic arthritis, inflammatory bowel disease and psoriasis), Infectious Diseases (e.g., HIV/AIDS), Neuroscience (e.g., mood disorders, neurodegenerative disorders and schizophrenia), Oncology (e.g., prostate cancer, hematologic malignancies, lung cancer and bladder cancer), Cardiovascular and Metabolism (e.g., thrombosis, diabetes and macular degeneration) and Pulmonary Hypertension (e.g., Pulmonary Arterial Hypertension). Medicines in this segment are distributed directly to retailers, wholesalers, distributors, hospitals and healthcare professionals for prescription use. Key products in the Pharmaceutical segment include: REMICADE (infliximab), a treatment for a number of immune-mediated inflammatory diseases; SIMPONI (golimumab), a subcutaneous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis and moderately active to severely active ulcerative colitis; SIMPONI ARIA (golimumab), an intravenous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis and active ankylosing spondylitis and active polyarticular juvenile idiopathic arthritis (pJIA) in people 2 years of age and older; STELARA (ustekinumab), a treatment for adults and children with moderate to severe plaque psoriasis, for adults with active psoriatic arthritis, for adults with moderately to severely active Crohn's disease and treatment of moderately to severely active ulcerative colitis; TREMFYA (guselkumab), a treatment for adults with moderate to severe plaque psoriasis and active psoriatic arthritis; EDURANT (rilpivirine), PREZISTA (darunavir) and PREZCOBIX/REZOLSTA (darunavir/cobicistat), antiretroviral medicines for the treatment of human immunodeficiency virus (HIV-1) in combination with other antiretroviral products and SYMTUZA (darunavir/cobicistat/emtricitabine/tenofovir alafenamide), a once-daily single tablet regimen for the treatment of HIV; CONCERTA (methylphenidate HCl) extended-release tablets CII, a treatment for attention deficit hyperactivity disorder; INVEGA SUSTENNA/XEPLION (paliperidone palmitate), for the treatment of schizophrenia and schizoaffective disorder in adults; INVEGA TRINZA/TREVICTA (paliperidone palmitate), for the treatment of schizophrenia in patients after they have been adequately treated with INVEGA SUSTENNA for at least four months; RISPERDAL CONSTA (risperidone long-acting injection), for the treatment of schizophrenia and the maintenance treatment of Bipolar 1 Disorder in adults; ZYTIGA

(abiraterone acetate), a treatment for patients with prostate cancer; ERLEADA (apalutamide), a next-generation androgen receptor inhibitor for the treatment of patients with prostate cancer; IMBRUVICA (ibrutinib), a treatment for certain B-cell malignancies, or blood cancers and chronic graft versus host disease; DARZALEX (daratumumab), a treatment for multiple myeloma; DARZALEX FASPRO (daratumumab and hyaluronidase-fihj), a treatment for multiple myeloma and light chain (AL) Amyloidosis; XARELTO (rivaroxaban), an oral anticoagulant for the prevention of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery, to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, and for the treatment and reduction of risk of recurrence of DVT and PE to reduce the risk of major cardiovascular events in patients with coronary artery disease (CAD) and peripheral artery disease (PAD), for the treatment and secondary prevention of thromboembolism in pediatric patients, and for thromboprophylaxis in pediatric patients following the Fontan procedure; INVOKANA (canagliflozin), for the treatment of adults with type 2 diabetes; INVOKAMET/VOKANAMET (canagliflozin/metformin HCl), a combination therapy of fixed doses of canagliflozin and metformin hydrochloride for the treatment of adults with type 2 diabetes; and INVOKAMET XR (canagliflozin/metformin hydrochloride extended-release), a once-daily, fixed-dose combination therapy of canagliflozin and metformin hydrochloride extended-release, for the treatment of adults with type 2 diabetes; OPSUMIT (macitentan) as monotherapy or in combination, indicated for the long-term treatment of pulmonary arterial hypertension (PAH); UPTRAVI (selexipag), the only approved oral and intravenous, selective IP receptor agonist targeting a prostacyclin pathway in PAH. Many of these medicines were developed in collaboration with strategic partners or are licensed from other companies and maintain active lifecycle development programs.

MedTech

The MedTech (previously referred to as Medical Devices) segment includes a broad portfolio of products used in the Interventional Solutions, Orthopaedics, Surgery and Vision categories. Interventional Solutions include Electrophysiology products (Biosense Webster) to treat cardiovascular diseases, Neurovascular care (Cerenovus) that treats hemorrhagic and ischemic stroke and the Heart Recovery portfolio (Abiomed) which includes technologies to treat severe coronary artery disease requiring high-risk PCI or AMI cardiogenic shock. The Orthopaedics portfolio (DePuy Synthes) comprises products in support of Hips, Knees, Trauma, and Spine, Sports & Other. The Surgery portfolios include advanced and general surgery offerings (Ethicon), solutions that focus on Breast Aesthetics (Mentor), and Ear, Nose and Throat (Acclarent) procedures. Johnson & Johnson Vision products include ACUVUE Brand contact lenses and ophthalmic technologies related to cataract and laser refractive surgery. These products are distributed to wholesalers, hospitals and retailers, and used predominantly in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

Geographic Areas

Johnson & Johnson and its subsidiaries (the Company) have approximately 152,700 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the healthcare field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The products made and sold in the international business include many of those described above under "– Segments of Business – Consumer Health," "– Pharmaceutical" and "– MedTech." However, the principal markets, products and methods of distribution in the international business vary with the country and the culture. The products sold in international business include those developed in the U.S. and by subsidiaries abroad.

Investments and activities in some countries outside the U.S. are subject to higher risks than comparable U.S. activities because the investment and commercial climate may be influenced by financial instability in international economies, restrictive economic policies and political and legal system uncertainties.

Raw Materials

Raw materials essential to the Company's business are generally readily available from multiple sources. Where there are exceptions, the temporary unavailability of those raw materials would not likely have a material adverse effect on the financial results of the Company.

Patents

The Company's subsidiaries have made a practice of obtaining patent protection on their products and processes where possible. They own, or are licensed under, a significant number of patents in the U.S. and other countries relating to their products, product uses, formulations and manufacturing processes, which in the aggregate are believed to be of material importance to the Company in the operation of its businesses. The Company's subsidiaries face patent challenges from third parties, including challenges seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. Significant legal proceedings and claims involving the Company's patent and other intellectual property are described in Note 19, "Legal Proceedings—Intellectual Property" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Sales of the Company's largest product, STELARA (ustekinumab), accounted for approximately 10.2% of the Company's total revenues for fiscal 2022. Accordingly, the patents related to this product are believed to be material to the

Company. Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson, owns patents specifically related to STELARA. The latest expiring United States composition of matter patent expires in 2023. The latest expiring European composition of matter patent expires in 2024.

Sales of the Company's second largest product, collectively DARZALEX (daratumumab) and DARZALEX FASPRO (daratumumab and hyaluronidase-fihj), accounted for approximately 8.4% of the Company's total revenues for fiscal 2022. Accordingly, the patents related to this product are believed to be material to the Company. Genmab A/S owns two patent families related to DARZALEX, and Janssen Biotech, Inc. has an exclusive license to those patent families. The two patent families both expire in the United States in 2029. The latest expiring licensed European patent expires in 2032. Janssen Biotech, Inc. owns a separate patent portfolio related to DARZALEX FASPRO.

Trademarks

The Company's subsidiaries have made a practice of selling their products under trademarks and of obtaining protection for these trademarks by all available means. These trademarks are protected by registration in the U.S. and other countries where such products are marketed. The Company considers these trademarks in the aggregate to be of material importance in the operation of its businesses.

Seasonality

Worldwide sales do not reflect any significant degree of seasonality; however, spending has typically been heavier in the fourth quarter of each year than in other quarters. This reflects increased spending decisions, principally for advertising and research and development activity.

Competition

In all of their product lines, the Company's subsidiaries compete with companies both locally and globally. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, both internally and externally sourced, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products, as well as protecting the underlying intellectual property of the Company's product portfolio, is important to the Company's success in all areas of its business. The competitive environment requires substantial investments in continuing research. In addition, the development and maintenance of customer demand for the Company's consumer products involve significant expenditures for advertising and promotion.

Environment

The Company is subject to a variety of U.S. and international environmental protection measures. The Company believes that its operations comply in all material respects with applicable environmental laws and regulations. The Company's compliance with these requirements is not expected to have a material effect upon its capital expenditures, cash flows, earnings or competitive position.

Regulation

The Company's businesses are subject to varying degrees of governmental regulation in the countries in which operations are conducted, and the general trend is toward increasingly stringent regulation and enforcement. The Company is subject to costly and complex U.S. and foreign laws and governmental regulations and any adverse regulatory action may materially adversely affect the Company's financial condition and business operations. In the U.S., the drug, device and cosmetic industries have long been subject to regulation by various federal and state agencies, primarily as to product safety, efficacy, manufacturing, advertising, labeling and safety reporting. The exercise of broad regulatory powers by the U.S. Food and Drug Administration (the U.S. FDA) continues to result in increases in the amounts of testing and documentation required for U.S. FDA approval of new drugs and devices and a corresponding increase in the expense of product introduction. Similar trends are also evident in major markets outside of the U.S. The new medical device regulatory framework and the evolving privacy, data localization, and emerging cyber security laws and regulations around the world are examples of such increased regulation. Five U.S. States (California, Connecticut, Colorado, Utah and Virginia) now have comprehensive privacy laws in place and China introduced broad personal information protection and data security regulations in 2022. With other jurisdictions enacting similar privacy laws, local data protection authorities will force greater accountability on the collection, access and use of personal data in the healthcare industry.

The regulatory agencies under whose purview the Company operates have administrative powers that may subject it to actions such as product withdrawals, recalls, seizure of products and other civil and criminal sanctions. In some cases, the Company's subsidiaries may deem it advisable to initiate product recalls regardless of whether it has been required or directed to.

The U.S. FDA and regulatory agencies around the globe are also increasing their enforcement activities. If the U.S. FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our drugs or medical

devices are ineffective or pose an unreasonable health risk, the U.S. FDA could ban such products, detain or seize adulterated or misbranded products, order a recall, repair, replacement, or refund of such products, refuse to grant pending applications for marketing authorization or require certificates of foreign governments for exports, and/or require us to notify health professionals and others that the products present unreasonable risks of substantial harm to the public health. The U.S. FDA may also assess civil or criminal penalties against us, our officers or employees and impose operating restrictions on a company-wide basis, or enjoin and/or restrain certain conduct resulting in violations of applicable law. The U.S. FDA may also recommend prosecution to the U.S. Department of Justice. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and limit our ability to obtain future clearances or approvals, and could result in a substantial modification to our business practices and operations. Equivalent enforcement mechanisms exist in different countries in which we conduct business.

The costs of human healthcare have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. In the U.S., attention has been focused by states, regulatory agencies and Congress on prices, profits, overutilization and the quality and costs of healthcare generally. Laws and regulations have been enacted to require adherence to strict compliance standards and prevent fraud and abuse in the healthcare industry. There is increased focus on interactions and financial relationships between healthcare companies and healthcare providers. Various transparency laws and regulations require disclosures of payments and other transfers of value made to physicians and teaching hospitals and, beginning with disclosures in 2022, to certain non-physician practitioners. Federal and foreign laws governing international business practices require strict compliance with anti-bribery standards and certain prohibitions with respect to payments to any foreign government official. Payers and Pharmacy Benefit Managers (PBMs) have become a more potent force in the market place and increased attention is being paid to drug pricing and appropriate drug and medical device utilization.

Our business has been and continues to be affected by federal and state legislation that alters the pricing, coverage, and reimbursement landscape. At the federal level, in August 2022, President Biden signed into law the Inflation Reduction Act (IRA), which includes provisions that effectively authorize the government to establish prices for certain high-spend single-source drugs and biologics reimbursed by the Medicare program, starting in 2026 for Medicare Part D drugs and 2028 for Medicare Part B drugs. It is not yet certain which products the federal government will select and subject to government-established prices, or how the federal government will establish prices for selected products, as the IRA specifies a ceiling price but not a minimum price. One or more of our products could be selected and subject to the government-established price.

The IRA also contains provisions that impose rebates if certain prices increase at a rate that outpaces the rate of inflation, beginning October 1, 2022, for Medicare Part D drugs and January 1, 2023, for Medicare Part B drugs. Separate IRA provisions redesign the Medicare Part D benefit in various ways, including by shifting a greater portion of costs to manufacturers within certain coverage phases and replacing the Part D coverage gap discount program with a new manufacturer discounting program. Failure to comply with IRA provisions may subject manufacturers to various penalties, including civil monetary penalties. The impact of the IRA on our business and the broader pharmaceutical industry remains uncertain, as the federal government has yet to make various IRA implementation decisions.

Additionally, we expect continued scrutiny on drug pricing and government price reporting from Congress, agencies, and other bodies at the federal and state levels.

There are a number of additional bills pending in Congress and healthcare reform proposals at the state level that would affect drug pricing, including in the Medicare and Medicaid programs. This changing legal landscape has both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of federal and state law, and potential modification or repeal of these laws, will ultimately affect the industry. The IRA and any other federal or state legislative change could affect the pricing and market conditions for our products.

In addition, business practices in the healthcare industry have come under increased scrutiny, particularly in the U.S., by government agencies and state attorneys general, and resulting investigations and prosecutions carry the risk of significant civil and criminal penalties. Of note is the increased enforcement activity by data protection authorities in various jurisdictions, particularly in the European Union, where significant fines have been levied on companies for data breaches, violations of privacy requirements, and unlawful cross-border data transfers. In the U.S., the Federal Trade Commission has stepped up enforcement of data privacy with several significant settlements and there have been a material increase in class-action lawsuits linked to the collection and use of biometric data.

Further, the Company relies on global supply chains, and production and distribution processes, that are complex, are subject to increasing regulatory requirements, and may be faced with unexpected changes such as those resulting from the

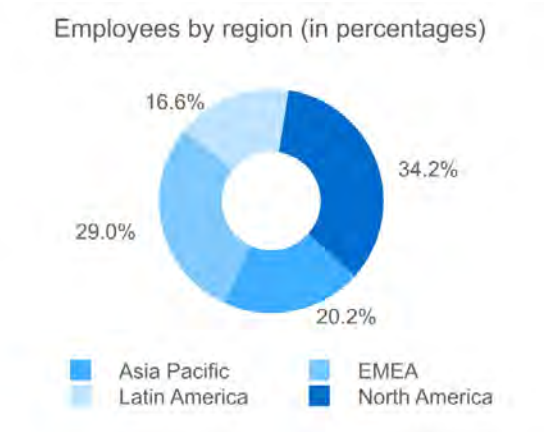
COVID-19 pandemic and Brexit that may affect sourcing, supply and pricing of materials used in the Company's products. These processes also are subject to complex and lengthy regulatory approvals.

Employees and Human Capital Management

As of January 1, 2023, and January 2, 2022, the number of employees were approximately:

	2022	2021
Employees[1]	155,800	144,300
Full-time equivalent (FTE) positions[2]	152,700	141,700

[1] "Employee" is defined as an individual working full-time or part-time, excluding fixed term employees, interns and co-op employees. Employee data may not include full population from more recently acquired companies and individuals on long-term disability are excluded. Contingent workers, contractors and subcontractors are also excluded. Abiomed headcount has been included in the above table.
[2] FTE represents the total number of full-time equivalent positions and does not reflect the total number of individual employees as some work part-time.



Strategy

The Company believes that its employees are critical to its continued success and are an essential element of its long-term strategy. Management is responsible for ensuring that its policies and processes reflect and reinforce the Company's desired corporate culture, including policies and processes related to strategy, risk management, and ethics and compliance. The Company's human capital management strategy is built on three fundamental focus areas:

- Attracting and recruiting the best talent
- Developing and retaining talent
- Empowering and inspiring talent

Underpinning these focus areas are ongoing efforts to cultivate and foster a culture built on diversity, equity and inclusion (DEI), innovation, health, well-being and safety, where the Company's employees are encouraged to succeed both professionally and personally while helping the Company achieve its business goals.

Culture and Employee Engagement

At the Company, employees are guided by Our Credo which sets forth the Company's responsibilities to patients, consumers, customers, healthcare professionals, employees, communities and shareholders. Employees worldwide must adhere to the Company's Code of Business Conduct which sets basic requirements and serves as a foundation for the Company policies, procedures and guidelines, all of which provide additional guidance on expected employee behaviors in every market where it operates. The Company conducts global surveys that offer its employees the ability to provide feedback and valuable insight to help address potential human resources risks and identify opportunities to improve. In 2022, 92% of global employees across 77 countries participated in Our Credo Survey which was offered in 36 languages.

Growth and Development

To continue to lead in the changing healthcare landscape, it is crucial that the Company continue to attract and retain top talent. The Company believes that its employees must be equipped with the right knowledge and skills and be provided with opportunities to grow and develop in their careers. Accordingly, professional development programs and educational resources
are available to all employees. The Company's objective is to foster a learning culture that helps shape each person's unique career path while creating a robust pipeline of talent to deliver on the Company's long-term strategies. In furtherance of this objective, the Company deploys a global approach to ensure development is for everyone, regardless of where they are on their career journey. In 2022, 46.2% of employees in Manager and above job categories who had movements (including upward promotions or lateral transfers) took advantage of career opportunities by moving across functions, country or business segment lines (excluding employees in the research and development organizations). The Company's voluntary turnover rate was 9%.

Diversity, Equity, and Inclusion (DEI)

The Company is committed to workplace diversity and to cultivating, fostering, and advancing a culture of equity and inclusion. In 2022, Johnson & Johnson introduced the Company's evolved enterprise Diversity, Equity and Inclusion strategy, which recognizes how DEI accelerates the Company's ability to meet the changing needs of the communities the Company serves to deliver Our Purpose to profoundly change the trajectory of health for humanity. The Company's DEI vision is: *Be yourself, change the world.* The Company's DEI Mission is: *Make diversity, equity and inclusion how we work everyday*. Our evolved enterprise DEI Strategy is aligned to our DEI Vision and Mission and rests on four core pillars:

- Accelerate our global culture of inclusion where every individual belongs
- Build a workforce that reflects the diversity of our communities
- Transform talent and business processes to achieve equitable access and outcomes for all
- Drive innovation and growth with our business to serve diverse markets around the world

The Company's DEI strategy is guided by internal and external insights, global best practices and continual employee feedback which remind the Company that while diversity changes by location, inclusion is the same everywhere.

Compensation and Benefits

As part of the Company's total rewards philosophy, the Company offers competitive compensation and benefits to attract and retain top talent. The Company is committed to fairness and equitable treatment in its compensation and benefits for employees at all levels. The Company observes legal minimum wage provisions and exceeds them where possible. The Company's total rewards offerings include an array of programs to support its employees' well-being, including annual performance incentive opportunities, pension and retirement savings programs, health and welfare benefits, paid time off, leave programs, flexible work schedules and employee assistance programs. In recognition of the Company's commitment to help employees balance their personal and professional responsibilities, the Company extended its paid parental leave benefit globally from 8 to 12 weeks for all eligible employees. In the U.S., the benefit was effective on January 1, 2022, with retroactive coverage for new family additions as of July 1, 2021.

Health, Wellness and Safety

The Company's investment in employee health, well-being and safety is built on its conviction that advancing health for humanity starts with advancing the health of its employees. With the right awareness, focus, practices and tools, the Company ensures that all its employees around the world, as well as temporary contractors and visitors to the Company's sites, can work safely. The Company has continuously expanded health and well-being programs throughout the Company and across the globe, incorporating new thinking and technologies to keep its offerings best-in-class and to help employees achieve their personal health goals. The programs and practices the Company advances for total health—physical, mental, emotional and financial—ensure employee health protection for emerging health risks. Protecting and supporting our employees as the COVID-19 pandemic has evolved continues to be a top priority and the Company's approach includes: ensuring the health and safety of our employees in the workplace through robust layers of protection; enhanced cleaning and access to cleaning supplies and personal protective equipment; supporting employees with benefits and well-being tools. The Company continues to address our employees needs through J&J Flex, a hybrid model that empowers the Company's office-based employees to find the right productivity and balance of in-person and remote work.

Available Information

The Company's main corporate website address is *www.jnj.com*. All of the Company's SEC filings are also available on the Company's website at *www.investor.jnj.com/sec.cfm*, as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*.

Investors and the public should note that the Company also announces information at *www.factsaboutourprescriptionopioids.com, www.factsabouttalc.com* and *www.LTLManagementInformation.com*.
We use these websites to communicate with investors and the public about our products, litigation and other matters. It is possible that the information we post to these websites could be deemed to be material information. Therefore, we encourage investors and others interested in the Company to review the information posted to these websites in conjunction with www.jnj.com, the Company's SEC filings, press releases, public conference calls and webcasts.

In addition, the Amended and Restated Certificate of Incorporation, By-Laws, the written charters of the Audit Committee, the Compensation & Benefits Committee, the Nominating & Corporate Governance Committee, the Regulatory Compliance & Sustainability Committee, the Science & Technology Committee and any special committee of the Board of Directors and the Company's Principles of Corporate Governance, Code of Business Conduct (for employees), Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers, and other corporate governance materials, are available at *www.investor.jnj.com/gov.cfm* on the Company's website and will be provided without charge to any shareholder submitting a written request, as provided above. The information on *www.jnj.com*, *www.factsaboutourprescriptionopioids.com, www.factsabouttalc.com* and *www.LTLManagementInformation.com* is not, and will not be deemed, a part of this Report or incorporated into any other filings the Company makes with the SEC.

Item 1A. RISK FACTORS

An investment in the Company's common stock or debt securities involves risks and uncertainties. The Company seeks to identify, manage and mitigate risks to our business, but uncertainties and risks are difficult to predict and many are outside of the Company's control and cannot therefore be eliminated. In addition to the other information in this report and the Company's other filings with the SEC, investors should consider carefully the factors set forth below. Investors should be aware that it is not possible to predict or identify all such factors and that the following is not meant to be a complete discussion of all potential risks or uncertainties. If known or unknown risks or uncertainties materialize, the Company's business, results of operations or financial condition could be adversely affected, potentially in a material way.

Risks Related to Our Business, Industry and Operations

The Company's businesses operate in highly competitive product markets and competitive pressures could adversely affect the Company's earnings.

The Company faces substantial competition in all three operating segments and in all geographic markets. The Company's businesses compete with companies of all sizes on the basis of cost-effectiveness, technological innovations, intellectual property rights, product performance, real or perceived product advantages, pricing and availability and rate of reimbursement. The Company also competes with other market participants in securing rights to acquisitions, collaborations and licensing agreements with third parties. Competition for rights to product candidates and technologies may result in significant investment and acquisition costs and onerous agreement terms for the Company. Competitors' development of more effective or less costly products, and/or their ability to secure patent and other intellectual property rights and successfully market products ahead of the Company, could negatively impact sales of the Company's existing products as well as its ability to bring new products to market despite significant prior investment in the related product development.

For the Company's Pharmaceutical businesses, loss of patent exclusivity for a product often is followed by a substantial reduction in sales as competitors gain regulatory approval for generic and other competing products and enter the market. Similar competition can be triggered by the loss of exclusivity for a biological product. For the Company's MedTech businesses, technological innovation, product quality, reputation and customer service are especially important to competitiveness. Development by other companies of new or improved products, processes and technologies could threaten to make the Company's products or technologies less desirable, less economical or obsolete. The Company's Consumer Health businesses face intense competition from other branded products and retailers' private-label brands. If the Company fails to sufficiently differentiate and market its brand name consumer products, this could adversely affect revenues and profitability of those products.

Interruptions and delays in manufacturing operations could adversely affect the Company's business, sales and reputation.

The Company's manufacture of products requires the timely delivery of sufficient amounts of complex, high-quality components and materials. The Company's subsidiaries operate 89 manufacturing facilities as well as sourcing from thousands of suppliers around the world. The Company has in the past, and may in the future, face unanticipated interruptions and delays in manufacturing through its internal or external supply chain. Manufacturing disruptions can occur for many reasons including regulatory action, production quality deviations or safety issues, labor disputes, labor shortages, site-specific incidents (such as fires), natural disasters such as hurricanes and other severe weather events, raw material shortages, political unrest, terrorist attacks and epidemics or pandemics. Such delays and difficulties in manufacturing can result in product shortages, declines in sales and reputational impact as well as significant remediation and related costs associated with addressing the shortage.

The Company relies on third parties to manufacture certain of our products. Any failure by or loss of a third-party manufacturer could result in delays and increased costs, which may adversely affect our business.

The Company relies on third parties to manufacture certain of our products. We depend on these third-party manufacturers to allocate to us a portion of their manufacturing capacity sufficient to meet our needs, to produce products of acceptable quality and at acceptable manufacturing yields and to deliver those products to us on a timely basis and at acceptable prices. However, we cannot guarantee that these third-party manufacturers will be able to meet our near-term or long-term manufacturing requirements, which could result in lost sales and have an adverse effect on our business.

Other risks associated with our reliance on third parties to manufacture these products include reliance on the third party for regulatory compliance and quality assurance, misappropriation of the Company's intellectual property, limited ability to manage our inventory, possible breach of the manufacturing agreement by the third party and the possible termination or nonrenewal of the manufacturing agreement by the third party at a time that is costly or inconvenient for us. Moreover, if any of our third-party manufacturers suffers any damage to facilities, loses benefits under material agreements, experiences power outages, encounters financial difficulties, is unable to secure necessary raw materials from its suppliers or suffers any other reduction in efficiency, the Company may experience significant business disruption. In the event of any such disruption, the

Company would need to seek and source other qualified third-party manufacturers, likely resulting in further delays and increased costs which could affect our business adversely.

Counterfeit versions of our products could harm our patients and have a negative impact on our revenues, earnings, reputation and business.
Our industry continues to be challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Third parties may illegally distribute and sell counterfeit versions of our products, which do not meet our rigorous manufacturing and testing standards. To distributors and patients, counterfeit products may be visually indistinguishable from the authentic version. Counterfeit medicines pose a risk to patient health and safety because of the conditions under which they are manufactured – often in unregulated, unlicensed, uninspected and unsanitary sites – as well as the lack of regulation of their contents.

The industry's failure to mitigate the threat of counterfeit medicines could adversely impact our business and reputation by impacting patient confidence in our authentic products, potentially resulting in lost sales, product recalls, and an increased threat of litigation. In addition, diversion of our products from their authorized market into other channels may result in reduced revenues and negatively affect our profitability.

Global health crises, pandemics, epidemics, or other outbreaks could adversely disrupt or impact certain aspects of the Company's business, results of operations and financial condition.
We are subject to risks associated with global health crises, epidemics, pandemics and other outbreaks (such incident(s), a health crisis or health crises), including the global outbreak of coronavirus and its variants (COVID-19). The COVID-19 pandemic has adversely impacted, and may continue to adversely impact, certain aspects of the Company's business, results of operations and financial condition, including lower sales and reduced customer demand and usage of certain of our products. The continued spread of COVID-19 or other health crises may cause the Company to modify its business practices, and take further actions as may be required by government authorities or as the Company determines are in the best interests of our patients, customers, employees and business partners. While the Company has robust business continuity plans in place across our global supply chain network to help mitigate the impact of health crises, these efforts may not completely prevent our business from being adversely affected and future impacts remain uncertain.

While the U.S. and other countries have substantially reopened their economies, the extent to which COVID-19, or other health crises, could impact the Company's future operations will depend on many factors which cannot be predicted with confidence, including the duration of an outbreak and impact of variants. A surge in COVID-19 or other health crises could result in the imposition of new mandates and prolonged restrictive measures implemented in order to control the spread of disease. The global spread of COVID-19 or other health crises could adversely impact the Company's operations, including, among other things, our manufacturing operations, supply chain, third-party suppliers, sales and marketing, and clinical trial operations. Any of these factors could adversely affect the Company's business, financial results, and global economic conditions generally.

We also face uncertainties related to our vaccine development programs, including uncertainties related to the risk that our continued development programs may not be successful, commercially viable or receive approval from regulatory authorities; risks associated with clinical trial and real-world data, including further analyses of its efficacy, safety and durability; the risk that continued evolution and mutation of disease and the duration of a particular outbreak may impede our ability to conduct trials within a specified time frame; the risk that data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by national immunization technical advisory groups (NITAGs) and regulatory authorities; disruptions in the relationships between us, our third-party suppliers, external manufacturers, and other third parties with whom we engage; the risk that other companies may produce superior or competitive products; the risk that demand for any products we may develop may no longer exist; risks related to the availability of raw materials to manufacture any such products; the risk that we may not be able to recoup costs associated with our R&D and manufacturing efforts and risks associated with any changes in the way we approach or provide additional research funding for potential drug development; the risk that we may not be able to create or scale up manufacturing capacity on a timely basis, that we may continue to experience manufacturing delays once a manufacturing site is activated, or have access to logistics or supply channels commensurate with global demand for any potential approved vaccine or product candidate, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine within the projected time periods indicated, and other challenges and risks associated with the pace of our vaccine development program; and pricing and access challenges for such products, including in the U.S.

Risks Related to Government Regulation and Legal Proceedings

Global sales in the Company's Pharmaceutical and MedTech segments may be negatively impacted by healthcare reforms and increasing pricing pressures.

Sales of the Company's Pharmaceutical and MedTech products are significantly affected by reimbursements by third-party payers such as government healthcare programs, private insurance plans and managed care organizations. As part of various efforts to contain healthcare costs, these payers are putting downward pressure on prices at which products will be reimbursed. In the U.S., increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, in part due to continued consolidation among healthcare providers, could result in further pricing pressures. In addition, recent legislation and ongoing political scrutiny or pricing, coverage and reimbursement could result in additional pricing pressures. Specifically, the Inflation Reduction Act of 2022 (IRA) may subject certain products to government-established pricing, potentially impose rebates, and subject manufacturers who fail to adhere to the government's interpretations of the law to penalties. Outside the U.S., numerous major markets, including the EU, United Kingdom, Japan and China, have pervasive government involvement in funding healthcare and, in that regard, directly or indirectly impose price controls, limit access to, or reimbursement for, the Company's products, or reduce the value of its intellectual property protection.

The Company is subject to significant legal proceedings that can result in significant expenses, fines and reputational damage.
In the ordinary course of business, Johnson & Johnson and its subsidiaries are subject to numerous claims and lawsuits involving various issues such as product liability, patent disputes and claims that their product sales, marketing and pricing practices violate various antitrust, unfair trade practices and/or consumer protection laws. The Company's more significant legal proceedings are described in Note 19, "Legal Proceedings" under Notes to the Consolidated Financial Statements included in Item 8 of this Report. Litigation, in general, and securities, derivative action, class action and multi-district litigation, in particular, can be expensive and disruptive. Some of these matters may include thousands of plaintiffs, may involve parties seeking large and/or indeterminate amounts, including punitive or exemplary damages, and may remain unresolved for several years. For example, the Company is a defendant in numerous lawsuits arising out of the use of body powders containing talc, primarily JOHNSON'S Baby Powder, and the Company's sale, manufacturing and marketing of opioids. While the Company believes it has substantial defenses in these matters, it is not feasible to predict the ultimate outcome of litigation. The Company could in the future be required to pay significant amounts as a result of settlements or judgments in these matters, potentially in excess of accruals, including matters where the Company could be held jointly and severally liable among other defendants. The resolution of, or increase in accruals for, one or more of these matters in any reporting period could have a material adverse effect on the Company's results of operations and cash flows for that period. The Company does not purchase third-party product liability insurance; however, the Company utilizes a wholly owned captive insurance company subject to certain limits.

Product reliability, safety and effectiveness concerns can have significant negative impacts on sales and results of operations, lead to litigation and cause reputational damage.
Concerns about product safety, whether raised internally or by litigants, regulators or consumer advocates, and whether or not based on scientific evidence, can result in safety alerts, product recalls, governmental investigations, regulatory action on the part of the U.S. Food and Drug Administration (or its counterpart in other countries), private claims and lawsuits, payment of fines and settlements, declining sales and reputational damage. These circumstances can also result in damage to brand image, brand equity and consumer trust in the Company's products. Product recalls have in the past, and could in the future, prompt government investigations and inspections, the shutdown of manufacturing facilities, continued product shortages and related sales declines, significant remediation costs, reputational damage, possible civil penalties and criminal prosecution.

The Company faces significant regulatory scrutiny, which imposes significant compliance costs and exposes the Company to government investigations, legal actions and penalties.
Like other companies in the healthcare industry, the Company is subject to extensive regulation, investigations and legal action by national, state and local government agencies in the U.S. and other countries in which it operates. Regulatory issues regarding compliance with current Good Manufacturing Practices (cGMP) (and comparable quality regulations in foreign countries) by manufacturers of drugs, devices and consumer products can lead to fines and penalties, product recalls, product shortages, interruptions in production, delays in new product approvals and litigation. In addition, the marketing, pricing and sale of the Company's products are subject to regulation, investigations and legal actions including under the Federal Food, Drug, and Cosmetic Act, the Medicaid Rebate Program, federal and state false claims acts, state unfair trade practices acts and consumer protection laws. Scrutiny of healthcare industry business practices by government agencies and state attorneys general in the U.S., and any resulting investigations and prosecutions, carry risk of significant civil and criminal penalties including, but not limited to, debarment from participation in government healthcare programs. Any such debarment could have a material adverse effect on the Company's business and results of operations. The most significant current investigations and litigation brought by government agencies are described in Note 19, "Legal Proceedings—Government Proceedings" under Notes to the Consolidated Financial Statements included in Item 8 of this Report.

Changes in tax laws or exposures to additional tax liabilities could negatively impact the Company's operating results.
Changes in tax laws or regulations around the world, including in the U.S. and as led by the Organization for Economic Cooperation and Development, such as the recent adoption by the EU, enactment by South Korea and the anticipated enactment

by additional countries of a global minimum tax, could negatively impact the Company's effective tax rate and results of operations. A change in statutory tax rate or certain international tax provisions in any country would result in the revaluation of the Company's deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is enacted. This change would result in an expense or benefit recorded to the Company's Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries where it operates. Changes to tax laws or regulations may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted.

See Note 8, "Income Taxes" under Notes to the Consolidated Financial Statements included in Item 8 of this Report for additional information.

The Company conducts business and files tax returns in numerous countries and is addressing tax audits and disputes with many tax authorities. In connection with various government initiatives, companies are required to disclose more information to tax authorities on operations around the world, which may lead to greater audit scrutiny of profits earned in other countries. The Company regularly assesses the likely outcomes of its tax audits and disputes to determine the appropriateness of its tax reserves. However, any tax authority could take a position on tax treatment that is contrary to the Company's expectations, which could result in tax liabilities in excess of reserves.

Risks Related to Our Intellectual Property

The Company faces increased challenges to intellectual property rights central to its business.
The Company owns or licenses a significant number of patents and other proprietary rights relating to its products and manufacturing processes. These rights are essential to the Company's businesses and materially important to the Company's results of operations. Public policy, both within and outside the U.S., has become increasingly unfavorable toward intellectual property rights. The Company cannot be certain that it will obtain adequate patent protection for new products and technologies in the United States and other important markets or that such protections, once granted, will last as long as originally anticipated.

Competitors routinely challenge the validity or extent of the Company's owned or licensed patents and proprietary rights through litigation, interferences, oppositions and other proceedings, such as inter partes review (IPR) proceedings before the United States Patent & Trademark Office (USPTO). These proceedings absorb resources and can be protracted as well as unpredictable. In addition, challenges that the Company's products infringe the patents of third parties could result in an injunction and/or the need to pay past damages and future royalties and adversely affect the competitive position and sales of the products in question.

The Company has faced increasing patent challenges from third parties seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the U.S., manufacturers of generic versions of innovative human pharmaceutical products may challenge the validity, or claim non-infringement, of innovator products through the Abbreviated New Drug Application, or ANDA, process with the U.S. FDA and related ANDA litigation. The Biologics Price Competition and Innovation Act (BPCIA), enacted in 2010, which created a new regulatory pathway for the approval by the U.S. FDA of biosimilar alternatives to innovator-developed biological products, also created mechanisms for biosimilar applicants to challenge the patents on the innovator biologics. The IPR process with the USPTO is also being used by competitors to challenge patents asserted in litigation.

In the event the Company is not successful in defending its patents against such challenges, or upon the "at-risk" launch by the generic or biosimilar firm of its product, the Company can lose a major portion of revenues for the referenced product in a very short period of time. Current legal proceedings involving the Company's patents and other intellectual property rights are described in Note 19, "Legal Proceedings—Intellectual Property" under Notes to the Consolidated Financial Statements included in Item 8 of this Report.

Risks Related to Product Development, Regulatory Approval and Commercialization

Significant challenges or delays in the Company's innovation and development of new products, technologies and indications could have an adverse impact on the Company's long-term success.
The Company's continued growth and success depends on its ability to innovate and develop new and differentiated products and services that address the evolving healthcare needs of patients, providers and consumers. Development of successful products and technologies is also necessary to offset revenue losses when the Company's existing products lose market share due to various factors such as competition and loss of patent exclusivity. New products introduced within the past five years

accounted for approximately 25% of 2022 sales. The Company cannot be certain when or whether it will be able to develop, license or otherwise acquire companies, products and technologies, whether particular product candidates will be granted regulatory approval, and, if approved, whether the products will be commercially successful.

The Company pursues product development through internal research and development as well as through collaborations, acquisitions, joint ventures and licensing or other arrangements with third parties. In all of these contexts, developing new products, particularly pharmaceutical and biotechnology products and medical devices, requires significant investment of resources over many years. Only a very few biopharmaceutical research and development programs result in commercially viable products. The process depends on many factors including the ability to: discern patients' and healthcare providers' future needs; develop promising new compounds, strategies and technologies; achieve successful clinical trial results; secure effective intellectual property protection; obtain regulatory approvals on a timely basis; and, if and when they reach the market, successfully differentiate the Company's products from competing products and approaches to treatment. New products or enhancements to existing products may not be accepted quickly or significantly in the marketplace due to product and price competition, changes in customer preferences or healthcare purchasing patterns, resistance by healthcare providers or uncertainty over third-party reimbursement. Even following initial regulatory approval, the success of a product can be adversely impacted by safety and efficacy findings in larger real-world patient populations, as well as market entry of competitive products.

Risks Related to Financial and Economic Market Conditions

The Company faces a variety of financial, economic, legal, social and political risks associated with conducting business internationally.
The Company's extensive operations and business activity throughout the world are accompanied by certain financial, economic, legal, social and political risks, including those listed below.

Foreign Currency Exchange: In fiscal 2022, approximately 49% of the Company's sales occurred outside of the U.S., with approximately 25% in Europe, 6% in the Western Hemisphere, excluding the U.S., and 18% in the Asia-Pacific and Africa region. Changes in non-U.S. currencies relative to the U.S. dollar impact the Company's revenues and expenses. While the Company uses financial instruments to mitigate the impact of fluctuations in currency exchange rates on its cash flows, unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the U.S. dollar may result in significant favorable or unfavorable translation effects when the operating results of the Company's non-U.S. business activity are translated into U.S. dollars.

Inflation and Currency Devaluation Risks: The Company faces challenges in maintaining profitability of operations in economies experiencing high inflation rates. Specifically, the Company has accounted for operations in Argentina, Turkey and Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. While the Company strives to maintain profit margins in these areas through cost reduction programs, productivity improvements and periodic price increases, it might experience operating losses as a result of continued inflation. In addition, the impact of currency devaluations in countries experiencing high inflation rates or significant currency exchange fluctuations could negatively impact the Company's operating results.

Illegal Importation of Pharmaceutical Products: The illegal importation of pharmaceutical products from countries where government price controls or other market dynamics result in lower prices may adversely affect the Company's sales and profitability in the U.S. and other countries in which the Company operates. With the exception of limited quantities of prescription drugs for personal use, foreign imports of pharmaceutical products are illegal under current U.S. law. However, the volume of illegal imports continues to rise as the ability of patients and other customers to obtain the lower-priced imports has grown significantly.

Anti-Bribery and Other Regulations: The Company is subject to various federal and foreign laws that govern its international business practices with respect to payments to government officials. Those laws include the U.S. Foreign Corrupt Practices Act (FCPA), which prohibits U.S. publicly traded companies from promising, offering, or giving anything of value to foreign officials with the corrupt intent of influencing the foreign official for the purpose of helping the Company obtain or retain business or gain any improper advantage. The Company's business is heavily regulated and therefore involves significant interaction with foreign officials. Also, in many countries outside the U.S., the healthcare providers who prescribe human pharmaceuticals are employed by the government and the purchasers of human pharmaceuticals are government entities; therefore, the Company's interactions with these prescribers and purchasers are subject to regulation under the FCPA. In addition to the U.S. application and enforcement of the FCPA, various jurisdictions in which the Company operates have laws

and regulations, including the U.K. Bribery Act 2010, aimed at preventing and penalizing corrupt and anticompetitive behavior. Enforcement activities under these laws could subject the Company to additional administrative and legal proceedings and actions, which could include claims for civil penalties, criminal sanctions, and administrative remedies, including exclusion from healthcare programs.

Other Financial, Economic, Legal, Social and Political Risks. Other risks inherent in conducting business globally include:

- local and regional economic environments and policies in the markets that we serve, including interest rates, monetary policy, inflation, economic growth, recession, commodity prices, and currency controls or other limitations on the ability to expatriate cash;
- protective economic policies taken by governments, such as trade protection measures and import/export licensing requirements;
- compliance with local regulations and laws including, in some countries, regulatory requirements restricting the Company's ability to manufacture or sell its products in the relevant market;
- diminished protection of intellectual property and contractual rights in certain jurisdictions;
- potential nationalization or expropriation of the Company's foreign assets;
- political or social upheavals, economic instability, repression, or human rights issues; and
- geopolitical events, including natural disasters, disruptions to markets due to war, armed conflict, terrorism, epidemics or pandemics.

Failure to maintain a satisfactory credit rating could adversely affect our liquidity, capital position, borrowing costs and access to capital markets.
We currently maintain investment grade credit ratings with Moody's Investors Service and Standard & Poor's Ratings Services. Rating agencies routinely evaluate us, and their ratings of our long-term and short-term debt are based on a number of factors. Any downgrade of our credit ratings by a credit rating agency, whether as a result of our actions or factors which are beyond our control, can increase the cost of borrowing under any indebtedness we may incur, reduce market capacity for our commercial paper or require the posting of additional collateral under our derivative contracts. There can be no assurance that we will be able to maintain our credit ratings, and any additional actual or anticipated changes or downgrades in our credit ratings, including any announcement that our ratings are under review for a downgrade, may have a negative impact on our liquidity, capital position and access to capital markets.

The Russia-Ukraine War, and actions taken in response to the Russia-Ukraine War, could adversely affect our business, results of operations or financial condition.

In February 2022, Russia launched a military invasion of Ukraine. The ongoing Russia-Ukraine War has provoked strong reactions from the United States, the United Kingdom, the European Union and various other countries and economic and political organizations around the world. We have been monitoring the geopolitical situation in Russia since the start of the Russia-Ukraine War and have suspended additional investment, enrollment of clinical trials, and supply of our personal care products in Russia. We continue to monitor the need for humanitarian relief in the region and continue to supply our medicines, medical devices and equipment in the region in compliance with the applicable sanctions. We will continue to monitor the geopolitical situation in Russia and to evaluate our activities and future operations in Russia.

Actions taken in response to the Russia-Ukraine War include the imposition of export controls and broad financial and economic sanctions against Russia, Belarus and specific areas of Ukraine. Additional sanctions or other measures may be imposed by the global community, including but not limited to limitations on our ability to file, prosecute and maintain patents, trademarks and other intellectual property rights. Furthermore, the Russian government has already taken action allowing Russian companies and individuals to exploit inventions owned by patent holders from the United States and many other countries without consent or compensation and we may not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products in and into Russia.

We have experienced, and expect to continue to experience, other risks related to the broad economic consequences of the Russia-Ukraine War, including foreign currency volatility, decreased demand for our products in countries affected by the Russia-Ukraine War and challenges to our global supply chain related to increased costs of materials and other inputs for our products and suppliers operating in Russia and Ukraine. We also continue to monitor the various sanctions and export controls imposed in response to the Russia-Ukraine War.

The full impact of the Russia-Ukraine War, and actions taken in response to the ongoing conflict, on the global economy and geopolitical relations, in general, and on our business in particular, remain uncertain. Any or all of the foregoing risks could

have an adverse effect on our business, results of operations or financial condition, particularly as the conflict continues for an indefinite period of time. Given that developments concerning the Russia-Ukraine War are ongoing and have been constantly evolving, additional impacts and risks may arise that are not presently known to us. The Russia-Ukraine War may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

Risks Related to the Planned Separation of our Consumer Health Business

The planned separation of the Company's Consumer Health business may not be completed on the terms or timeline currently contemplated, if at all, and may not achieve the expected results.

In November 2021, the Company announced its intention to separate the Company's Consumer Health business, with the intention to create a standalone publicly traded company, which was subsequently named Kenvue, Inc. ("Kenvue"). The planned separation is intended to qualify as a tax-free transaction for U.S. federal income tax purposes. The Company is targeting completion of the planned separation in 2023. Completion of the planned separation will be subject to the satisfaction of certain conditions, including, among others, consultations with works councils and other employee representative bodies, as required, final approval by the Company's Board of Directors, the continuing effectiveness and validity of the Company's private letter ruling from the Internal Revenue Service ("IRS") and receipt of favorable opinions of the Company's U.S. tax advisors with respect to the tax-free nature of the transaction, and the receipt of other regulatory approvals. There can be no assurance regarding the ultimate timing of the planned separation or that such separation will be completed. Unanticipated developments could delay, prevent or otherwise adversely affect the planned separation, including but not limited to disruptions in general or financial market conditions or potential problems or delays in obtaining various regulatory and tax approvals or clearances.

The costs to complete the planned separation will be significant. In addition, the Company may be unable to achieve some or all of the strategic and financial benefits that it expects to achieve from the planned separation of the Company's Consumer Health business.

The Company has incurred, and is expected to incur, significant expenses in connection with the planned separation. In addition, the Company may not be able to achieve the full strategic and financial benefits that are expected to result from the planned separation. The anticipated benefits of the planned separation are based on a number of assumptions, some of which may prove incorrect.

Following the planned separation, the price of shares of the Company's common stock may fluctuate significantly.

The Company cannot predict the effect of the planned separation on the trading price of shares of its common stock, and the market value of shares of its common stock may be less than, equal to or greater than the market value of shares of its common stock prior to the planned separation. In addition, the price of the Company's common stock may be more volatile around the time of the planned separation.

The planned separation could result in substantial tax liability.

The Company has received a private letter ruling from the IRS as to the tax-free nature of the planned separation under the U.S. Internal Revenue Code of 1986, as amended. The planned separation is conditioned on, among other things, the continuing effectiveness and validity of the Company's private letter ruling from the IRS and receipt of favorable opinions of the Company's U.S. tax advisors. The private letter ruling and opinions will be based on, among other things, various facts, assumptions, representations and undertakings from the Company and Kenvue regarding the past and future conduct of the companies' respective businesses and other matters. If any of these facts, assumptions, representations or undertakings are incorrect or not otherwise satisfied, the Company and its shareholders may not be able to rely on the ruling or the opinions of tax advisors. Notwithstanding the private letter ruling and opinions of tax advisors, if subsequent to the planned separation the IRS determines that certain steps of the transaction do not qualify for tax-free treatment for U.S. federal income tax purposes, the resulting tax liability to the Company and its shareholders could be substantial. The planned separation may also not qualify for tax-free treatment in other countries around the world, and as a result may trigger substantial tax liability to the Company.

Other Risks

Our business depends on our ability to recruit and retain talented, highly skilled employees and a diverse workforce.

Our continued growth requires us to recruit and retain talented employees representing diverse backgrounds, experiences, and skill sets. The market for highly skilled workers and leaders in our industry is extremely competitive and our ability to compete depends on our ability to hire, develop and motivate highly skilled personnel in all areas of our organization. Maintaining our brand and reputation, as well as a diverse, equitable and inclusive work environment enables us to attract top talent. If we are less successful in our recruiting efforts, or if we cannot retain highly skilled workers and key leaders, our ability to develop and deliver successful products and services may be adversely affected. In addition, effective succession planning is important to our long-term success. Any unsuccessful implementation of our succession plans or failure to ensure effective transfer of

knowledge and smooth transitions involving key employees could adversely affect our business, financial condition, or results of operations.

Climate change or legal, regulatory or market measures to address climate change may negatively affect our business and results of operations.
Climate change resulting from increased concentrations of carbon dioxide and other greenhouse gases in the atmosphere could present risks to our operations, including an adverse impact on global temperatures, weather patterns and the frequency and severity of extreme weather and natural disasters. Natural disasters and extreme weather conditions, such as a hurricane, tornado, earthquake, wildfire or flooding, may pose physical risks to our facilities and disrupt the operation of our supply chain. The impacts of the changing climate on water resources may result in water scarcity, limiting our ability to access sufficient high-quality water in certain locations, which may increase operational costs.

Concern over climate change may also result in new or additional legal or regulatory requirements designed to reduce greenhouse gas emissions and/or mitigate the effects of climate change on the environment. If such laws or regulations are more stringent than current legal or regulatory obligations, we may experience disruption in, or an increase in the costs associated with sourcing, manufacturing and distribution of our products, which may adversely affect our business, results of operations or financial condition. Further, the impacts of climate change have an influence on customer preferences, and failure to provide climate-friendly products could potentially result in loss of market share.

An information security incident, including a cybersecurity breach, could have a negative impact to the Company's business or reputation.
To meet business objectives, the Company relies on both internal information technology (IT) systems and networks, and those of third parties and their vendors, to process and store sensitive data, including confidential research, business plans, financial information, intellectual property, and personal data that may be subject to legal protection, and ensure the continuity of the Company's supply chain. The extensive information security and cybersecurity threats, which affect companies globally, pose a risk to the security and availability of these systems and networks, and the confidentiality, integrity, and availability of the Company's sensitive data. The Company continually assesses these threats and makes investments to increase internal protection, detection, and response capabilities, as well as ensure the Company's third-party providers have required capabilities and controls, to address this risk. To date, the Company has not experienced any material impact to the business or operations resulting from information or cybersecurity attacks; however, because of the frequently changing attack techniques, along with the increased volume and sophistication of the attacks, there is the potential for the Company to be adversely impacted. This impact could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action. The Company maintains cybersecurity insurance in the event of an information security or cyber incident; however, the coverage may not be sufficient to cover all financial, legal, business or reputational losses.

As a result of the Russia-Ukraine War, there has been, and we expect there will continue to be, an increased risk of information security or cybersecurity incidents, including cyberattacks perpetrated by Russia or others at its direction. Although we have taken steps to enhance our protections against these attacks, we may not be able to address the threat of information security or cybersecurity incidents proactively or implement adequate preventative measures and we may not be able to detect and address any such disruption or security breach promptly, or at all, which could adversely affect our business, results of operations or financial condition. Moreover, we are aware of incidents in which our third-party partners have been the target of information security or cybersecurity incidents as a result of the Russia-Ukraine War. Although, to date, our IT Systems have not been compromised by these incidents, it is possible that future information security or cybersecurity incidents involving our customers, manufacturers, suppliers or other third-party partners could successfully compromise our IT Systems, which could adversely affect our business, results of operations or financial condition.

A breach of privacy laws or unauthorized access, loss or misuse of personal data could have a negative impact to the Company's business or reputation.
The Company is subject to privacy and data protection laws across the globe that impose broad compliance obligations on the collection, use, storage, access, transfer and protection of personal data. Breach of such requirements could result in substantial fines, penalties, private right of actions, claims and damage to our reputation and business. New privacy laws are expected in other territories, together with greater privacy enforcement by governmental authorities globally, particularly on data localization requirements and international data flows. The Company has established privacy compliance programs and controls that our businesses worldwide are required to comply with, but with many technology and data-driven initiatives being prioritized across the Company and involving multiple vendors and third parties, there are potential risks of controls imposed on cross border data flows, unauthorized access, and loss of personal data through internal and external threats that could impact our business operations and research activities.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

The Company's subsidiaries operate 89 manufacturing facilities occupying approximately 14.9 million square feet of floor space. The manufacturing facilities are used by the industry segments of the Company's business approximately as follows:

Segment	Square Feet (in thousands)
Consumer Health	4,562
Pharmaceutical	5,456
MedTech	4,930
Worldwide Total	14,948

Within the U.S., four facilities are used by the Consumer Health segment, five by the Pharmaceutical segment and 19 by the MedTech segment. Outside of the U.S., 23 facilities are used by the Consumer Health segment, 13 by the Pharmaceutical segment and 25 by the MedTech segment.

The locations of the manufacturing facilities by major geographic areas of the world are as follows:

Geographic Area	Number of Facilities	Square Feet (in thousands)
United States	28	4,169
Europe	27	6,016
Western Hemisphere, excluding U.S.	9	1,733
Africa, Asia and Pacific	25	3,030
Worldwide Total	89	14,948

In addition to the manufacturing facilities discussed above, the Company maintains numerous office and warehouse facilities throughout the world.

The Company's subsidiaries generally seek to own, rather than lease, their manufacturing facilities, although some, principally in non-U.S. locations, are leased. Office and warehouse facilities are often leased. The Company also engages contract manufacturers.

The Company is committed to maintaining all of its properties in good operating condition.

Segment information on additions to property, plant and equipment is contained in Note 17 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 3. LEGAL PROCEEDINGS

The information called for by this item is incorporated herein by reference to the information set forth in Note 19 "Legal Proceedings" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

EXECUTIVE OFFICERS OF THE REGISTRANT

Listed below are the executive officers of the Company. There are no family relationships between any of the executive officers, and there is no arrangement or understanding between any executive officer and any other person pursuant to which the executive officer was selected. At the annual meeting of the Board of Directors, the executive officers are elected by the Board to hold office for one year and until their respective successors are elected and qualified, or until earlier resignation or removal.

Information with regard to the directors of the Company is incorporated herein by reference to the material captioned "Item 1. Election of Directors" in the Proxy Statement.

Name	Age	Position
Vanessa Broadhurst	54	Member, Executive Committee; Executive Vice President, Global Corporate Affairs[(a)]
Joaquin Duato	60	Chairman of the Board; Chief Executive Officer[(b)]
Peter M. Fasolo, Ph.D.	60	Member, Executive Committee; Executive Vice President, Chief Human Resources Officer[(c)]
Elizabeth Forminard	52	Member, Executive Committee; Executive Vice President, General Counsel[(d)]
William N. Hait, M.D., Ph. D.	73	Member, Executive Committee; Executive Vice President, Chief External Innovation and Medical Safety Officer; Interim Head Janssen R&D[(e)]
Ashley McEvoy	52	Member, Executive Committee; Executive Vice President, Worldwide Chairman, MedTech[(f)]
Thibaut Mongon	53	Member, Executive Committee, Executive Vice President, Worldwide Chairman, Consumer Health[(g)]
James Swanson	57	Member, Executive Committee; Executive Vice President, Chief Information Officer[(h)]
Jennifer L. Taubert	59	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Pharmaceuticals[(i)]
Kathryn E. Wengel	57	Member, Executive Committee; Executive Vice President, Chief Technical Operations & Risk Officer[(j)]
Joseph J. Wolk	56	Member, Executive Committee; Executive Vice President, Chief Financial Officer[(k)]

(a) Ms. V. Broadhurst joined the Company in 2005 as Worldwide Vice President, Anemia & Oncology Supportive Care. She then went on to become Vice President of the Cardiovascular & Institutional Franchise in 2008, and President of Janssen Therapeutics in 2011 before becoming U.S. President, Internal Medicine in 2012. From 2013 to 2017, she held General Manager roles at Amgen in Inflammation & Cardiovascular, and Cardiovascular & Bone. In 2017, Ms. Broadhurst rejoined Johnson & Johnson as U.S. President, Cardiovascular & Metabolism and a member of the Janssen Americas Leadership Team. In this role she also provided operational oversight of the full portfolio of Janssen medicines in Puerto Rico and Canada. In 2018, she was appointed Company Group Chairman, Global Commercial Strategy Organization. In 2022, Ms. Broadhurst was named Executive Vice President, Global Corporate Affairs and a member of the Executive Committee, leading the Company's global marketing, communication, Global Public Health and philanthropy functions.

(b) Mr. J. Duato became Chairman of the Board of Directors in January 2023 subsequent to his appointment as Chief Executive Officer and a Director in January 2022. He joined the Company in 1989 with Janssen-Farmaceutica S.A. (Spain), a subsidiary of the Company, and held executive positions of increasing responsibility in all business sectors and across multiple geographies and functions. In 2009, he was named Company Group Chairman, Pharmaceuticals, and in 2011, he was named Worldwide Chairman, Pharmaceuticals. In 2016, Mr. Duato became a member of the Executive Committee and was named Executive Vice President, Worldwide Chairman, Pharmaceuticals. In July 2018, Mr. Duato was promoted to Vice Chairman of the Executive Committee, where he provided strategic direction for the Pharmaceutical and Consumer Health sectors and oversaw both the Global Supply Chain, Information Technology and Health & Wellness teams. As a dual citizen of Spain and the United States, Mr. Duato's international perspective and global lens gives him a deep appreciation of diverse thoughts and opinions.

(c) Dr. P. M. Fasolo joined the Company in 2004 as Worldwide Vice President, Human Resources in the MedTech segment, and subsequently served as the Company's Chief Talent Officer. He left Johnson & Johnson in 2007 to join Kohlberg Kravis Roberts & Co. as Chief Talent Officer. Dr. Fasolo returned to the Company in 2010 as the Vice President, Global Human Resources, and in 2011, he became a member of the Executive Committee. In April 2016, he was named Executive Vice President, Chief Human Resources Officer. Dr. Fasolo has responsibility for global talent, recruiting, diversity, compensation, benefits, employee relations and all aspects of the human resources agenda for the Company. He also serves on the Boards of the Human Resources Policy Association, Tufts University and Save the Children and was named a Fellow of the National Academy of Human Resources in 2017.

(d) Ms. Elizabeth Forminard joined the Company in 2006 as Vice President, Law, Consumer Healthcare Global Business Unit and continued to serve in roles of increasing responsibility. In 2012, she was promoted to General Counsel, Medical Devices & Diagnostics and became General Counsel, Consumer Group & Supply Chain in 2013. She was appointed Worldwide Vice President, Corporate Governance in 2016. From 2019 to 2022, she served as General Counsel, Pharmaceuticals. In October 2022, she was named Executive Vice President, General Counsel and became a member of the Executive Committee. Ms. Forminard has worldwide responsibility for the legal and privacy functions, and leads the development and execution of the Company's environment, social and governance strategy.

(e) Dr. W. Hait joined the Company in 2007 as Senior Vice President, Worldwide Head of Oncology Research. He then served as the first Global Therapeutic Area Head for Oncology from 2009 to 2011, and then as Global Head, Janssen Research & Development from 2011 through 2018. From 2018 to 2022, he was Global Head, Johnson & Johnson Global External Innovation. In 2022, he became Executive Vice President, Chief External Innovation, Medical Safety and Global Public Health Officer, and a member of the Executive Committee. He is responsible for leading external sourcing and creation of transformational innovation to help Johnson & Johnson achieve its mission to improve human health utilizing the Company's excellence in pharmaceuticals, medical devices and consumer products. He also has oversight over Global Public Health and the Office of the Chief Medical Officer. As Interim Head of Janssen R&D, Dr. Hait's mission is to focus the best research and development teams in the world at the intersection of unmet medical need and breakthroughs in science and technology to make medicines with benefit for patients worldwide.

(f) Ms. A. McEvoy joined the Company in 1996 as Assistant Brand Manager of McNeil Consumer Health, a subsidiary of the Company, advancing through positions of increasing responsibilities until she was appointed Company Group Chairman, Vision Care in 2012, followed by Company Group Chairman, Consumer Medical Devices in 2014. In July 2018, Ms. McEvoy was promoted to Executive Vice President, Worldwide Chairman, MedTech, and became a member of the Executive Committee. Ms. McEvoy has responsibility for the surgery, orthopaedics, interventional solutions and eye health businesses across Ethicon, DePuy Synthes, Biosense Webster, Abiomed, and Johnson & Johnson Vision.

(g) Mr. T. Mongon joined the Company in 2000 as Director of Marketing for the Vision Care group in France and subsequently held positions of increasing responsibility until he transitioned to the Pharmaceutical sector in 2012, as the Global Commercial Strategy Leader for the Neuroscience therapeutic area. In 2014, he joined the Consumer Health sector as Company Group Chairman Asia-Pacific. In 2019, he was promoted to Executive Vice President and Worldwide Chairman, Consumer Health, and became a member of the Executive Committee. Mr. Mongon has responsibility for the global development of Johnson & Johnson's health and wellness products and solutions in beauty, OTC, oral care, baby care, women's health, and wound care.

(h) Mr. J. Swanson rejoined the Company in 2019 as Chief Information Officer of Johnson & Johnson from Bayer Crop Science, where he served as a member of the Executive Leadership Team and as CIO and Head of Digital Transformation. From 1996 to 2005, Mr. Swanson held positions of increasing responsibility at the Company, including Project Manager, Director IT, Sr. Director IT and Vice President, Chief Information Officer. Mr. Swanson is responsible for enhancing Johnson & Johnson's business impact and shaping its direction through the strategic use of technology. Mr. Swanson, Executive Vice President, Enterprise Chief Information Officer, joined the Executive Committee effective January 3, 2022.

(i) Ms. J. L. Taubert joined the Company in 2005 as Worldwide Vice President, and she held several executive positions of increasing responsibility in the Pharmaceutical sector. In 2012, she was appointed Company Group Chairman, North America Pharmaceuticals, and in 2015 became Company Group Chairman, The Americas, Pharmaceuticals. In July 2018, Ms. Taubert was promoted to Executive Vice President, Worldwide Chairman, Pharmaceuticals, and became a member of the Executive Committee. Ms. Taubert is responsible for the Pharmaceutical sector globally, including shaping the company's strategy of transformational medical innovation and for successfully bringing to market critical new medicines that significantly improve the lives of patients living with cancer, immune-related diseases, cardiovascular disease, infectious diseases, pulmonary hypertension and serious mental illness.

(j) Ms. K. E. Wengel joined the Company in 1988 as Project Engineer and Engineering Supervisor at Janssen, a subsidiary of the Company. During her tenure with the Company, she has held a variety of strategic leadership and executive positions, including in roles within operations, quality, engineering, new products, information technology, and other technical and business functions. In 2018, she was named Executive Vice President, Chief Global Supply

Chain Officer, and became a member of the Executive Committee. In January 2023, she was appointed Executive Vice President, Chief Technical Operations & Risk Officer. Ms. Wengel has enterprise-wide responsibilities for key technical operations functions, including Procurement, Engineering & Property Services, Sustainability and cross-sector Supply Chain teams focused on standards, services, strategic programs and data science, and serves as Chair of the Company's Supply Chain Management Committee. She also oversees critical risk functions, including Quality & Compliance, Health Care Compliance, Environmental Health & Safety, Global Security and Global Brand Protection.

(k) Mr. J. J. Wolk joined the Company in 1998 as Finance Manager, Business Development for Ortho-McNeil, a subsidiary of the Company, and through the years held a variety of senior leadership roles in several segments and functions across the Company's subsidiaries, in Pharmaceuticals, Medical Devices and Supply Chain. From 2014 to 2016, he served as Vice President, Finance and Chief Financial Officer of the Janssen Pharmaceutical Companies of Johnson & Johnson. In 2016, Mr. Wolk became the Vice President, Investor Relations. In July 2018, he was appointed Executive Vice President, Chief Financial Officer and became a member of the Executive Committee. Mr. Wolk plays a strategic role in the overall management of the Company, and leads the development and execution of the Company's global long-term financial strategy.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

As of February 10, 2023, there were 124,211 record holders of common stock of the Company. Additional information called for by this item is incorporated herein by reference to the following sections of this Report: Note 16 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements included in Item 8; and Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters – Equity Compensation Plan Information."

Issuer Purchases of Equity Securities

On September 14, 2022, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's Common Stock. Share repurchases may be made at management's discretion from time to time on the open market or through privately negotiated transactions. The repurchase program has no time limit and may be suspended for periods or discontinued at any time.

The following table provides information with respect to common stock purchases by the Company during the fiscal fourth quarter of 2022. Common stock purchases on the open market are made as part of a systematic plan to meet the needs of the Company's compensation programs. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal fourth quarter.

Fiscal Period	Total Number of Shares Purchased[1]	Avg. Price Paid Per Share	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs[2]	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs[3]
October 3, 2022 through October 30, 2022	3,921,949	$ 165.29	3,179,491	-
October 31, 2022 through November 27, 2022	1,444,006	173.26	-	-
November 28, 2022 through January 1, 2023	2,379,100	178.18	-	-
Total	7,745,055		3,179,491	13,876,567

(1) During the fiscal fourth quarter of 2022, the Company repurchased an aggregate of 7,745,055 shares of Johnson & Johnson Common Stock in open-market transactions, of which 3,179,491 shares were purchased pursuant to the repurchase program that was publicly announced on September 14, 2022, and of which 4,565,564 shares were purchased as part of a systematic plan to meet the needs of the Company's compensation programs.

(2) As of January 1, 2023, an aggregate of 15,411,776 shares were purchased for a total of $2.5 billion since the inception of the repurchase program announced on September 14, 2022.

(3) As of January 1, 2023, the maximum number of shares that may yet be purchased under the plan is 13,876,567 based on the closing price of Johnson & Johnson Common Stock on the New York Stock Exchange on December 30, 2022 of $176.65 per share.

Item 6. Reserved

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF RESULTS OF OPERATIONS AND FINANCIAL CONDITION

Organization and Business Segments

Description of the Company and Business Segments

Johnson & Johnson and its subsidiaries (the Company) have approximately 152,700 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the healthcare field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The Company is organized into three business segments: Consumer Health, Pharmaceutical and MedTech. The Consumer Health segment includes a broad range of products used in the Baby Care, Oral Care, Skin Health/Beauty, Over-the-Counter pharmaceutical, Women's Health and Wound Care markets. These products are marketed to the general public and sold online (eCommerce) and to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on the following therapeutic areas, including Immunology, Infectious diseases, Neuroscience, Oncology, Pulmonary Hypertension, and Cardiovascular and Metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, distributors, hospitals and healthcare professionals for prescription use. The MedTech segment includes a broad portfolio of products used in the Orthopaedic, Surgery, Interventional Solutions (cardiovascular and neurovascular) and Vision fields. These products are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Consumer Health, Pharmaceutical and MedTech business segments.

In all of its product lines, the Company competes with other companies both locally and globally, throughout the world. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products, as well as protecting the underlying intellectual property of the Company's product portfolio, is important to the Company's success in all areas of its business. The competitive environment requires substantial investments in continuing research. In addition, the development and maintenance of customer demand for the Company's consumer products involves significant expenditures for advertising and promotion.

Management's Objectives

With "Our Credo" as the foundation, the Company's purpose is to blend heart, science and ingenuity to profoundly change the trajectory of health for humanity. The Company is committed to bringing its full breadth and depth to ensure health for people today and for future generations. United around this common ambition, the Company is poised to fulfill its purpose and successfully meet the demands of the rapidly evolving markets in which it competes.

The Company is broadly based in human healthcare, and is committed to creating value by developing accessible, high quality, innovative products and services. New products introduced within the past five years accounted for approximately 25% of 2022 sales. In 2022, $14.6 billion was invested in research and development reflecting management's commitment to create life-enhancing innovations and to create value through partnerships that will profoundly change the trajectory of health for humanity.

A critical driver of the Company's success is the diversity of its 152,700 employees worldwide. Employees are empowered and inspired to lead with Our Credo and purpose as guides. This allows every employee to use the Company's reach and size to advance the Company's purpose, and to also lead with agility and urgency. Leveraging the extensive resources across the enterprise enables the Company to innovate and execute with excellence. This ensures the Company can remain focused on addressing the unmet needs of society every day and invest for an enduring impact, ultimately delivering value to its patients, consumers and healthcare professionals, employees, communities and shareholders.

Results of Operations

Analysis of Consolidated Sales

For discussion on results of operations and financial condition pertaining to the fiscal years 2021 and 2020 see the Company's Annual Report on Form 10-K for the fiscal year ended January 2, 2022, Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition.

In 2022, worldwide sales increased 1.3% to $94.9 billion as compared to an increase of 13.6% in 2021. These sales changes consisted of the following:

Sales increase/(decrease) due to:	2022	2021
Volume	6.9 %	12.9 %
Price	(0.8)	(0.7)
Currency	(4.8)	1.4
Total	**1.3 %**	**13.6 %**

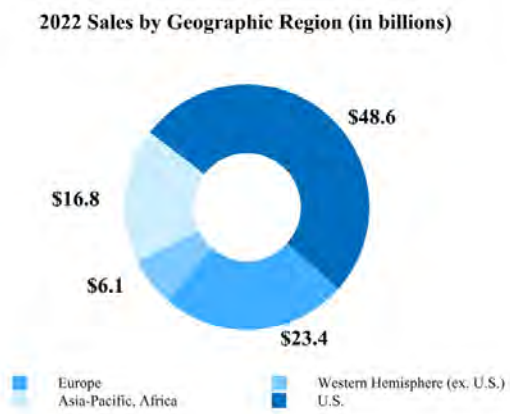
The net impact of acquisitions and divestitures on the worldwide sales growth was a negative impact of 0.1% in 2022 and a negative impact of 0.6% in 2021.

Sales by U.S. companies were $48.6 billion in 2022 and $47.2 billion in 2021. This represents increases of 3.0% in 2022 and 9.3% in 2021. Sales by international companies were $46.4 billion in 2022 and $46.6 billion in 2021. This represents a decrease of 0.6% in 2022 and an increase of 18.2% in 2021.

The five-year compound annual growth rates for worldwide, U.S. and international sales were 4.4%, 4.0% and 4.9%, respectively. The ten-year compound annual growth rates for worldwide, U.S. and international sales were 3.5%, 5.0% and 2.2%, respectively.

In 2022, sales by companies in Europe experienced a decline of 0.6% as compared to the prior year, which included operational growth of 11.0% and a negative currency impact of 11.6%. Sales by companies in the Western Hemisphere, excluding the U.S., achieved growth of 6.5% as compared to the prior year, which included operational growth of 10.2%, and a negative currency impact of 3.7%. Sales by companies in the Asia-Pacific, Africa region experienced a decline of 2.8% as compared to the prior year, including operational growth of 6.2% and a negative currency impact of 9.0%.

In 2022, the Company utilized three wholesalers distributing products for all three segments that represented approximately 16.5%, 13.0% and 12.0% of the total consolidated revenues. In 2021, the Company had three wholesalers distributing products for all three segments that represented approximately 14.0%, 11.0% and 11.0% of the total consolidated revenues.



Note: values may have been rounded

Analysis of Sales by Business Segments

Consumer Health Segment

Consumer Health segment sales in 2022 were $15.0 billion, a decrease of 0.5% from 2021, which included 3.6% operational growth and a negative currency impact of 4.1%. U.S. Consumer Health segment sales were $6.6 billion, an increase of 1.3%. International sales were $8.4 billion, a decrease of 1.9%, which included 5.3% operational growth and a negative currency impact of 7.2%. In 2022, acquisitions and divestitures had a net negative impact of 0.3% on the operational sales growth of the worldwide Consumer Health segment.

Major Consumer Health Franchise Sales*:

(Dollars in Millions)	2022	2021	Total Change	Operations Change	Currency Change
OTC[1]	$ 6,031	5,627	7.2 %	11.2 %	(4.0) %
Skin Health/Beauty	4,352	4,541	(4.2)	(0.4)	(3.8)
Oral Care	1,505	1,645	(8.5)	(4.7)	(3.8)
Baby Care	1,461	1,566	(6.7)	(2.4)	(4.3)
Women's Health	904	917	(1.5)	7.0	(8.5)
Wound Care/Other	700	739	(5.3)	(3.8)	(1.5)
Total Consumer Health Sales	**$ 14,953**	**15,035**	**(0.5) %**	**3.6 %**	**(4.1) %**

*Certain prior year amounts have been reclassified to conform to current year presentation

[1]Fiscal 2021 reflects approximately $0.4 billion of certain international OTC products, primarily in China, which were reclassified from the Pharmaceutical segment to the Consumer Health segment based on operational changes

The OTC franchise sales of $6.0 billion increased 7.2% as compared to the prior year. Operational growth was primarily attributable to increased Cough/Cold/Flu, adult and pediatric incidences, price actions primarily in the U.S. and increased consumption in China due to easing of COVID-19 restrictions. Growth was partially offset by supply constraints.

The Skin Health/Beauty franchise sales of $4.4 billion declined 4.2% as compared to the prior year. The operational decline was driven by supply constraints in the U.S. partially offset by price actions and strong new product performance in the Asia Pacific and Latin America region.

The Oral Care franchise sales of $1.5 billion declined 8.5% as compared to the prior year. The operational decline was due to portfolio simplification in the U.S., competitive pressures in EMEA and China, category decline and pricing pressures in EMEA, as well as suspension of personal care sales in Russia and negative COVID-19 impacts in China.

The Baby Care franchise sales of $1.5 billion declined 6.7% as compared to the prior year. The operational decline was driven by category deceleration and competitive pressures in the U.S., suspension of personal care sales in Russia and weakness in India.

The Women's Health franchise sales of $0.9 billion declined 1.5% as compared to the prior year. Operational growth driven by lapping prior year supply constraints in EMEA, strength in India, and price actions in LATAM was partially offset by suspension of personal care sales in Russia and negative currency impacts.

The Wound Care/Other franchise sales of $0.7 billion declined 5.3% as compared to the prior year. The operational decline was driven by lapping strong prior year consumption, competitive pressure in the U.S., and decreased consumption in China.

In November 2021, the Company announced its intention to separate the Company's Consumer Health business (Kenvue as the name for the planned New Consumer Health Company), with the intention to create a new, publicly traded company by the end of the fiscal year 2023.

Pharmaceutical Segment

Pharmaceutical segment sales in 2022 were $52.6 billion, an increase of 1.7% from 2021, which included operational growth of 6.7% and a negative currency impact of 5.0%. U.S. sales were $28.6 billion, an increase of 2.3%. International sales were $24.0 billion, an increase of 1.0%, which included 11.9% operational growth and a negative currency impact of 10.9%. In 2022, acquisitions and divestitures had a net negative impact of 0.1% on the operational sales growth of the worldwide Pharmaceutical segment. Adjustments to previous sales reserve estimates were approximately $0.1 billion and $0.7 billion in fiscal years 2022 and 2021, respectively.

Major Pharmaceutical Therapeutic Area Sales*:

(Dollars in Millions)	2022	2021	Total Change	Operations Change	Currency Change
Total Immunology	**$ 16,935**	**16,750**	**1.1 %**	**4.8 %**	**(3.7) %**
REMICADE	2,343	3,190	(26.6)	(25.3)	(1.3)
SIMPONI/SIMPONI ARIA	2,184	2,276	(4.0)	1.0	(5.0)
STELARA	9,723	9,134	6.5	10.4	(3.9)
TREMFYA	2,668	2,127	25.4	30.1	(4.7)
Other Immunology	17	24	(28.2)	(28.2)	0.0
Total Infectious Diseases	**5,449**	**5,825**	**(6.5)**	**0.8**	**(7.3)**
COVID-19 VACCINE	2,179	2,385	(8.6)	2.0	(10.6)
EDURANT/rilpivirine	1,008	994	1.5	11.8	(10.3)
PREZISTA/ PREZCOBIX/REZOLSTA/ SYMTUZA	1,943	2,083	(6.7)	(4.4)	(2.3)
Other Infectious Diseases[2]	318	363	(12.3)	(7.2)	(5.1)
Total Neuroscience	**6,893**	**6,988**	**(1.4)**	**3.4**	**(4.8)**
CONCERTA/methylphenidate	644	667	(3.5)	4.1	(7.6)
INVEGA SUSTENNA/XEPLION/ INVEGA TRINZA/TREVICTA	4,140	4,022	3.0	6.9	(3.9)
RISPERDAL CONSTA	485	592	(18.1)	(13.0)	(5.1)
Other Neuroscience[2]	1,623	1,706	(4.9)	0.4	(5.3)
Total Oncology	**15,983**	**14,548**	**9.9**	**16.9**	**(7.0)**
DARZALEX	7,977	6,023	32.4	39.5	(7.1)
ERLEADA	1,881	1,291	45.7	53.0	(7.3)
IMBRUVICA	3,784	4,369	(13.4)	(7.6)	(5.8)
ZYTIGA /abiraterone acetate	1,770	2,297	(22.9)	(13.6)	(9.3)
Other Oncology	571	568	0.6	6.0	(5.4)
Total Pulmonary Hypertension	**3,417**	**3,450**	**(1.0)**	**3.0**	**(4.0)**
OPSUMIT	1,783	1,819	(2.0)	2.6	(4.6)
UPTRAVI	1,322	1,237	6.9	8.6	(1.7)
Other Pulmonary Hypertension	313	395	(20.8)	(13.1)	(7.7)
Total Cardiovascular / Metabolism / Other	**3,887**	**4,119**	**(5.6)**	**(4.0)**	**(1.6)**
XARELTO	2,473	2,438	1.4	1.4	—
INVOKANA/ INVOKAMET	448	563	(20.4)	(17.2)	(3.2)
Other[1,2]	966	1,119	(13.6)	(9.3)	(4.3)
Total Pharmaceutical Sales	**$ 52,563**	**51,680**	**1.7 %**	**6.7 %**	**(5.0) %**

*Certain prior year amounts have been reclassified to conform to current year presentation

(1) Inclusive of PROCRIT / EPREX which was previously disclosed separately

(2) Fiscal 2021 reflects approximately $0.4 billion of certain international OTC products, primarily in China, which were reclassified from the Pharmaceutical segment to the Consumer Health segment based on operational changes

Immunology products achieved sales of $16.9 billion in 2022, representing an increase of 1.1% as compared to the prior year. Operational growth was driven by strong uptake of STELARA (ustekinumab) in Crohn's disease and Ulcerative Colitis and strength of TREMFYA (guselkumab) in Psoriasis and uptake in Psoriatic Arthritis. This was partially offset by lower sales of REMICADE (infliximab) due to biosimilar competition.

Biosimilar versions of REMICADE have been introduced in the United States and certain markets outside the United States and additional competitors continue to enter the market. Continued infliximab biosimilar competition will result in a further reduction in sales of REMICADE.

The latest expiring United States patent for STELARA (ustekinumab) will expire in September 2023. STELARA (ustekinumab) U.S. sales in fiscal 2022 were approximately $6.4 billion and the expiration of this product patent or loss of market exclusivity will result in a reduction in sales.

Infectious disease products sales were $5.4 billion in 2022, representing a decline of 6.5% as compared to the prior year. Operational growth was driven by the COVID-19 vaccine outside the U.S partially offset by lower sales of PREZISTA and PREZCOBIX/REZOLSTA (darunavir/cobicistat) due to increased competition and loss of exclusivity of PREZISTA in certain countries outside the U.S.

Neuroscience products sales were $6.9 billion, in 2022, representing a decline of 1.4% as compared to the prior year. The operational sales growth of INVEGA SUSTENNA/XEPLION (paliperidone palmitate) and INVEGA TRINZA/TREVICTA from new patient starts and persistence as well as the launch of INVEGA HAFYERA was offset by negative currency impacts and lower sales of RISPERDAL CONSTA.

Oncology products achieved sales of $16.0 billion in 2022, representing an increase of 9.9% as compared to the prior year. Contributions to operational growth were strong sales of DARZALEX (daratumumab) driven by share gains in all regions, continued strong market growth, and uptake of the subcutaneous formulation as well as the continued global launch uptake of ERLEADA (apalutamide). This was partially offset by declining sales of IMBRUVICA (ibrutinib) due to competitive pressures and market suppression and ZYTIGA due to loss of exclusivity in the European Union in the second half of 2022.

Pulmonary Hypertension products sales were $3.4 billion, a decline of 1.0% as compared to the prior year. The operational sales growth of OPSUMIT (macitentan) and UPTRAVI (selexipag) due to continued share gains and market growth was offset by COVID-19 related impacts and continued declines in Other Pulmonary Hypertension.

Cardiovascular/Metabolism/Other products sales were $3.9 billion, a decline of 5.6% as compared to the prior year. The operational decline was primarily attributable to lower sales of INVOKANA/INVOKAMET (canagliflozin) due to share erosion and PROCRIT/ EPREX (epoetin alfa) due to biosimilar competition.

The Company updated its policy so that no end customer will be permitted direct delivery of product to a location other than the billing location. The policy impacts contract pharmacy transactions involving non-grantee 340B covered entities for most of the Company’s drugs, subject to multiple exceptions. Both grantee and non-grantee covered entities can maintain certain contract pharmacy arrangements under policy exceptions. The Company has been and will continue to offer 340B discounts to covered entities on all of its covered outpatient drugs, and it believes its policy will improve its ability to identify inappropriate duplicate discounts and diversion prohibited by the 340B statute. The 340B Drug Pricing Program is a U.S. federal government program requiring drug manufacturers to provide significant discounts on covered outpatient drugs to covered entities. This policy update had discount implications which positively impacted sales to customers in 2022.

During 2022, the Company advanced its pipeline with several regulatory submissions and approvals for new drugs and additional indications for existing drugs as follows:

Product Name (Chemical Name)	Indication	US Approval	EU Approval	US Filing	EU Filing
aprocitentan	Treatment for difficult to treat hypertension			▯	
CABENUVA (rilpivirine and cabotegravir)	HIV treatment for adolescents	▯			
CARVYKTI (ciltacabtagene autoleucel)	Treatment for patients with relapsed or refractory Multiple Myeloma	▯	▯		
ERLEADA (apalutamide)	Tablet reduction			▯	▯
IMBRUVICA (ibrutinib)	Treatment for Pediatric Patients with Chronic Graft-Versus-Host Disease	▯			
	Treatment for Frontline Chronic Lymphocytic Leukemia (I + V fixed duration) (GLOW)		▯		
niraparib	Treatment of L1 Prostate cancer metastatic castration-resistant in combination with abiraterone acetate and Prednisone				▯
STELARA (ustekinumab)	Treatment of Pediatric Patients with Juvenile Psoriatic Arthritis	▯			
Talquetamab	Treatment of Patients with Relapsed Refractory Multiple Myeloma			▯	
teclistamab (BCMA/CD3)	Treatment of Patients with Relapsed Refractory Multiple Myeloma	▯	▯		

MedTech Segment**
The MedTech segment sales in 2022 were $27.4 billion, an increase of 1.4% from 2021, which included operational growth of 6.2% and a negative currency impact of 4.8%. U.S. sales were $13.4 billion, an increase of 5.4% as compared to the prior year. International sales were $14.1 billion, a decrease of 2.3% as compared to the prior year, which included operational growth of 6.9% and a negative currency impact of 9.2%. In 2022, the net impact of acquisitions and divestitures on the MedTech segment worldwide operational sales growth was a positive 0.1%.

Major MedTech Franchise Sales*:

(Dollars in Millions)	2022	2021	Total Change	Operations Change	Currency Change
Surgery	**$ 9,690**	**9,812**	**(1.2)%**	**3.8 %**	**(5.0) %**
Advanced	4,569	4,622	(1.1)	3.8	(4.9)
General	5,121	5,190	(1.3)	3.8	(5.1)
Orthopaedics	**8,587**	**8,588**	**0.0**	**3.7**	**(3.7)**
Hips	1,514	1,480	2.3	5.8	(3.5)
Knees	1,359	1,325	2.6	6.1	(3.5)
Trauma	2,871	2,885	(0.5)	3.1	(3.6)
Spine, Sports & Other	2,843	2,898	(1.9)	1.9	(3.8)
Vision	**4,849**	**4,688**	**3.4**	**9.5**	**(6.1)**
Contact Lenses/Other	3,543	3,440	3.0	9.6	(6.6)
Surgical	1,306	1,248	4.6	9.4	(4.8)
Interventional Solutions	**4,300**	**3,971**	**8.3**	**13.7**	**(5.4)**
Total MedTech Sales	**$ 27,427**	**27,060**	**1.4 %**	**6.2 %**	**(4.8) %**

*Certain prior year amounts have been reclassified to conform to current year presentation
**Previously referred to as Medical Devices

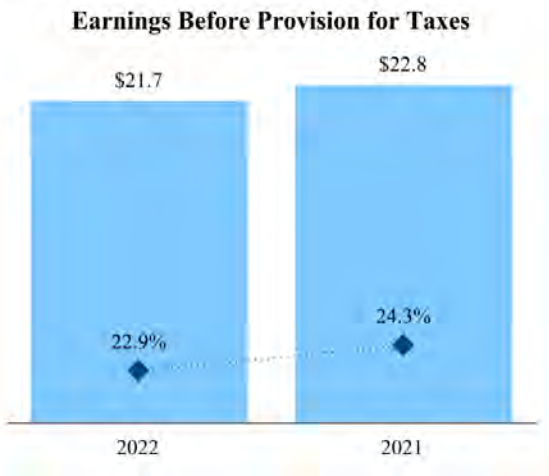
The Surgery franchise sales were $9.7 billion in 2022, representing a decline of 1.2% from 2021. The operational growth in Advanced Surgery was primarily driven by the following: Endocutter market recovery and new products partially offset by competitive pressures in the U.S.; Biosurgery market recovery and the success of new products partially offset by strong U.S. market demand in the prior year for infection prevention products; and Energy products driven by market recovery and new product penetration coupled with competitive supply challenges. The operational growth in General Surgery was primarily driven by market recovery and technology penetration.

The Orthopaedics franchise sales were $8.6 billion in 2022, which was flat to the prior year. The Orthopaedics franchise included operational sales growth of 3.7% offset by a negative currency impact of 3.7%. The operational growth in hips reflects the market recovery combined with continued strength of the portfolio including the ACTIS stem and enabling technologies – KINCISE and VELYS Hip Navigation. This growth was partially offset by impacts of volume-based procurement in China and the timing of tenders outside the U.S. The operational growth in knees was primarily driven by procedure recovery, strength of the ATTUNE portfolio and pull through related to the VELYS Robotic assisted solution. This growth was partially offset by impacts of volume-based procurement in China and timing of tenders outside the U.S. The operational growth in Trauma was driven by global market recovery and uptake of new products. The operational growth in Spine, Sports & Other was primarily driven by procedure recovery and new product introductions. This growth was partially offset by competitive pressures in Spine and impacts of volume-based procurement in China.

The Vision franchise achieved sales of $4.8 billion in 2022, representing an increase of 3.4% from 2021. The Contact Lenses/Other operational growth was due to market recovery, price actions, commercial execution and benefits from new products. Surgical Vision operational growth was primarily due to market recovery and the success of new products and was partially offset by a higher prior year U.S. Refractory market.

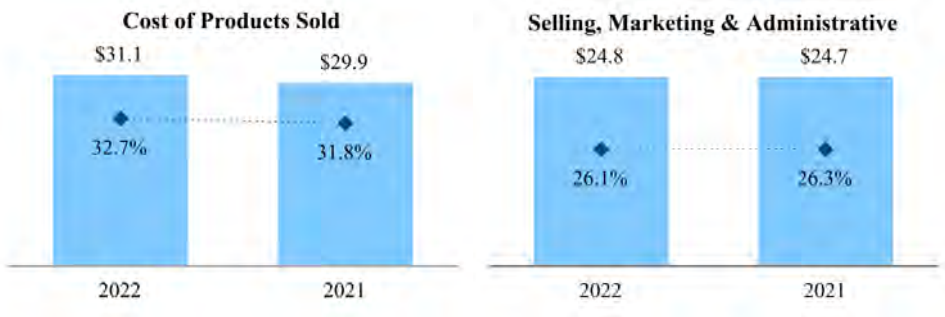
The Interventional Solutions franchise achieved sales of $4.3 billion in 2022, representing an increase of 8.3% from 2021. Operational growth was driven by market recovery and success of new products and commercial strategies. Interventional solutions also includes sales from Abiomed, Inc. (Abiomed) which were reflected as of December 22, 2022.

Analysis of Consolidated Earnings Before Provision for Taxes on Income
Consolidated earnings before provision for taxes on income was $21.7 billion and $22.8 billion for the years 2022 and 2021, respectively. As a percent to sales, consolidated earnings before provision for taxes on income was 22.9% and 24.3%, in 2022 and 2021, respectively.



(Dollars in billions. Percentages in chart are as a percent to total sales)

Cost of Products Sold and Selling, Marketing and Administrative Expenses:



(Dollars in billions. Percentages in chart are as a percent to total sales)

Cost of products sold increased as a percent to sales driven by:
- One-time COVID-19 vaccine manufacturing exit related costs
- Currency impacts in the Pharmaceutical segment
- Commodity inflation in the MedTech and Consumer Health segments

partially offset by
- Supply chain benefits in the Consumer Health segment

The intangible asset amortization expense included in cost of products sold was $4.3 billion and $4.7 billion for the fiscal years 2022 and 2021, respectively.

Selling, Marketing and Administrative Expenses decreased as a percent to sales driven by:
- Reduction of brand marketing expenses in the Pharmaceutical and Consumer Health businesses

Research and Development Expense:
Research and development expense by segment of business was as follows:

	2022		2021	
(Dollars in Millions)	**Amount**	**% of Sales***	**Amount**	**% of Sales***
Consumer Health	$ 493	3.3 %	$ 459	3.1 %
Pharmaceutical	11,622	22.1	11,878	23.0
MedTech	2,488	9.1	2,377	8.8
Total research and development expense	$ 14,603	15.4 %	$ 14,714	15.7 %
Percent increase/(decrease) over the prior year	(0.8)%		21.0 %	

*As a percent to segment sales

Research and development activities represent a significant part of the Company's business. These expenditures relate to the processes of discovering, testing and developing new products, upfront payments and developmental milestones, improving existing products, as well as ensuring product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products.

Research and Development decreased as a percent to sales primarily driven by:
- Lower milestone payments in the Pharmaceutical business

In-Process Research and Development (IPR&D): In the fiscal year 2022, the Company recorded an intangible asset impairment charge of approximately $0.8 billion related to an in-process research and development asset, bermekimab (JnJ-77474462), an investigational drug for the treatment of Atopic Dermatitis (AD) and Hidradenitis Suppurativa (HS). Additional information regarding efficacy of the AD indication and HS indication became available which led the Company to the decision to terminate the development of bermekimab for both AD and HS. The Company acquired all rights to bermekimab from XBiotech, Inc. in the fiscal year 2020. In fiscal year 2021, the Company recorded a partial IPR&D charge of $0.9 billion primarily related to expected development delays in the general surgery digital robotics platform (Ottava) acquired with the Auris Health acquisition in 2019. The impairment charge was calculated based on revisions to the discounted cash flow valuation model reflecting a delay of first in human procedures of approximately two years from the initial acquisition model assumption of the second half of 2022. The Company will continue to monitor the remaining $1.5 billion Ottava platform intangible asset as development program activities are ongoing.

Other (Income) Expense, Net: Other (income) expense, net is the account where the Company records gains and losses related to the sale and write-down of certain investments in equity securities held by Johnson & Johnson Innovation - JJDC, Inc. (JJDC), changes in the fair value of securities, investment (income)/loss related to employee benefit programs, gains and losses on divestitures, certain transactional currency gains and losses, acquisition and divestiture related costs, litigation accruals and settlements, as well as royalty income.

Other (income) expense, net for the fiscal year 2022 was unfavorable by $1.4 billion as compared to the prior year primarily due to the following:

(Dollars in Billions)(Income)/Expense	2022	2021	Change
Consumer Health separation costs	$ 1.0	0.1	0.9
Litigation related[1]	0.9	2.3	(1.4)
Changes in the fair value of securities	0.7	(0.5)	1.2
One-time COVID-19 vaccine manufacturing exit related costs	0.7	0.0	0.7
Acquisition, Integration and Divestiture related[2]	0.1	(0.5)	0.6
Restructuring related	0.1	0.1	0.0
Employee benefit plan related	(1.2)	(0.6)	(0.6)
Other	(0.4)	(0.4)	—
Total Other (Income) Expense, Net	$ 1.9	0.5	1.4

[1]2022 was primarily related to pelvic mesh and 2021 was primarily related to talc and Risperdal Gynecomastia
[2]2022 was primarily costs related to the acquisition of Abiomed. 2021 was primarily related to divestiture gains of two pharmaceutical brands outside the U.S.

Interest (Income) Expense: Interest (income) expense in the fiscal of 2022 was net interest income of $214 million as compared to interest expense of $130 million in the fiscal year 2021 primarily due to higher rates of interest earned on cash balances. Cash, cash equivalents and marketable securities totaled $23.5 billion at the end of 2022, and averaged $27.6 billion as compared to the cash, cash equivalents and marketable securities total of $31.6 billion and $28.4 billion average cash balance in 2021. The total debt balance at the end of 2022 was $39.7 billion with an average debt balance of $36.7 billion as compared to $33.8 billion at the end of 2021 and an average debt balance of $34.5 billion. The lower average cash, cash equivalents and marketable securities and higher average debt balance were primarily due to the acquisition of Abiomed in late December of 2022.

Income Before Tax by Segment

Income (loss) before tax by segment of business were as follows:

	Income Before Tax		Segment Sales		Percent of Segment Sales	
(Dollars in Millions)	**2022**	**2021**	**2022**	**2021**	**2022**	**2021**
Consumer Health[3]	$ 2,930	1,573	14,953	15,035	19.6 %	10.5
Pharmaceutical[3]	15,901	17,969	52,563	51,680	30.3	34.8
MedTech	4,607	4,373	27,427	27,060	16.8	16.2
Segment earnings before tax[1]	23,438	23,915	94,943	93,775	24.7	25.5
Less: Expenses not allocated to segments[2]	624	1,072				
Less: Consumer Health separation costs	1,089	67				
Worldwide income before tax	$ 21,725	22,776	94,943	93,775	22.9 %	24.3

(1) See Note 17 to the Consolidated Financial Statements for more details.
(2) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.
(3) Prior year income before tax of approximately $0.2 billion has been reclassified as certain international OTC products, primarily in China, were reclassified from the Pharmaceutical segment to the Consumer Health segment based on operational changes.

Consumer Health Segment:

In 2022, the Consumer Health segment income before tax as a percent of sales was 19.6% versus 10.5% in 2021. The increase in the income before tax as a percent of sales was primarily driven by the following:

- Lower litigation expense of $0.2 billion in 2022 versus $1.6 billion (primarily talc related) in 2021
- Reduction in brand marketing expenses in 2022 versus 2021
- Supply chain benefits in 2022

partially offset by:

- Commodity inflation in 2022

Pharmaceutical Segment:

In 2022, the Pharmaceutical segment income before tax as a percent to sales was 30.3% versus 34.8% in 2021. The decrease in the income before tax as a percent of sales was primarily driven by the following:

- One-time COVID-19 vaccine manufacturing exit related costs of $1.5 billion in 2022
- Unfavorable changes in the fair value of securities ($0.7 billion loss in 2022 vs. $0.5 billion gain in 2021)
- An IPR&D charge of $0.8 billion in 2022 related to bermekimab (JnJ-77474462), an investigational drug for the treatment of Atopic Dermatitis (AD) and Hidradenitis Suppurativa (HS)
- Lower divestiture gains of $0.1 billion in 2022 versus $0.6 billion related to two pharmaceutical brands outside the U.S. in fiscal 2021
- Currency impacts in Cost of Products Sold

partially offset by:

- Lower litigation related expense of $0.1 billion in 2022 versus $0.6 billion (primarily related to Risperdal Gynecomastia) in 2021
- Lower Research & Development milestone payments in 2022
- Lower brand marketing expenses in 2022 versus 2021

In fiscal 2020 and 2021, the Company entered into a series of contract manufacturing arrangements for vaccine production with third party contract manufacturing organizations. These arrangements provided the Company with supplemental commercial capacity for vaccine production and potentially transferable rights to such production if capacity is not required. The Company continues to evaluate and monitor both its internal and external supply arrangements. In fiscal 2022, the COVID-19 Vaccine related costs (mentioned above) included the remaining commitments and obligations, including external manufacturing network exit and related inventory costs and required clinical trial expenses, associated with the Company's modification of its

COVID-19 vaccine research program and manufacturing capacity to levels that meet all remaining customer contractual requirements.

MedTech Segment:

In 2022, the MedTech segment income before tax as a percent to sales was 16.8% versus 16.2% in 2021. The increase in the income before tax as a percent to sales was primarily driven by the following:

- An IPR&D charge of $0.9 billion in 2021 related to the general surgery offering in digital robotics (Ottava) acquired with the Auris Health acquisition in 2019 partially offset by:
- Higher litigation related expense of $0.6 billion in 2022, primarily related to pelvic mesh costs versus $0.1 billion in 2021
- Acquisition related costs of $0.3 billion in 2022 related to the Abiomed acquisition versus $0.1 billion in 2021

Restructuring: In the fiscal second quarter of 2018, the Company announced plans to implement actions across its Global Supply Chain that are intended to enable the Company to focus resources and increase investments in critical capabilities, technologies and solutions necessary to manufacture and supply its product portfolio of the future, enhance agility and drive growth. The Global Supply Chain actions included expanding its use of strategic collaborations, and bolstering its initiatives to reduce complexity, improving cost-competitiveness, enhancing capabilities and optimizing its supply chain network. The Company has achieved approximately $0.8 billion in annual pre-tax cost savings as outlined in the restructuring actions. In 2022, the Company recorded a pre-tax charge of $0.5 billion, which is included on the following lines of the Consolidated Statement of Earnings, $0.3 billion in restructuring, $0.1 billion in other (income) expense and $0.1 billion in cost of products sold. Total project costs of approximately $2.2 billion have been recorded since the restructuring was announced. The program was completed in the fiscal fourth quarter of 2022.

See Note 20 to the Consolidated Financial Statements for additional details related to the restructuring programs.

Provision for Taxes on Income: The worldwide effective income tax rate was 17.4% in 2022 and 8.3% in 2021.

In the fiscal 2022, the Company incurred approximately $0.5 billion net incremental international tax cost related to the legal separation of the Consumer Health business, and may continue to incur additional cost in fiscal 2023.

On December 15, 2022, the European Union (EU) Member States formally adopted the EU's Pillar Two Directive, which generally provides for a minimum effective tax rate of 15%, as established by the Organization for Economic Co-operation and Development (OECD) Pillar Two Framework that was supported by over 130 countries worldwide. The EU effective dates are January 1, 2024, and January 1, 2025, for different aspects of the directive.

A significant number of other countries are expected to also implement similar legislation, including South Korea which approved legislation on December 23, 2022 with a full effective date of January 1, 2024. The Company is continuing to evaluate the potential impact on future periods of the Pillar Two Framework, pending legislative adoption by additional individual countries, including those within the European Union.

For discussion related to the fiscal 2022 provision for taxes refer to Note 8 to the Consolidated Financial Statements.

Liquidity and Capital Resources

Liquidity & Cash Flows

Cash and cash equivalents were $14.1 billion at the end of 2022 as compared to $14.5 billion at the end of 2021.

The primary sources and uses of cash that contributed to the $0.4 billion decrease were:

(Dollars In Billions)	
$ 14.5	Q4 2021 Cash and cash equivalents balance
21.2	cash generated from operating activities
(12.4)	net cash used by investing activities
(8.9)	net cash used by financing activities
$ (0.3)	effect of exchange rate and rounding
$ 14.1	Q4 2022 Cash and cash equivalents balance

In addition, the Company had $9.4 billion in marketable securities at the end of fiscal year 2022 and $17.1 billion at the end of fiscal year 2021. See Note 1 to the Consolidated Financial Statements for additional details on cash, cash equivalents and marketable securities.

Cash flow from operations of $21.2 billion was the result of:

(Dollars In Billions)	
$ 17.9	Net Earnings
7.3	non-cash expenses and other adjustments primarily for depreciation and amortization, stock-based compensation and asset write-downs partially offset by the deferred tax provision, net gain on sale of assets/businesses and credit losses and accounts receivable allowances
(2.0)	a decrease in current and non-current liabilities
0.7	a decrease in other current and non-current assets
1.1	an increase in accounts payable and accrued liabilities
(3.8)	an increase in accounts receivable and inventories
$ 21.2	Cash Flow from operations

Investing activities use of $12.4 billion of cash was primarily used for:

(Dollars In Billions)	
$ (4.0)	additions to property, plant and equipment
(17.7)	acquisitions
0.5	proceeds from the disposal of assets/businesses, net
9.2	net sales of investments
(0.2)	Credit support agreements activity, net
(0.2)	other (primarily licenses and milestones) and rounding
$ (12.4)	Net cash used for investing activities

Financing activities use of $8.9 billion of cash was primarily used for:

(Dollars In Billions)	
$ (11.7)	dividends to shareholders
(6.0)	repurchase of common stock
7.5	net proceeds from short and long term debt
1.3	proceeds from stock options exercised/employee withholding tax on stock awards, net
$ (8.9)	Net cash used for financing activities

As of January 1, 2023, the Company's notes payable and long-term debt was in excess of cash, cash equivalents and marketable securities. As of January 1, 2023, the net debt position was $16.1 billion as compared to the prior year of $2.1 billion. The increase was primarily due to the acquisition of Abiomed, Inc. in December 2022. The debt balance at the end of 2022 was $39.7 billion as compared to $33.8 billion in 2021. Considering recent market conditions, the Company has re-evaluated its operating cash flows and liquidity profile and does not foresee any significant incremental risk. The Company anticipates that operating cash flows, the ability to raise funds from external sources, borrowing capacity from existing committed credit facilities and access to the commercial paper markets will continue to provide sufficient resources to fund operating needs, including the Company's remaining balance to be paid on the agreement to settle opioid litigation for approximately $2.7 billion and the establishment of the $2.0 billion trust for talc related liabilities (See Note 19 to the Consolidated Financial Statements for additional details). In addition, the Company monitors the global capital markets on an ongoing basis and from time to time may raise capital when market conditions are favorable. Effective beginning in fiscal 2022, the U.S. Tax Cuts and Job Act of 2017 (TCJA) requires the Company to deduct U.S. and international research and development expenditures for tax purposes over 5 to 15 years, instead of in the current fiscal year. As a result, in fiscal 2022, the Company experienced an increase in annual cash tax payments of approximately $1.2 billion above what otherwise would have been remitted to the U.S Treasury. The Company concurrently records a deferred tax benefit for the future amortization of the research and development (R&D) for tax purposes. The requirement to expense R&D as incurred is unchanged for U.S. GAAP purposes and the impact to pre-tax R&D expense is not affected by this provision.

On September 14, 2022, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's Common Stock. Share repurchases may be made at management’s discretion from time to time on the open market or through privately negotiated transactions. The repurchase program has no time limit and may be suspended for periods or discontinued at any time. Any shares acquired will be available

for general corporate purposes. The Company intends to finance the share repurchase program through available cash. Through January 1, 2023, approximately $2.5 billion has been repurchased under the program.

The following table summarizes the Company's material contractual obligations and their aggregate maturities as of January 1, 2023: To satisfy these obligations, the Company intends to use cash from operations.

(Dollars in Millions)	Tax Legislation (TCJA)	Debt Obligations	Interest on Debt Obligations	Total
2023	$ 1,522	1,551	893	3,966
2024	2,029	1,392	843	4,264
2025	2,536	1,667	789	4,992
2026	—	1,996	744	2,740
2027	—	2,271	736	3,007
After 2026	—	19,562	8,772	28,334
Total	**$ 6,087**	**28,439**	**12,777**	**47,303**

For tax matters, see Note 8 to the Consolidated Financial Statements.

Financing and Market Risk

The Company uses financial instruments to manage the impact of foreign exchange rate changes on cash flows. Accordingly, the Company enters into forward foreign exchange contracts to protect the value of certain foreign currency assets and liabilities and to hedge future foreign currency transactions primarily related to product costs. Gains or losses on these contracts are offset by the gains or losses on the underlying transactions. A 10% appreciation of the U.S. Dollar from the January 1, 2023 market rates would increase the unrealized value of the Company's forward contracts by $0.1 billion. Conversely, a 10% depreciation of the U.S. Dollar from the January 1, 2023 market rates would decrease the unrealized value of the Company's forward contracts by $0.1 billion. In either scenario, the gain or loss on the forward contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated earnings and cash flows.

The Company hedges the exposure to fluctuations in currency exchange rates, and the effect on certain assets and liabilities in foreign currency, by entering into currency swap contracts. A 1% change in the spread between U.S. and foreign interest rates on the Company's interest rate sensitive financial instruments would either increase or decrease the unrealized value of the Company's swap contracts by approximately $1.7 billion. In either scenario, at maturity, the gain or loss on the swap contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated cash flows.

The Company does not enter into financial instruments for trading or speculative purposes. Further, the Company has a policy of only entering into contracts with parties that have at least an investment grade credit rating. The counterparties to these contracts are major financial institutions and there is no significant concentration of exposure with any one counterparty. Management believes the risk of loss is remote. The Company entered into credit support agreements (CSA) with certain derivative counterparties establishing collateral thresholds based on respective credit ratings and netting agreements. See Note 6 to the Consolidated Financial Statements for additional details on credit support agreements.

The Company invests in both fixed rate and floating rate interest earning securities which carry a degree of interest rate risk. The fair market value of fixed rate securities may be adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than predicted if interest rates fall. A 1% (100 basis points) change in spread on the Company's interest rate sensitive investments would either increase or decrease the unrealized value of cash equivalents and current marketable securities by less than $0.1 billion.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2022, the Company secured a new 364-day Credit Facility of $10 billion, which expires on September 7, 2023. In November 2022, the Company secured an additional 364-day revolving Credit Facility of $10 billion, which has an expiration of November 21, 2023. Interest charged on borrowings under the credit line agreement is based on either Secured Overnight Financing Rate (SOFR) Reference Rate or other applicable market rate as allowed plus applicable margins. Commitment fees under the agreement are not material.

Total borrowings at the end of 2022 and 2021 were $39.7 billion and $33.8 billion, respectively. The increase in borrowings was due to the acquisition of Abiomed, Inc. In 2022, net debt (cash and current marketable securities, net of debt) was $16.1 billion compared to net debt of $2.1 billion in 2021. Total debt represented 34.1% of total capital (shareholders' equity and total debt) in 2022 and 31.3% of total capital in 2021. Shareholders' equity per share at the end of 2022 was $29.39 compared to $28.16 at year-end 2021.

A summary of borrowings can be found in Note 7 to the Consolidated Financial Statements.

Dividends
The Company increased its dividend in 2022 for the 60th consecutive year. Cash dividends paid were $4.45 per share in 2022 and $4.19 per share in 2021.

On January 3, 2023, the Board of Directors declared a regular cash dividend of $1.13 per share, payable on March 7, 2023 to shareholders of record as of February 21, 2023.

Other Information

Critical Accounting Policies and Estimates

Management's discussion and analysis of results of operations and financial condition are based on the Company's consolidated financial statements that have been prepared in accordance with accounting principles generally accepted in the U.S. (GAAP). The preparation of these financial statements requires that management make estimates and assumptions that affect the amounts reported for revenues, expenses, assets, liabilities and other related disclosures. Actual results may or may not differ from these estimates. The Company believes that the understanding of certain key accounting policies and estimates are essential in achieving more insight into the Company's operating results and financial condition. These key accounting policies include revenue recognition, income taxes, legal and self-insurance contingencies, valuation of long-lived assets, assumptions used to determine the amounts recorded for pensions and other employee benefit plans and accounting for stock based awards.

Revenue Recognition: The Company recognizes revenue from product sales when obligations under the terms of a contract with the customer are satisfied; generally, this occurs with the transfer of control of the goods to customers. The Company's global payment terms are typically between 30 to 90 days. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns, discounts to customers and governmental clawback provisions are accounted for as variable consideration and recorded as a reduction in sales.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including consideration of competitor pricing. Rebates are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns are estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales return accruals.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The sales returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer Health and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the MedTech segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual net trade sales during the fiscal years 2022, 2021 and 2020.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the same period as related sales. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue. The Company also earns profit-share payments through collaborative arrangements of certain products, which are included in sales to customers. Profit-share payments were less than 2.0% of the total revenues in fiscal year 2022 and less than 3.0% of the total revenues in fiscal years 2021 and 2020 and are included in sales to customers.

In addition, the Company enters into collaboration arrangements that contain multiple revenue generating activities. Amounts due from collaborative partners for these arrangements are recognized as each activity is performed or delivered, based on the relative selling price. Upfront fees received as part of these arrangements are deferred and recognized over the performance period. See Note 1 to the Consolidated Financial Statements for additional disclosures on collaborations.

Reasonably likely changes to assumptions used to calculate the accruals for rebates, returns and promotions are not anticipated to have a material effect on the financial statements. The Company currently discloses the impact of changes to assumptions in the quarterly or annual filing in which there is a material financial statement impact.

Below are tables that show the progression of accrued rebates, returns, promotions, reserve for doubtful accounts and reserve for cash discounts by segment of business for the fiscal years ended January 1, 2023 and January 2, 2022.

Consumer Health Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits	Balance at End of Period
2022				
Accrued rebates [1]	$ 287	1,052	(948)	391
Accrued returns	76	83	(88)	71
Accrued promotions	387	2,077	(2,008)	456
Subtotal	$ 750	3,212	(3,044)	918
Reserve for doubtful accounts	32	5	(3)	34
Reserve for cash discounts	15	210	(208)	17
Total	$ 797	3,427	(3,255)	969
2021				
Accrued rebates[1]	$ 289	893	(895)	287
Accrued returns	76	136	(136)	76
Accrued promotions	428	1,958	(1,999)	387
Subtotal	$ 793	2,987	(3,030)	750
Reserve for doubtful accounts	39	0	(7)	32
Reserve for cash discounts	12	213	(210)	15
Total	$ 844	3,200	(3,247)	797

(1) Includes reserve for customer rebates of $82 million at January 1, 2023 and $80 million at January 2, 2022, recorded as a contra asset.

Pharmaceutical Segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/Credits[2]	Balance at End of Period
2022				
Accrued rebates [1]	$ 10,331	43,026	(41,068)	12,289
Accrued returns	520	444	(315)	649
Accrued promotions	3	5	(7)	1
Subtotal	$ 10,854	43,475	(41,390)	12,939
Reserve for doubtful accounts	50	0	(6)	44
Reserve for cash discounts	94	1,281	(1,265)	110
Total	$ 10,998	44,756	(42,661)	13,093
2021				
Accrued rebates [1]	$ 9,837	37,922	(37,428)	10,331
Accrued returns	460	345	(285)	520
Accrued promotions	6	13	(16)	3
Subtotal	$ 10,303	38,280	(37,729)	10,854
Reserve for doubtful accounts	52	18	(20)	50
Reserve for cash discounts	70	1,163	(1,139)	94
Total	$ 10,425	39,461	(38,888)	10,998

(1) Includes reserve for customer rebates of $203 million at January 1, 2023 and $218 million at January 2, 2022, recorded as a contra asset.

(2) Includes prior period adjustments

MedTech Segment

(Dollars in Millions)		Balance at Beginning of Period	Accruals	Payments/Credits	Balance at End of Period
2022					
Accrued rebates[1]	$	1,446	6,131	(6,107)	1,470
Accrued returns		134	531	(531)	134
Accrued promotions		54	102	(113)	43
Subtotal	$	1,634	6,764	(6,751)	1,647
Reserve for doubtful accounts		148	6	(29)	125
Reserve for cash discounts		10	99	(100)	9
Total	$	1,792	6,869	(6,880)	1,781
2021					
Accrued rebates[1]	$	1,174	5,942	(5,670)	1,446
Accrued returns		138	559	(563)	134
Accrued promotions		52	140	(138)	54
Subtotal	$	1,364	6,641	(6,371)	1,634
Reserve for doubtful accounts		202	12	(66)	148
Reserve for cash discounts		9	96	(95)	10
Total	$	1,575	6,749	(6,532)	1,792

(1) Includes reserve for customer rebates of $802 million at January 1, 2023 and $845 million at January 2, 2022, recorded as a contra asset.

Income Taxes: Income taxes are recorded based on amounts refundable or payable for the current year and include the results of any difference between U.S. GAAP accounting and tax reporting, recorded as deferred tax assets or liabilities. The Company estimates deferred tax assets and liabilities based on enacted tax regulations and rates. Future changes in tax laws and rates may affect recorded deferred tax assets and liabilities.

The Company has unrecognized tax benefits for uncertain tax positions. The Company follows U.S. GAAP, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Management believes that changes in these estimates would not have a material effect on the Company's results of operations, cash flows or financial position.

The Company has recorded deferred tax liabilities on all undistributed earnings prior to December 31, 2017 from its international subsidiaries. The Company has not provided deferred taxes on the undistributed earnings subsequent to January 1, 2018 from certain international subsidiaries where the earnings are considered to be indefinitely reinvested. The Company intends to continue to reinvest these earnings in those international operations. If the Company decides at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company estimates that the tax effect of this repatriation would be approximately $0.5 billion under currently enacted tax laws and regulations and at current currency exchange rates. This amount does not include the possible benefit of U.S. foreign tax credits, which may substantially offset this cost.

See Note 1 and Note 8 to the Consolidated Financial Statements for further information regarding income taxes.

Legal and Self Insurance Contingencies: The Company records accruals for various contingencies, including legal proceedings and product liability claims as these arise in the normal course of business. The accruals are based on management's judgment as to the probability of losses and, where applicable, actuarially determined estimates. The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated.

The Company follows the provisions of U.S. GAAP when recording litigation related contingencies. A liability is recorded when a loss is probable and can be reasonably estimated.

See Notes 1 and 19 to the Consolidated Financial Statements for further information regarding product liability and legal proceedings.

Long-Lived and Intangible Assets: The Company assesses changes, both qualitatively and quantitatively, in economic conditions and makes assumptions regarding estimated future cash flows in evaluating the value of the Company's property, plant and equipment, goodwill and intangible assets. As these assumptions and estimates may change over time, it may or may not be necessary for the Company to record impairment charges.

Employee Benefit Plans: The Company sponsors various retirement and pension plans, including defined benefit, defined contribution and termination indemnity plans, which cover most employees worldwide. These plans are based on assumptions for the discount rate, expected return on plan assets, mortality rates, expected salary increases, healthcare cost trend rates and attrition rates. See Note 10 to the Consolidated Financial Statements for further details on these rates.

Stock Based Compensation: The Company recognizes compensation expense associated with the issuance of equity instruments to employees for their services. Based on the type of equity instrument, the fair value is estimated on the date of grant using either the Black-Scholes option valuation model or a combination of both the Black-Scholes option valuation model and Monte Carlo valuation model, and is expensed in the financial statements over the service period. The input assumptions used in determining fair value are the expected life, expected volatility, risk-free rate and expected dividend yield. For performance share units, the fair market value is calculated for the two component goals at the date of grant: adjusted operational earnings per share and relative total shareholder return. The fair values for the earnings per share goal of each performance share unit was estimated on the date of grant using the fair market value of the shares at the time of the award, discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. See Note 16 to the Consolidated Financial Statements for additional information.

New Accounting Pronouncements
Refer to Note 1 to the Consolidated Financial Statements for recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of January 1, 2023.

Economic and Market Factors

The Company is aware that its products are used in an environment where, for more than a decade, policymakers, consumers and businesses have expressed concerns about the rising cost of healthcare. In response to these concerns, the Company has a long-standing policy of pricing products responsibly. For the period 2012 - 2022, in the U.S., the weighted average compound annual growth rate of the Company's net price increases for healthcare products (prescription and over-the-counter drugs, hospital and professional products) was below the U.S. Consumer Price Index (CPI).

The Company operates in certain countries where the economic conditions continue to present significant challenges. The Company continues to monitor these situations and take appropriate actions. Inflation rates continue to have an effect on worldwide economies and, consequently, on the way companies operate. The Company has accounted for operations in Argentina and Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. Beginning in the fiscal second quarter of 2022, the Company accounted for operations in Turkey as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. This did not have a material impact to the Company's results in the period. In the face of increasing costs, the Company strives to maintain its profit margins through cost reduction programs, productivity improvements and periodic price increases.

Russia-Ukraine War

Although the long-term implications of Russia's invasion of Ukraine are difficult to predict at this time, the financial impact of the conflict in the fiscal 2022, including accounts receivable or inventory reserves, was not material. As of both the fiscal years ending January 1, 2023 and January 2, 2022, the business of the Company's Ukraine subsidiaries represented less than 1% of the Company's consolidated assets and revenues. As of both the fiscal years ending January 1, 2023 and January 2, 2022, the business of the Company's Russian subsidiaries represented less than 1% of the Company's consolidated assets and represented 1% of revenues. In early March, the Company took steps to suspend all advertising, enrollment in clinical trials, and any additional investment in Russia. Additionally, at the end of March, the Company made the decision to suspend supply of personal care products in Russia. The Company continues to supply its other products as patients rely on many of the products for healthcare purposes.

The Company is exposed to fluctuations in currency exchange rates. A 1% change in the value of the U.S. Dollar as compared to all foreign currencies in which the Company had sales, income or expense in 2022 would have increased or decreased the translation of foreign sales by approximately $0.5 billion and net income by approximately $0.1 billion.

Governments around the world consider various proposals to make changes to tax laws, which may include increasing or decreasing existing statutory tax rates. In connection with various government initiatives, companies are required to disclose more information to tax authorities on operations around the world, which may lead to greater audit scrutiny of profits earned in other countries. A change in statutory tax rate in any country would result in the revaluation of the Company's deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is enacted. This change would result in an expense or benefit recorded to the Company's Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries where it operates. Changes to the statutory tax rate may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted.

The Company faces various worldwide healthcare changes that may continue to result in pricing pressures that include healthcare cost containment and government legislation relating to sales, promotions, pricing and reimbursement of healthcare products.

Changes in the behavior and spending patterns of purchasers of healthcare products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing healthcare insurance coverage, as a result of the current global economic downturn, may continue to impact the Company's businesses.

The Company also operates in an environment increasingly hostile to intellectual property rights. Firms have filed Abbreviated New Drug Applications or Biosimilar Biological Product Applications with the U.S. FDA or otherwise challenged the coverage and/or validity of the Company's patents, seeking to market generic or biosimilar forms of many of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the event the Company is not successful in defending the patent claims challenged in the resulting lawsuits, generic or biosimilar versions of the products at issue will be introduced to the market, resulting in the potential for substantial market share and revenue losses for those products, and which may result in a non-cash impairment charge in any associated intangible asset. There is also a risk that one or more competitors could launch a generic or biosimilar version of the product at issue following regulatory approval even though one or more valid patents are in place.

Legal Proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability, intellectual property, commercial, employment, indemnification and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of business.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of January 1, 2023, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based

on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; ability to achieve comprehensive multi-party settlements; complexity of related cross-claims and counterclaims; and/or there are numerous parties involved. To the extent adverse awards, judgments or verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution of, or increase in accruals for, one or more of these matters in any reporting period may have a material adverse effect on the Company's results of operations and cash flows for that period.

See Note 19 to the Consolidated Financial Statements included in Item 8 of this report for further information regarding legal proceedings.

Common Stock

The Company’s Common Stock is listed on the New York Stock Exchange under the symbol JNJ. As of February 10, 2023, there were 124,211 record holders of Common Stock of the Company.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The information called for by this item is incorporated herein by reference to “Item 7. Management’s Discussion and Analysis of Results of Operations and Financial Condition - Liquidity and Capital Resources - Financing and Market Risk” of this Report; and Note 1 “Summary of Significant Accounting Policies - Financial Instruments” of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Audited Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
At January 1, 2023 and January 2, 2022
(Dollars in Millions Except Share and Per Share Amounts) (Note 1)

		2022	2021
Assets			
Current assets			
Cash and cash equivalents (Notes 1 and 2)	$	14,127	14,487
Marketable securities (Notes 1 and 2)		9,392	17,121
Accounts receivable trade, less allowances for doubtful accounts $203 (2021, $230)		16,160	15,283
Inventories (Notes 1 and 3)		12,483	10,387
Prepaid expenses and other receivables		3,132	3,701
Total current assets		**55,294**	**60,979**
Property, plant and equipment, net (Notes 1 and 4)		19,803	18,962
Intangible assets, net (Notes 1 and 5)		48,325	46,392
Goodwill (Notes 1 and 5)		45,231	35,246
Deferred taxes on income (Note 8)		9,123	10,223
Other assets		9,602	10,216
Total assets	**$**	**187,378**	**182,018**
Liabilities and Shareholders' Equity			
Current liabilities			
Loans and notes payable (Note 7)	$	12,771	3,766
Accounts payable		11,703	11,055
Accrued liabilities		11,456	13,612
Accrued rebates, returns and promotions		14,417	12,095
Accrued compensation and employee related obligations		3,328	3,586
Accrued taxes on income (Note 8)		2,127	1,112
Total current liabilities		**55,802**	**45,226**
Long-term debt (Note 7)		26,888	29,985
Deferred taxes on income (Note 8)		6,374	7,487
Employee related obligations (Notes 9 and 10)		6,767	8,898
Long-term taxes payable (Note 1)		4,306	5,713
Other liabilities		10,437	10,686
Total liabilities		**110,574**	**107,995**
Commitments and Contingencies (Note 19)			
Shareholders' equity			
Preferred stock — without par value (authorized and unissued 2,000,000 shares)		—	—
Common stock — par value $1.00 per share (Note 12) (authorized 4,320,000,000 shares; issued 3,119,843,000 shares)		3,120	3,120
Accumulated other comprehensive income (loss) (Note 13)		(12,967)	(13,058)
Retained earnings		128,345	123,060
		118,498	113,122
Less: common stock held in treasury, at cost (Note 12) (506,246,000 shares and 490,878,000 shares)		41,694	39,099
Total shareholders' equity		**76,804**	**74,023**
Total liabilities and shareholders' equity	**$**	**187,378**	**182,018**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EARNINGS
(Dollars and Shares in Millions Except Per Share Amounts) (Note 1)

	2022	2021	2020
Sales to customers	$ 94,943	93,775	82,584
Cost of products sold	31,089	29,855	28,427
Gross profit	63,854	63,920	54,157
Selling, marketing and administrative expenses	24,765	24,659	22,084
Research and development expense	14,603	14,714	12,159
In-process research and development (Note 5)	783	900	181
Interest income	(490)	(53)	(111)
Interest expense, net of portion capitalized (Note 4)	276	183	201
Other (income) expense, net	1,871	489	2,899
Restructuring (Note 20)	321	252	247
Earnings before provision for taxes on income	21,725	22,776	16,497
Provision for taxes on income (Note 8)	3,784	1,898	1,783
Net earnings	**$ 17,941**	**20,878**	**14,714**
Net earnings per share (Notes 1 and 15)			
Basic	**$ 6.83**	**7.93**	**5.59**
Diluted	**$ 6.73**	**7.81**	**5.51**
Average shares outstanding (Notes 1 and 15)			
Basic	**2,625.2**	**2,632.1**	**2,632.8**
Diluted	**2,663.9**	**2,674.0**	**2,670.7**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Dollars in Millions) (Note 1)

	2022	2021	2020
Net earnings	$ 17,941	20,878	14,714
Other comprehensive income (loss), net of tax			
Foreign currency translation	(1,796)	(1,079)	(233)
Securities:			
Unrealized holding gain (loss) arising during period	(24)	(4)	1
Reclassifications to earnings	—	—	—
Net change	(24)	(4)	1
Employee benefit plans:			
Prior service credit (cost), net of amortization	(160)	(169)	1,298
Gain (loss), net of amortization	1,854	4,318	(1,135)
Effect of exchange rates	111	106	(229)
Net change	1,805	4,255	(66)
Derivatives & hedges:			
Unrealized gain (loss) arising during period	454	(199)	1,000
Reclassifications to earnings	(348)	(789)	(53)
Net change	106	(988)	947
Other comprehensive income (loss)	91	2,184	649
Comprehensive income	$ 18,032	23,062	15,363

The tax effects in other comprehensive income for the fiscal years 2022, 2021 and 2020 respectively: Foreign Currency Translation; $460 million, $346 million and $536 million; Securities: $6 million and $1 million in 2022 and 2021, Employee Benefit Plans: $461 million, $1,198 million and $21 million, Derivatives & Hedges: $30 million, $263 million and $252 million.

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY
(Dollars in Millions) (Note 1)

	Total	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Common Stock Issued Amount	Treasury Stock Amount
Balance, December 29, 2019	**$ 59,471**	**110,659**	**(15,891)**	**3,120**	**(38,417)**
Net earnings	14,714	14,714			
Cash dividends paid ($3.98 per share)	(10,481)	(10,481)			
Employee compensation and stock option plans	2,217	(931)			3,148
Repurchase of common stock	(3,221)				(3,221)
Other	(71)	(71)			
Other comprehensive income (loss), net of tax	649		649		
Balance, January 3, 2021	**63,278**	**113,890**	**(15,242)**	**3,120**	**(38,490)**
Net earnings	20,878	20,878			
Cash dividends paid ($4.19 per share)	(11,032)	(11,032)			
Employee compensation and stock option plans	2,171	(676)			2,847
Repurchase of common stock	(3,456)				(3,456)
Other comprehensive income (loss), net of tax	2,184		2,184		
Balance, January 2, 2022	**74,023**	**123,060**	**(13,058)**	**3,120**	**(39,099)**
Net earnings	17,941	17,941			
Cash dividends paid ($4.45 per share)	(11,682)	(11,682)			
Employee compensation and stock option plans	2,466	(974)			3,440
Repurchase of common stock	(6,035)				(6,035)
Other comprehensive income (loss), net of tax	91		91		
Balance, January 1, 2023	**$ 76,804**	**128,345**	**(12,967)**	**3,120**	**(41,694)**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Dollars in Millions) (Note 1)

	2022	2021	2020
Cash flows from operating activities			
Net earnings	$ 17,941	20,878	14,714
Adjustments to reconcile net earnings to cash flows from operating activities:			
Depreciation and amortization of property and intangibles	6,970	7,390	7,231
Stock based compensation	1,138	1,135	1,005
Asset write-downs	1,216	989	233
Contingent consideration reversal	—	—	(1,148)
Net gain on sale of assets/businesses	(380)	(617)	(111)
Deferred tax provision	(1,663)	(2,079)	(1,141)
Credit losses and accounts receivable allowances	(17)	(48)	63
Changes in assets and liabilities, net of effects from acquisitions and divestitures:			
(Increase)/Decrease in accounts receivable	(1,290)	(2,402)	774
Increase in inventories	(2,527)	(1,248)	(265)
Increase in accounts payable and accrued liabilities	1,098	2,437	5,141
Decrease/(Increase) in other current and non-current assets	687	(1,964)	(3,704)
(Decrease)/Increase in other current and non-current liabilities	(1,979)	(1,061)	744
Net cash flows from operating activities	**21,194**	**23,410**	**23,536**
Cash flows from investing activities			
Additions to property, plant and equipment	(4,009)	(3,652)	(3,347)
Proceeds from the disposal of assets/businesses, net	543	711	305
Acquisitions, net of cash acquired (Note 18)	(17,652)	(60)	(7,323)
Purchases of investments	(32,384)	(30,394)	(21,089)
Sales of investments	41,609	25,006	12,137
Credit support agreements activity, net	(249)	214	(987)
Other (primarily licenses and milestones)	(229)	(508)	(521)
Net cash used by investing activities	**(12,371)**	**(8,683)**	**(20,825)**
Cash flows from financing activities			
Dividends to shareholders	(11,682)	(11,032)	(10,481)
Repurchase of common stock	(6,035)	(3,456)	(3,221)
Proceeds from short-term debt	16,134	1,997	3,391
Repayment of short-term debt	(6,550)	(1,190)	(2,663)
Proceeds from long-term debt, net of issuance costs	2	5	7,431
Repayment of long-term debt	(2,134)	(1,802)	(1,064)
Proceeds from the exercise of stock options/employee withholding tax on stock awards, net	1,329	1,036	1,114
Credit support agreements activity, net	(28)	281	(333)
Other	93	114	(294)
Net cash used by financing activities	**(8,871)**	**(14,047)**	**(6,120)**
Effect of exchange rate changes on cash and cash equivalents	(312)	(178)	89
(Decrease)/Increase in cash and cash equivalents	(360)	502	(3,320)
Cash and cash equivalents, beginning of year (Note 1)	14,487	13,985	17,305
Cash and cash equivalents, end of year (Note 1)	**$ 14,127**	**14,487**	**13,985**
Supplemental cash flow data			
Cash paid during the year for:			
Interest	$ 982	990	904
Interest, net of amount capitalized	933	941	841
Income taxes	5,223	4,768	4,619

Supplemental schedule of non-cash investing and financing activities				
Treasury stock issued for employee compensation and stock option plans, net of cash proceeds/ employee withholding tax on stock awards	$	2,114	1,811	1,937
Conversion of debt		—	—	27
Acquisitions				
Fair value of assets acquired	$	18,710	61	7,755
Fair value of liabilities assumed		(1,058)	(1)	(432)
Net cash paid for acquisitions (Note 18)	**$**	**17,652**	**60**	**7,323**

See Notes to Consolidated Financial Statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Johnson & Johnson and its subsidiaries (the Company). Intercompany accounts and transactions are eliminated. Columns and rows within tables may not add due to rounding. Percentages have been calculated using actual, non-rounded figures.

Description of the Company and Business Segments

The Company has approximately 152,700 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the healthcare field. The Company conducts business in virtually all countries of the world and its primary focus is on products related to human health and well-being.

The Company is organized into three business segments: Consumer Health, Pharmaceutical and MedTech. The Consumer Health segment includes a broad range of products used in the Baby Care, Oral Care, Skin Health/Beauty, Over-the-Counter pharmaceutical, Women's Health and Wound Care markets. These products are marketed to the general public and sold online (eCommerce) and to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on the following therapeutic areas, including Immunology, Infectious diseases, Neuroscience, Oncology, Pulmonary Hypertension, and Cardiovascular and Metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, distributors, hospitals and healthcare professionals for prescription use. The MedTech segment includes a broad portfolio of products used in the Orthopaedic, Surgery, Interventional Solutions (cardiovascular and neurovascular) and Vision fields. These products are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

In November 2021, the Company announced its intention to separate the Company's Consumer Health business (Kenvue as the name for the planned New Consumer Health Company), with the intention to create a new, publicly traded company by the end of the fiscal year 2023.

New Accounting Standards

Recently Adopted Accounting Standards

There were no new material accounting standards adopted in fiscal 2022.

Recently Issued Accounting Standards

Not Adopted as of January 1, 2023

ASU 2022-04: Liabilities-Supplier Finance Programs (Topic 405-50) – Disclosure of Supplier Finance Program Obligations

This update requires that a buyer in a supplier finance program disclose additional information about the program to allow financial statement users to better understand the effect of the programs on an entity's working capital, liquidity, and cash flows. This update will be effective for the Company for fiscal years beginning after December 15, 2022, except for the amendment on roll forward information, which is effective for fiscal years beginning after December 15, 2023. Early adoption is permitted. The Company is currently assessing the impact of this update on its disclosures and will adopt this standard in the fiscal first quarter of 2023.

Cash Equivalents

The Company classifies all highly liquid investments with stated maturities of three months or less from date of purchase as cash equivalents and all highly liquid investments with stated maturities of greater than three months from the date of purchase as current marketable securities. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating. The Company invests its cash primarily in government securities and obligations, corporate debt securities, money market funds and reverse repurchase agreements (RRAs).

RRAs are collateralized by deposits in the form of Government Securities and Obligations for an amount not less than 102% of their value. The Company does not record an asset or liability as the Company is not permitted to sell or repledge the associated collateral. The Company has a policy that the collateral has at least an A (or equivalent) credit rating. The Company utilizes a third party custodian to manage the exchange of funds and ensure that collateral received is maintained at 102% of the value of the RRAs on a daily basis. RRAs with stated maturities of greater than three months from the date of purchase are classified as marketable securities.

Investments

Investments classified as held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings. Investments classified as available-for-sale debt securities are carried at estimated fair value with unrealized gains and

losses recorded as a component of accumulated other comprehensive income. Available-for-sale securities available for current operations are classified as current assets otherwise, they are classified as long term. Management determines the appropriate classification of its investment in debt and equity securities at the time of purchase and re-evaluates such determination at each balance sheet date. The Company reviews its investments for impairment and adjusts these investments to fair value through earnings, as required.

Property, Plant and Equipment and Depreciation

Property, plant and equipment are stated at cost. The Company utilizes the straight-line method of depreciation over the estimated useful lives of the assets:

Building and building equipment	30 years
Land and leasehold improvements	10 - 20 years
Machinery and equipment	2 - 13 years

The Company capitalizes certain computer software and development costs, included in machinery and equipment, when incurred in connection with developing or obtaining computer software for internal use. Capitalized software costs are amortized over the estimated useful lives of the software, which generally range from 3 to 8 years.

The Company reviews long-lived assets to assess recoverability using undiscounted cash flows. When certain events or changes in operating or economic conditions occur, an impairment assessment may be performed on the recoverability of the carrying value of these assets. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows.

Revenue Recognition

The Company recognizes revenue from product sales when obligations under the terms of a contract with the customer are satisfied; generally, this occurs with the transfer of control of the goods to customers. The Company's global payment terms are typically between 30 to 90 days. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns, discounts to customers and governmental clawback provisions are accounted for as variable consideration and recorded as a reduction in sales. The liability is recognized within Accrued Rebates, Returns, and Promotions on the consolidated balance sheet.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including consideration of competitor pricing. Rebates are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. A significant portion of the liability related to rebates is from the sale of the Company's pharmaceutical products within the U.S., primarily the Managed Care, Medicare and Medicaid programs, which amounted to $9.6 billion and $7.7 billion as of January 1, 2023 and January 2, 2022, respectively. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns are estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales return accruals.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The sales returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer Health and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the MedTech segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual net trade sales during each of the fiscal years 2022, 2021 and 2020.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the same period as related sales. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue. The Company also earns profit-share payments through collaborative arrangements for certain products, which are included in sales to customers. Profit-share payments were less than 2.0% of the total revenues in fiscal year 2022 and less than 3.0% of the total revenues in fiscal years 2021 and 2020 and are included in sales to customers.

See Note 17 to the Consolidated Financial Statements for further disaggregation of revenue.

Shipping and Handling
Shipping and handling costs incurred were $1.1 billion, $1.1 billion and $1.0 billion in fiscal years 2022, 2021 and 2020, respectively, and are included in selling, marketing and administrative expense. The amount of revenue received for shipping and handling is less than 1.0% of sales to customers for all periods presented.

Inventories
Inventories are stated at the lower of cost or net realizable value determined by the first-in, first-out method.

Intangible Assets and Goodwill
The authoritative literature on U.S. GAAP requires that goodwill and intangible assets with indefinite lives be assessed annually for impairment. The Company completed its annual impairment test for 2022 in the fiscal fourth quarter. Future impairment tests will be performed annually in the fiscal fourth quarter, or sooner if warranted. Purchased in-process research and development is accounted for as an indefinite lived intangible asset until the underlying project is completed, at which point the intangible asset will be accounted for as a definite lived intangible asset. If warranted the purchased in-process research and development could be written off or partially impaired depending on the underlying program.

Intangible assets that have finite useful lives continue to be amortized over their useful lives, and are reviewed for impairment when warranted by economic conditions. See Note 5 for further details on Intangible Assets and Goodwill.

Financial Instruments
As required by U.S. GAAP, all derivative instruments are recorded on the balance sheet at fair value. Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value, with Level 1 having the highest priority and Level 3 having the lowest. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The Company documents all relationships between hedged items and derivatives. The overall risk management strategy includes reasons for undertaking hedge transactions and entering into derivatives. The objectives of this strategy are: (1) minimize foreign currency exposure's impact on the Company's financial performance; (2) protect the Company's cash flow from adverse movements in foreign exchange rates; (3) ensure the appropriateness of financial instruments; and (4) manage the enterprise risk associated with financial institutions. See Note 6 for additional information on Financial Instruments.

Leases
The Company determines whether an arrangement is a lease at contract inception by establishing if the contract conveys the right to control the use of identified property, plant, or equipment for a period of time in exchange for consideration. Right of Use (ROU) Assets and Lease Liabilities for operating leases are included in Other assets, Accrued liabilities, and Other liabilities on the consolidated balance sheet. The ROU Assets represent the right to use an underlying asset for the lease term and lease liabilities represent an obligation to make lease payments arising from the lease. Commitments under finance leases are not significant, and are included in Property, plant and equipment, Loans and notes payable, and Long-term debt on the consolidated balance sheet.

ROU Assets and Lease Liabilities are recognized at the lease commencement date based on the present value of all minimum lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments, when the implicit rate is not readily determinable. Lease terms may include options to extend or terminate the lease. These options are included in the lease term when it is reasonably certain that the Company will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term. The Company has elected the following policy elections on adoption: use of portfolio approach on leases of assets under master service agreements, exclusion of short term leases on the balance sheet, and not separating lease and non-lease components.

The Company primarily has operating lease for space, vehicles, manufacturing equipment and data processing equipment. The ROU asset pertaining to operating leases was $1.1 billion and $0.9 billion in fiscal years 2022 and 2021, respectively. The lease liability was $1.3 billion and $1.0 billion in fiscal years 2022 and 2021, respectively. The operating lease costs were $0.3 billion in fiscal years 2022, 2021 and 2020, respectively. Cash paid for amounts included in the measurement of lease liabilities were $0.3 billion in fiscal years 2022, 2021 and 2020, respectively.

Product Liability
Accruals for product liability claims are recorded, on an undiscounted basis, when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated based on existing information and actuarially determined estimates where applicable. The accruals are adjusted periodically as additional information becomes available. The Company

accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated.

Research and Development

Research and development expenses are expensed as incurred in accordance with ASC 730, Research and Development. Upfront and milestone payments made to third parties in connection with research and development collaborations are expensed as incurred up to the point of regulatory approval. Payments made to third parties subsequent to regulatory approval are capitalized and amortized over the remaining useful life of the related product. Amounts capitalized for such payments are included in other intangibles, net of accumulated amortization.

The Company enters into collaborative arrangements, typically with other pharmaceutical or biotechnology companies, to develop and commercialize drug candidates or intellectual property. These arrangements typically involve two (or more) parties who are active participants in the collaboration and are exposed to significant risks and rewards dependent on the commercial success of the activities. These collaborations usually involve various activities by one or more parties, including research and development, marketing and selling and distribution. Often, these collaborations require upfront, milestone and royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development. Amounts due from collaborative partners related to development activities are generally reflected as a reduction of research and development expense because the performance of contract development services is not central to the Company’s operations. In general, the income statement presentation for these collaborations is as follows:

Nature/Type of Collaboration	Statement of Earnings Presentation
Third-party sale of product & profit share payments received	Sales to customers
Royalties/milestones paid to collaborative partner (post-regulatory approval)*	Cost of products sold
Royalties received from collaborative partner	Other income (expense), net
Upfront payments & milestones paid to collaborative partner (pre-regulatory approval)	Research and development expense
Research and development payments to collaborative partner	Research and development expense
Research and development payments received from collaborative partner or government entity	Reduction of Research and development expense

* Milestones are capitalized as intangible assets and amortized to cost of products sold over the useful life.

For all years presented, there was no individual project that represented greater than 5% of the total annual consolidated research and development expense.

The Company has a number of products and compounds developed in collaboration with strategic partners including XARELTO, co-developed with Bayer HealthCare AG and IMBRUVICA, developed in collaboration and co-marketed with Pharmacyclics LLC, an AbbVie company.

Separately, the Company has a number of licensing arrangements for products and compounds including DARZALEX, licensed from Genmab A/S.

Advertising

Costs associated with advertising are expensed in the year incurred and are included in selling, marketing and administrative expenses. Advertising expenses worldwide, which comprised television, radio, print media and Internet advertising, were $2.1 billion, $2.7 billion and $2.1 billion in fiscal years 2022, 2021 and 2020, respectively.

Income Taxes

Income taxes are recorded based on amounts refundable or payable for the current year and include the results of any difference between U.S. GAAP accounting and tax reporting, recorded as deferred tax assets or liabilities. The Company estimates deferred tax assets and liabilities based on enacted tax regulations and rates. Future changes in tax laws and rates may affect recorded deferred tax assets and liabilities in the future.

The Company has unrecognized tax benefits for uncertain tax positions. The Company follows U.S. GAAP which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Management believes that changes in these estimates would not have a material effect on the Company's results of operations, cash flows or financial position.

In 2017, the United States enacted into law new U.S. tax legislation, the U.S. Tax Cuts and Jobs Act (TCJA). This law included provisions for a comprehensive overhaul of the corporate income tax code, including a reduction of the statutory corporate tax rate from 35% to 21%, effective on January 1, 2018. The TCJA included a provision for a tax on all previously

undistributed earnings of U.S. companies located in foreign jurisdictions. Undistributed earnings in the form of cash and cash equivalents were taxed at a rate of 15.5% and all other earnings were taxed at a rate of 8.0%. This tax is payable over 8 years and will not accrue interest. These payments began in 2018 and will continue through 2025. The remaining balance at the end of the 2022 was approximately $6.1 billion, of which $4.6 billion is classified as noncurrent and reflected as "Long-term taxes payable" on the Company's balance sheet. The balance of this account is related to receivables from tax authorities not expected to be received in the next 12 months.

The TCJA also includes provisions for a tax on global intangible low-taxed income (GILTI). GILTI is described as the excess of a U.S. shareholder's total net foreign income over a deemed return on tangible assets, as provided by the TCJA. In January 2018, the FASB issued guidance that allows companies to elect as an accounting policy whether to record the tax effects of GILTI in the period the tax liability is generated (i.e., "period cost") or provide for deferred tax assets and liabilities related to basis differences that exist and are expected to effect the amount of GILTI inclusion in future years upon reversal (i.e., "deferred method"). The Company has elected to account for GILTI under the deferred method. The deferred tax amounts recorded are based on the evaluation of temporary differences that are expected to reverse as GILTI is incurred in future periods.

The Company has recorded deferred tax liabilities on all undistributed earnings prior to December 31, 2017 from its international subsidiaries. The Company has not provided deferred taxes on the undistributed earnings subsequent to January 1, 2018 from certain international subsidiaries where the earnings are considered to be indefinitely reinvested. The Company intends to continue to reinvest these earnings in those international operations. If the Company decides at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company estimates that the tax effect of this repatriation would be approximately $0.5 billion under currently enacted tax laws and regulations and at current currency exchange rates. This amount does not include the possible benefit of U.S. foreign tax credits, which may substantially offset this cost.

See Note 8 to the Consolidated Financial Statements for further information regarding income taxes.

Net Earnings Per Share

Basic earnings per share is computed by dividing net earnings available to common shareholders by the weighted average number of common shares outstanding for the period. Diluted earnings per share reflects the potential dilution that could occur if securities were exercised or converted into common stock using the treasury stock method.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the amounts reported. Estimates are used when accounting for sales discounts, rebates, allowances and incentives, product liabilities, income taxes, withholding taxes, depreciation, amortization, employee benefits, contingencies and intangible asset and liability valuations. Actual results may or may not differ from those estimates.

The Company follows the provisions of U.S. GAAP when recording litigation related contingencies. A liability is recorded when a loss is probable and can be reasonably estimated. The best estimate of a loss within a range is accrued; however, if no estimate in the range is better than any other, the minimum amount is accrued.

Annual Closing Date

The Company follows the concept of a fiscal year, which ends on the Sunday nearest to the end of the month of December. Normally each fiscal year consists of 52 weeks, but every five or six years the fiscal year consists of 53 weeks, and therefore includes additional shipping days, as was the case in fiscal year 2020, and will be the case again in fiscal year 2026.

Reclassification

Certain prior period amounts have been reclassified to conform to current year presentation.

2. Cash, Cash Equivalents and Current Marketable Securities

At the end of the fiscal year 2022 and 2021, cash, cash equivalents and current marketable securities were comprised of:

(Dollars in Millions)	2022				
	Carrying Amount	Unrecognized Loss	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	$ 4,926	—	4,926	4,926	—
U.S. Reverse repurchase agreements	1,419	—	1,419	1,419	—
Corporate debt securities[1]	873	(1)	872	—	873
Money market funds	5,368	—	5,368	5,368	—
Time deposits[1]	446	—	446	446	—
Subtotal	$ 13,032	(1)	13,031	12,159	873
U.S. Gov't Securities	$ 9,959	(28)	9,931	1,922	8,009
U.S. Gov't Agencies	210	(5)	205	—	205
Corporate and other debt securities	352	(1)	351	46	305
Subtotal available for sale[2]	$ 10,521	(34)	10,487	1,968	8,519
Total cash, cash equivalents and current marketable securities			**$**	**14,127**	**9,392**

(Dollars in Millions)	2021				
	Carrying Amount	Unrecognized Loss	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	$ 2,936	—	2,936	2,936	—
Non-U.S. Sovereign Securities[1]	1,006	—	1,006	90	916
U.S. Reverse repurchase agreements	1,659	—	1,659	1,659	—
Corporate debt securities[1]	3,479	(1)	3,478	200	3,279
Money market funds	1,901	—	1,901	1,901	—
Time deposits[1]	900	—	900	900	—
Subtotal	11,881	(1)	11,880	7,686	4,195
U.S. Gov't Securities	$ 19,485	(4)	19,481	6,785	12,696
Corporate and other debt securities	246	—	246	16	230
Subtotal available for sale[2]	$ 19,731	(4)	19,727	6,801	12,926
Total cash, cash equivalents and current marketable securities				**$ 14,487**	**17,121**

[1] Held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings.
[2] Available for sale debt securities are reported at fair value with unrealized gains and losses reported net of taxes in other comprehensive income.

Fair value of government securities and obligations and corporate debt securities were estimated using quoted broker prices and significant other observable inputs.

The contractual maturities of the available for sale debt securities at January 1, 2023 are as follows:

(Dollars in Millions)	Cost Basis	Fair Value
Due within one year	$ 10,430	10,399
Due after one year through five years	91	88
Due after five years through ten years	—	—
Total debt securities	$ 10,521	10,487

The Company invests its excess cash in both deposits with major banks throughout the world and other high-quality money market instruments. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating.

3. Inventories

At the end of fiscal years 2022 and 2021, inventories were comprised of:

(Dollars in Millions)	**2022**	**2021**
Raw materials and supplies	$ 2,070	1,592
Goods in process	1,700	2,287
Finished goods	8,713	6,508
Total inventories	**$ 12,483**	**10,387**

4. Property, Plant and Equipment

At the end of fiscal years 2022 and 2021, property, plant and equipment at cost and accumulated depreciation were:

(Dollars in Millions)	**2022**	**2021**
Land and land improvements	$ 859	884
Buildings and building equipment	12,989	12,882
Machinery and equipment	30,431	29,774
Construction in progress	4,974	4,139
Total property, plant and equipment, gross	$ 49,253	47,679
Less accumulated depreciation	29,450	28,717
Total property, plant and equipment, net	**$ 19,803**	**18,962**

The Company capitalizes interest expense as part of the cost of construction of facilities and equipment. Interest expense capitalized in fiscal years 2022, 2021 and 2020 was $49 million, $49 million and $63 million, respectively.

Depreciation expense, including the amortization of capitalized interest in fiscal years 2022, 2021 and 2020 was $2.7 billion, $2.7 billion and $2.6 billion, respectively.

Upon retirement or other disposal of property, plant and equipment, the costs and related amounts of accumulated depreciation or amortization are eliminated from the asset and accumulated depreciation accounts, respectively. The difference, if any, between the net asset value and the proceeds are recorded in earnings.

5. Intangible Assets and Goodwill

At the end of fiscal years 2022 and 2021, the gross and net amounts of intangible assets were:

(Dollars in Millions)	2022	2021
Intangible assets with definite lives:		
Patents and trademarks — gross	$ 44,012	38,572
Less accumulated amortization	(22,266)	(20,088)
Patents and trademarks — net[1]	**$ 21,746**	**18,484**
Customer relationships and other intangibles — gross	$ 22,987	23,011
Less accumulated amortization	(12,901)	(11,925)
Customer relationships and other intangibles — net[2]	**$ 10,086**	**11,086**
Intangible assets with indefinite lives:		
Trademarks	$ 6,807	6,985
Purchased in-process research and development[3]	9,686	9,837
Total intangible assets with indefinite lives	**$ 16,493**	**16,822**
Total intangible assets — net	**$ 48,325**	**46,392**

[1]The change was primarily related to the intangible assets acquired with the acquisition of Abiomed, Inc. which was partially offset by amortization expense of previously existing intangible assets and the result of currency translation effects.
[2]The majority is comprised of customer relationships
[3]The reduction was primarily related to an intangible asset impairment charge of approximately $0.8 billion recorded in the fiscal year 2022 related to an in-process research and development asset, bermekimab (JnJ-77474462), an investigational drug for the treatment of Atopic Dermatitis (AD) and Hidradenitis Suppurativa (HS) acquired with the acquisition of XBiotech, Inc. in the fiscal year 2020. Additional information regarding efficacy of the AD and HS indications became available which led the Company to the decision to terminate the development of bermekimab for AD and HS. An additional reduction of $0.7 billion was driven by Monarch assets that reached commercialization and are now classified as having definite lives. This was partially offset by approximately $1.1 billion of IPR&D acquired with Abiomed, Inc.

Goodwill as of January 1, 2023 and January 2, 2022, as allocated by segment of business, was as follows:

(Dollars in Millions)	Consumer Health	Pharmaceutical	MedTech	Total
Goodwill at January 3, 2021	$ 10,336	11,009	15,048	36,393
Goodwill, related to acquisitions	—	—	—	—
Goodwill, related to divestitures	(9)	—	—	(9)
Currency translation/other	(517)	(429)	(192)	(1,138)
Goodwill at January 2, 2022	$ 9,810	10,580	14,856	35,246
Goodwill, related to acquisitions	—	—	11,056	11,056
Goodwill, related to divestitures	—	—	—	—
Currency translation/other	(626)	(396)	(49)	(1,071)
Goodwill at January 1, 2023	**$ 9,184**	**10,184**	**25,863**	**45,231**

The weighted average amortization period for patents and trademarks is 12 years. The weighted average amortization period for customer relationships and other intangible assets is 21 years. The amortization expense of amortizable assets included in Cost of products sold was $4.3 billion, $4.7 billion and $4.7 billion before tax, for the fiscal years ended January 1, 2023, January 2, 2022 and January 3, 2021, respectively. Intangible asset write-downs are included in Other (income) expense, net.

The estimated amortization expense for approved products, before tax, for the five succeeding years is approximately:

(Dollars in Millions)				
2023	**2024**	**2025**	**2026**	**2027**
$4,600	4,400	3,600	3,000	2,400

See Note 18 to the Consolidated Financial Statements for additional details related to acquisitions and divestitures.

6. Fair Value Measurements

The Company uses forward foreign exchange contracts to manage its exposure to the variability of cash flows, primarily related to the foreign exchange rate changes of future intercompany products and third-party purchases of materials denominated in a foreign currency. The Company uses cross currency interest rate swaps to manage currency risk primarily related to borrowings. Both types of derivatives are designated as cash flow hedges.

Additionally, the Company primarily uses interest rate swaps as an instrument to manage interest rate risk related to fixed rate borrowings. These derivatives are designated as fair value hedges. The Company uses cross currency interest rate swaps and forward foreign exchange contracts designated as net investment hedges. Additionally, the Company uses forward foreign exchange contracts to offset its exposure to certain foreign currency assets and liabilities. These forward foreign exchange contracts are not designated as hedges and therefore, changes in the fair values of these derivatives are recognized in earnings, thereby offsetting the current earnings effect of the related foreign currency assets and liabilities.

In the fiscal fourth quarter of 2022, the Company entered into forward starting interest rate swaps with notional amounts totaling $2.4 billion in contemplation of hedging interest rate risk associated with long-term financing for the Consumer Health segment separation. These forward starting interest rate swaps are not designated as hedges and therefore, changes in the fair values of these derivatives are recognized in earnings. At the end of the fiscal year 2022, the changes in fair value was not material and therefore not included in the table below.

The Company does not enter into derivative financial instruments for trading or speculative purposes, or that contain credit risk related contingent features. The Company maintains credit support agreements (CSA) with certain derivative counterparties establishing collateral thresholds based on respective credit ratings and netting agreements. As of January 1, 2023, the total amount of cash collateral paid by the Company under the CSA amounted to $0.8 billion net, related to net investment and cash flow hedges. On an ongoing basis, the Company monitors counter-party credit ratings. The Company considers credit non-performance risk to be low, because the Company primarily enters into agreements with commercial institutions that have at least an investment grade credit rating. Refer to the table on significant financial assets and liabilities measured at fair value contained in this footnote for receivables and payables with these commercial institutions. As of January 1, 2023, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of $43.3 billion, $36.2 billion and $12.4 billion, respectively. As of January 2, 2022, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of $45.8 billion, $37.4 billion and $10.0 billion, respectively.

All derivative instruments are recorded on the balance sheet at fair value. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The designation as a cash flow hedge is made at the entrance date of the derivative contract. At inception, all derivatives are expected to be highly effective. Foreign exchange contracts designated as cash flow hedges are accounted for under the forward method and all gains/losses associated with these contracts will be recognized in the income statement when the hedged item impacts earnings. Changes in the fair value of these derivatives are recorded in accumulated other comprehensive income until the underlying transaction affects earnings, and are then reclassified to earnings in the same account as the hedged transaction.

Gains and losses associated with interest rate swaps and changes in fair value of hedged debt attributable to changes in interest rates are recorded to interest expense in the period in which they occur. Gains and losses on net investment hedges are accounted through the currency translation account within accumulated other comprehensive income. The portion excluded from effectiveness testing is recorded through interest (income) expense using the spot method. On an ongoing basis, the Company assesses whether each derivative continues to be highly effective in offsetting changes of hedged items. If and when a derivative is no longer expected to be highly effective, hedge accounting is discontinued.

The Company designated its Euro denominated notes issued in May 2016 with due dates ranging from 2022 to 2035 as a net investment hedge of the Company's investments in certain of its international subsidiaries that use the Euro as their functional currency in order to reduce the volatility caused by changes in exchange rates.

As of January 1, 2023, the balance of deferred net loss on derivatives included in accumulated other comprehensive income was $230 million after-tax. For additional information, see the Consolidated Statements of Comprehensive Income and Note 13. The Company expects that substantially all of the amounts related to forward foreign exchange contracts will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months, excluding interest rate contracts and net investment hedges. The amount ultimately realized in earnings may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity of the derivative.

The following table is a summary of the activity related to derivatives and hedges for the fiscal years ended January 1, 2023 and January 2, 2022, net of tax:

	January 1, 2023					January 2, 2022				
(Dollars in Millions)	Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense	Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense
The effects of fair value, net investment and cash flow hedging:										
Gain (Loss) on fair value hedging relationship:										
Interest rate swaps contracts:										
Hedged items	$ —	—	—	(1,098)	—	—	—	—	(109)	—
Derivatives designated as hedging instruments	—	—	—	1,098	—	—	—	—	109	—
Gain (Loss) on net investment hedging relationship:										
Cross currency interest rate swaps contracts:										
Amount of gain or (loss) recognized in income on derivative amount excluded from effectiveness testing	$ —	—	—	140	—	—	—	—	174	—
Amount of gain or (loss) recognized in AOCI	—	—	—	140	—	—	—	—	174	—
Gain (Loss) on cash flow hedging relationship:										
Forward foreign exchange contracts:										
Amount of gain or (loss) reclassified from AOCI into income	(72)	(271)	149	—	(23)	17	119	30	—	47
Amount of gain or (loss) recognized in AOCI	5	319	61	—	(113)	(94)	(557)	123	—	146
Cross currency interest rate swaps contracts:										
Amount of gain or (loss) reclassified from AOCI into income	—	—	—	425	—	—	—	—	402	—
Amount of gain or (loss) recognized in AOCI	$ —	—	—	42	—	—	—	—	9	—

As of January 1, 2023 and January 2, 2022, the following amounts were recorded on the consolidated balance sheet related to cumulative basis adjustment for fair value hedges

Line item in the Consolidated Balance Sheet in which the hedged item is included	**Carrying Amount of the Hedged Liability**		**Cumulative Amount of Fair Value Hedging Adjustment Included in the Carrying Amount of the Hedged Liability**	
(Dollars in Millions)	January 1, 2023	January 2, 2022	January 1, 2023	January 2, 2022
Long-term Debt	$ 8,665	$ 9,793	$ (1,435)	$ (142)

The following table is the effect of derivatives not designated as hedging instrument for the fiscal years ended January 1, 2023 and January 2, 2022:

(Dollars in Millions)	Location of Gain /(Loss) Recognized in Income on Derivative	Gain/(Loss) Recognized In Income on Derivative	
Derivatives Not Designated as Hedging Instruments		January 1, 2023	January 2, 2022
Foreign Exchange Contracts	Other (income) expense	$ 94	(70)

The following table is the effect of net investment hedges for the fiscal years ended January 1, 2023 and January 2, 2022:

	Gain/(Loss) Recognized In Accumulated OCI		Location of Gain or (Loss) Reclassified from Accumulated Other Comprehensive Income Into Income	Gain/(Loss) Reclassified From Accumulated OCI Into Income	
(Dollars in Millions)	January 1, 2023	January 2, 2022		January 1, 2023	January 2, 2022
Debt	$ 197	387	Interest (income) expense	—	—
Cross Currency interest rate swaps	$ 766	548	Interest (income) expense	—	—

The Company holds equity investments with readily determinable fair values and equity investments without readily determinable fair values. The Company measures equity investments that do not have readily determinable fair values at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer.

The following table is a summary of the activity related to equity investments for the fiscal years ended January 1, 2023 and January 2, 2022:

	January 2, 2022			January 1, 2023	
(Dollars in Millions)	Carrying Value	Changes in Fair Value Reflected in Net Income[1]	Sales/ Purchases/Other[2]	Carrying Value	Non Current Other Assets
Equity Investments with readily determinable value	$ 1,884	(538)	(770)	576	576
Equity Investments without readily determinable value	$ 500	91	107	698	698

	January 3, 2021			January 2, 2022	
(Dollars in Millions)	Carrying Value	Changes in Fair Value Reflected in Net Income[1]	Sales/ Purchases/Other[2]	Carrying Value	Non Current Other Assets
Equity Investments with readily determinable value	$ 1,481	198	205	1,884	1,884
Equity Investments without readily determinable value	$ 738	394	(632)	500	500

[1] Recorded in Other Income/Expense
[2] Other includes impact of currency

For the fiscal years ended January 1, 2023 and January 2, 2022 for equity investments without readily determinable market values, $51 million and $28 million, respectively, of the changes in fair value reflected in net income were the result of impairments. There were offsetting impacts of $142 million and $422 million, respectively, of changes in the fair value reflected in net income due to changes in observable prices and gains on the disposal of investments. The impact in fiscal year 2021, was driven by the gain on disposal of the Grail investment. In fiscal year 2022, the Company sold all of its equity investments in argenx SE for proceeds of $0.6 billion.

Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. In accordance with ASC 820, a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described below with Level 1 having the highest priority and Level 3 having the lowest.

The fair value of a derivative financial instrument (i.e., forward foreign exchange contracts, interest rate contracts) is the aggregation by currency of all future cash flows discounted to its present value at the prevailing market interest rates and subsequently converted to the U.S. Dollar at the current spot foreign exchange rate. The Company does not believe that fair values of these derivative instruments materially differ from the amounts that could be realized upon settlement or maturity, or that the changes in fair value will have a material effect on the Company's results of operations, cash flows or financial position. The Company also holds equity investments which are classified as Level 1 and debt securities which are classified as Level 2. The Company holds acquisition related contingent liabilities based upon certain regulatory and commercial events, which are classified as Level 3, whose values are determined using discounted cash flow methodologies or similar techniques for which the determination of fair value requires significant judgment or estimations.

The following three levels of inputs are used to measure fair value:

Level 1 — Quoted prices in active markets for identical assets and liabilities.

Level 2 — Significant other observable inputs.

Level 3 — Significant unobservable inputs.

The Company's significant financial assets and liabilities measured at fair value as of the fiscal year ended January 1, 2023 and January 2, 2022 were as follows:

	2022				2021
(Dollars in Millions)	Level 1	Level 2	Level 3	Total	Total [1]
Derivatives designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	$ —	629	—	629	540
Interest rate contracts [2]	—	1,534	—	1,534	796
Total	$ —	**2,163**	—	**2,163**	**1,336**
Liabilities:					
Forward foreign exchange contracts	—	511	—	511	881
Interest rate contracts [2]	—	2,778	—	2,778	979
Total	$ —	**3,289**	—	**3,289**	**1,860**
Derivatives not designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	$ —	38	—	38	24
Liabilities:					
Forward foreign exchange contracts	—	68	—	68	28
Available For Sale Other Investments:					
Equity investments[3]	576	—	—	576	1,884
Debt securities[4]	—	10,487	—	10,487	19,727
Other Liabilities					
Contingent Consideration[5]	$		1,120	1,120	533

Gross to Net Derivative Reconciliation	2022	2021
(Dollars in Millions)		
Total Gross Assets	$ 2,201	1,360
Credit Support Agreement (CSA)	(2,176)	(1,285)
Total Net Asset	25	75
Total Gross Liabilities	3,357	1,888
Credit Support Agreement (CSA)	(3,023)	(1,855)
Total Net Liabilities	$ 334	33

Summarized information about changes in liabilities for contingent consideration is as follows:

	2022	2021	2020
(Dollars in Millions)			
Beginning Balance	$ 533	633	1,715
Changes in estimated fair value [6]	(194)	(52)	(1,089)
Additions [7]	792	—	106
Payments	(11)	(48)	(99)
Ending Balance	$ 1,120	533	633

(1) 2021 assets and liabilities are all classified as Level 2 with the exception of equity investments of $1,884 million, which are classified as Level 1 and contingent consideration of $533 million, classified as Level 3.

(2) Includes cross currency interest rate swaps and interest rate swaps.

(3) Classified as non-current other assets.
(4) Classified as cash equivalents and current marketable securities.
(5) Includes $1,116 million, $520 million and $594 million, classified as non-current other liabilities as of January 1, 2023, January 2, 2022 and January 3, 2021, respectively. Includes $4 million, $13 million and $39 million classified as current liabilities as of January 1, 2023, January 2, 2022 and January 3, 2021, respectively.
(6) Ongoing fair value adjustment amounts are recorded primarily in Research and Development expense. The Company recorded a contingent consideration reversal of $1,148 million in 2020 related to the timing of certain developmental milestones associated with the Auris Health acquisition. The reversal of the contingent consideration was recorded in Other income and expense.
(7) In fiscal year 2022, the Company recorded $704 million of contingent consideration related to Abiomed.

See Notes 2 and 7 for financial assets and liabilities held at carrying amount on the Consolidated Balance Sheet.

7. Borrowings

The components of long-term debt are as follows:

(Dollars in Millions)	2022	Effective Rate %	2021	Effective Rate %
0.250% Notes due 2022 (1B Euro 1.1311)[3]	$ —	— %	$ 1,131 [3]	0.26 %
2.25% Notes due 2022	—	—	1,000	2.31
6.73% Debentures due 2023	250	6.73	250	6.73
3.375% Notes due 2023	801	3.17	802	3.18
2.05% Notes due 2023	500	2.09	499	2.09
0.650% Notes due 2024 (750MM Euro 1.0651)[2]/(750MM Euro 1.1311)[3]	792 [2]	0.68	847 [3]	0.68
5.50% Notes due 2024 (500MM 1.2037 GBP)[2]/(500MM GBP 1.3485)[3]	600 [2]	6.75	672 [3]	6.75
2.625% Notes due 2025	749	2.63	749	2.63
0.55% Notes due 2025	918	0.57	983	0.57
2.45% Notes due 2026	1,996	2.47	1,995	2.47
2.95% Notes due 2027	877	2.96	978	2.96
0.95% Notes due 2027	1,394	0.96	1,478	0.96
1.150% Notes due 2028 (750MM Euro 1.0651)[2]/(750MM Euro 1.1311)[3]	794 [2]	1.21	843 [3]	1.21
2.90% Notes due 2028	1,496	2.91	1,495	2.91
6.95% Notes due 2029	298	7.14	298	7.14
1.30% Notes due 2030	1,607	1.30	1,723	1.30
4.95% Debentures due 2033	498	4.95	498	4.95
4.375% Notes due 2033	854	4.24	854	4.24
1.650% Notes due 2035 (1.5B Euro 1.0651)[2]/(1.5B Euro 1.1311)[3]	1,591 [2]	1.68	1,683 [3]	1.68
3.55% Notes due 2036	842	3.59	974	3.59
5.95% Notes due 2037	993	5.99	993	5.99
3.625% Notes due 2037	1,336	3.64	1,475	3.64
5.85% Debentures due 2038	697	5.85	696	5.85
3.400% Notes due 2038	992	3.42	992	3.42
4.50% Debentures due 2040	540	4.63	540	4.63
2.10% Notes due 2040	828	2.14	974	2.14
4.85% Notes due 2041	297	4.89	297	4.89
4.50% Notes due 2043	496	4.52	496	4.52
3.70% Notes due 2046	1,976	3.74	1,975	3.74
3.75% Notes due 2047	812	3.76	971	3.76
3.500% Notes due 2048	743	3.52	743	3.52
2.250% Notes due 2050	808	2.29	983	2.29
2.450% Notes due 2060	1,055	2.49	1,222	2.49
Other	9	—	7	—
Subtotal	**28,439** [4]	**3.04 %** [1]	**32,116** [4]	**2.89 %** [1]
Less current portion	1,551		2,131	
Total long-term debt	**$ 26,888**		**$ 29,985**	

(1) Weighted average effective rate.
(2) Translation rate at January 1, 2023.
(3) Translation rate at January 2, 2022.

(4) The excess of the carrying value over the fair value of debt was $1.6 billion at the end of fiscal year 2022 and the excess of the fair value over the carrying value of debt was $3.2 billion at the end of fiscal year 2021.

Fair value of the long-term debt was estimated using market prices, which were corroborated by quoted broker prices and significant other observable inputs.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2022, the Company secured a new 364-day Credit Facility of $10 billion, which expires on September 7, 2023. In November 2022, the Company secured an additional 364-day Credit Facility of $10 billion, which expires on November 21, 2023. Interest charged on borrowings under the credit line agreement is based on either the Term SOFR Reference Rate or other applicable market rates as allowed under the terms of the agreement, plus applicable margins. Commitment fees under the agreements are not material.

Throughout fiscal years 2022 and 2021, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $12.8 billion and $3.8 billion at the end of fiscal years 2022 and 2021, respectively. The current portion of the long term debt was $1.6 billion and $2.1 billion in 2022 and 2021, respectively, and the remainder is commercial paper and local borrowing by international subsidiaries.

The current debt balance as of January 1, 2023 includes $11.2 billion of commercial paper which has a weighted average interest rate of 4.23% and a weighted average maturity of approximately two months.

Aggregate maturities of long-term debt obligations commencing in 2023 are:

(Dollars in Millions)					
2023	**2024**	**2025**	**2026**	**2027**	**After 2026**
$1,551	1,392	1,667	1,996	2,271	19,562

8. Income Taxes

The provision for taxes on income consists of:

(Dollars in Millions)	2022	2021	2020
Currently payable:			
U.S. taxes	$ 2,378	1,525	1,026
International taxes	3,069	2,452	1,898
Total currently payable	5,447	3,977	2,924
Deferred:			
U.S. taxes	(2,081)	583	(76)
International taxes	418	(2,662)	(1,065)
Total deferred	(1,663)	(2,079)	(1,141)
Provision for taxes on income	**$ 3,784**	**1,898**	**1,783**

A comparison of income tax expense at the U.S. statutory rate of 21% in fiscal years 2022, 2021 and 2020, to the Company's effective tax rate is as follows:

(Dollars in Millions)	2022	2021	2020
U.S.	$ 5,369	6,110	4,312
International	16,356	16,666	12,185
Earnings before taxes on income:	$ 21,725	22,776	16,497
Tax rates:			
U.S. statutory rate	21.0 %	21.0	21.0
International operations [1]	(4.5)	(16.4)	(9.9)
Consumer health separation	2.2	—	—
U.S. taxes on international income [2]	(1.9)	6.7	2.7
Tax benefits from loss on capital assets	—	(1.3)	(1.2)
Tax benefits on share-based compensation	(1.3)	(1.0)	(1.5)
All other [3]	1.9	(0.7)	(0.3)
Effective Rate	17.4 %	8.3	10.8

[1] For all periods presented the Company has subsidiaries operating in Puerto Rico under various tax incentives. International operations reflect the impacts of operations in jurisdictions with statutory tax rates different than the U.S., particularly Ireland, Switzerland and Puerto Rico, which is a favorable impact on the effective tax rate as compared with the U.S. statutory rate. The 2021 amounts include the reorganization of international subsidiaries; the 2020 amounts include the impact of the new tax legislation enactment in Switzerland, both of which are further described below.

[2] Includes the impact of the GILTI tax, the Foreign-Derived Intangible Income deduction and other foreign income that is taxable under the U.S. tax code. The 2022 amount includes the impact of certain provisions of the 2017 TCJA that became effective in fiscal 2022. The 2021 amounts include the reorganization of international subsidiaries; the 2020 amounts include the impact of the new tax legislation enactment in Switzerland, both of which are further described below.

[3] Certain prior year amounts have been reclassified to conform to current year presentation.

The fiscal year 2022 effective tax rate increased 9.1% as compared to the fiscal year 2021 effective tax rate. As part of the planned separation of the Company's Consumer Health business, the Company has recognized approximately $0.5 billion in net incremental tax costs in fiscal year 2022, which increased the 2022 effective tax rate by approximately 2.2%.

Additionally, the Company recorded certain non-recurring favorable tax items in fiscal year 2021 which resulted in an unfavorable impact to the Company's fiscal 2022 effective tax rate when compared to the prior fiscal year. These items are described below. The Company's 2022 tax rate also benefited from certain provisions of the Tax Cuts and Jobs Act of 2017 that became effective in fiscal 2022, the impairment of bermekimab for AD and HS IPR&D (for further information see Note 5 of the 2022 10-K Consolidated Financial Statements) and changes in the fair value of securities in the Company's investment portfolio, both recorded at the U.S. statutory rate.

The fiscal year 2021 tax rate decreased by 2.5% compared to the fiscal year 2020 tax rate, which was primarily driven by the following items. In fiscal year 2021, the Company reorganized the ownership structure of certain wholly-owned international subsidiaries. As part of this reorganization, the Company increased the tax basis of certain assets to fair value in accordance with applicable local regulations. The net impact of this restructuring was approximately $0.6 billion net benefit or 2.7% benefit to the Company's annual effective tax rate, comprised of the following items:

- approximately $2.3 billion of local deferred tax assets to record the remeasurement of the tax basis of these assets to fair value, this benefit has been reflected as "International Operations" on the Company's effective tax rate reconciliation.
- approximately $1.7 billion of U.S. deferred tax expense relating to the GILTI deferred tax liability resulting from the remeasurement of these deferred tax assets. This expense has been reflected as "U.S. tax on international income" on the Company's effective tax rate reconciliation.

Also, in the fiscal fourth quarter of 2021, the Company recognized a loss on certain U.S. affiliates related to the previously impaired book value of certain intangibles, which reduced the 2021 tax rate by approximately 1.3% which is reflected as a "Tax benefits from loss on capital assets" on the effective tax rate reconciliation. Additionally other fiscal 2021 impacts to the rate were primarily driven by litigation and acquisition related items as follows:

- the Company accrued additional legal expenses, of approximately $1.6 billion for talc at an effective tax rate of 23.5% and $0.8 billion for Risperdal Gynecomastia settlements at an effective tax rate of 16.4% (See Note 19 to the Consolidated Financial Statements for more details).
- the Company recorded a partial IPR&D charge of $0.9 billion for the Ottava intangible asset (acquired with the Auris Health acquisition in 2019) at an effective rate of 22.4%.

In fiscal year 2019, Switzerland enacted the Federal Act on Tax Reform and AHV Financing (TRAF) and became effective for fiscal year 2020. The Federal transitional provisions of TRAF allow companies, under certain conditions, to adjust the tax basis in certain assets to fair value (i.e., "step-up") to be depreciated and amortized resulting in an incremental Swiss tax deduction over the transitional period.

TRAF also provides for parameters which enable the Swiss cantons to establish localized tax rates and regulations for companies. The new cantonal tax parameters include favorable tax benefits for patents and additional research and development tax deductions. The cantonal transitional provisions of TRAF allowed companies to elect either 1) tax basis step-up similar to the Federal transition benefit or 2) alternative statutory tax rate for a period not to exceed 5 years. The Company has operations located in various Swiss cantons.

During the fiscal year 2020, the final canton where the Company maintains significant operations enacted TRAF legislation. Additionally, the Company received rulings from the Swiss Federal and cantonal tax authorities in the remaining jurisdictions where it has significant operations. These rulings resulted in the Company revising its estimate on the tax basis adjustment (i.e., "step-up") for its assets and as a result, the Company recorded additional deferred tax benefits in 2020. The Company recognized a net benefit in the fiscal year 2020 for Swiss Tax Reform of approximately $0.4 billion or 2.6% benefit to the Company's annual effective tax rate, comprised of the following items:

- approximately $0.3 billion tax benefit relating to the remeasurement of Swiss deferred tax assets and liabilities for the change in the Federal and cantonal tax rates, where enactment occurred in the fiscal year 2020; this benefit has been reflected as "International Operations" on the Company's effective tax rate reconciliation.
- a $450 million deferred tax asset related to the estimated value of a Federal tax basis step-up of the Company's Swiss subsidiaries' assets as described above; this benefit has been reflected as "International Operations" on the Company's effective tax rate reconciliation.
- approximately $0.3 billion of U.S. deferred tax expense relating to the GILTI deferred tax liability resulting from the remeasurement of the Swiss deferred tax assets and liabilities in the fiscal year 2020. This benefit has been reflected as "U.S. tax on international income" on the Company's effective tax rate reconciliation.

The Company does not expect to receive future rulings regarding the transitional provisions of TRAF.

Also, in the fiscal year 2020, the Company recognized a capital loss on certain U.S. affiliates related to the previously impaired book value of certain intangibles, which reduced the 2020 tax rate by approximately 1.2% which is reflected as a "Tax benefits from loss on capital assets" on the effective tax rate reconciliation. In addition, in the fiscal year 2020, the Company had lower income in higher tax jurisdictions, primarily driven by:

- the impact of the accrual of litigation costs related to talc for $4.0 billion which reduced the U.S. earnings before taxes at an effective tax rate of 23.5%;
- the accrual of additional legal costs, including an additional $1.0 billion associated with a revised agreement in principle to settle opioid litigation at an effective tax rate of 21.4%

The Company also reduced the contingent consideration liability related to the Auris Health acquisition in 2019 and reversed some of its unrecognized tax benefits due to the completion of several years of tax examinations in certain jurisdictions during the fiscal year 2020.

Temporary differences and carryforwards at the end of fiscal years 2022 and 2021 were as follows:

	2022 Deferred Tax		2021 Deferred Tax[1]	
(Dollars in Millions)	Asset	Liability	Asset	Liability
Employee related obligations	$ 725		1,244	
Stock based compensation	687		679	
Depreciation of property, plant and equipment		(858)		(876)
Goodwill and intangibles		(4,271) [3]		(2,659) [2]
R&D capitalized for tax	2,611		1,664	
Reserves & liabilities	2,761		2,882	
Income reported for tax purposes	2,045		2,566	
Net realizable operating loss carryforwards[4]	1,260		1,720	
Undistributed foreign earnings	1,565	(1,693)	1,015	(1,461)
Global intangible low-taxed income		(3,547)		(4,853)
Miscellaneous international	1,053	(65)	870	(39)
Miscellaneous U.S.	476			(16)
Total deferred income taxes	**$ 13,183**	**(10,434)**	**12,640**	**(9,904)**

[1] Certain prior year amounts have been reclassified to conform to current year presentation.
[2] Amount is inclusive of the $2.3 billion deferred tax asset established as part of the reorganized ownership structure of certain wholly-owned international subsidiaries, as previously described.
[3] Amount is inclusive of the $1.8 billion deferred tax liability due to the acquisition of Abiomed.
[4] Net of valuation allowances of $0.9 billion in both 2022 and 2021.

The Company has wholly-owned international subsidiaries that have cumulative net losses. The Company believes that it is more likely than not that these subsidiaries will generate future taxable income sufficient to utilize these deferred tax assets. However, in certain jurisdictions, valuation allowances have been recorded against deferred tax assets for loss carryforwards that are not more likely than not to be realized.

The following table summarizes the activity related to unrecognized tax benefits:

(Dollars in Millions)	2022	2021	2020
Beginning of year	$ 3,323	3,373	3,853
Increases related to current year tax positions	523	242	265
Increases related to prior period tax positions	143	23	668
Decreases related to prior period tax positions	(148)	(128)	(551)
Settlements	(1)	(187)	(839)
Lapse of statute of limitations	(11)	—	(23)
End of year	**$ 3,829**	**3,323**	**3,373**

The unrecognized tax benefits of $3.8 billion at January 1, 2023, if recognized, would affect the Company's annual effective tax rate. The Company conducts business and files tax returns in numerous countries and currently has tax audits in progress with a number of tax authorities. With respect to the United States, the IRS has completed its audit for the tax years through 2012 and is currently auditing tax years 2013 through 2016. In the fiscal year 2020, the Company made its final payments for approximately $0.7 billion to the U.S. Treasury related to the final settlement of 2010-2012 tax audit liability.

In other major jurisdictions where the Company conducts business, the years that remain open to tax audits go back to the year 2008. The Company believes it is possible that some tax audits may be completed over the next twelve months by taxing authorities in some jurisdictions, including in the United States. However, the Company is not able to provide a reasonably reliable estimate of the timing of any other future tax payments or change in uncertain tax positions, if any.

The Company classifies liabilities for unrecognized tax benefits and related interest and penalties as long-term liabilities. Interest expense and penalties related to unrecognized tax benefits are classified as income tax expense. The Company recognized after tax interest expense of $139 million, $44 million and $32 million in fiscal years 2022, 2021 and 2020, respectively. The total amount of accrued interest was $651 million and $512 million in fiscal years 2022 and 2021, respectively.

9. Employee Related Obligations

At the end of fiscal 2022 and fiscal 2021, employee related obligations recorded on the Consolidated Balance Sheets were:

(Dollars in Millions)		2022	2021
Pension benefits	$	2,698	4,088
Postretirement benefits		1,734	2,069
Postemployment benefits		2,832	3,117
Deferred compensation		100	181
Total employee obligations		7,364	9,455
Less current benefits payable		597	557
Employee related obligations — non-current	**$**	**6,767**	**8,898**

Prepaid employee related obligations of $4,581 million and $4,436 million for 2022 and 2021, respectively, are included in Other assets on the Consolidated Balance Sheets.

10. Pensions and Other Benefit Plans

The Company sponsors various retirement and pension plans, including defined benefit, defined contribution and termination indemnity plans, which cover most employees worldwide. The Company also provides post-retirement benefits, primarily healthcare, to all eligible U.S. retired employees and their dependents.

Many international employees are covered by government-sponsored programs and the cost to the Company is not significant.

In the U.S, non-union pension benefits for employees hired before January 1, 2015 are primarily based on the employee's compensation during the last five years before retirement and the number of years of service (the Final Average Pay formula). U.S. pension benefits for employees hired after 2014, are calculated using a different formula based on employee compensation over total years of service (the Retirement Value formula).

In January 2021, the Company announced that, effective on January 1, 2026, all eligible U.S. non-union employees, regardless of hire date, will earn benefits under the Retirement Value formula. This amendment does not affect the benefits accrued under the Final Average Pay formula for service before January 1, 2026.

International subsidiaries have plans under which funds are deposited with trustees, annuities are purchased under group contracts, or reserves are provided.

The Company does not fund retiree healthcare benefits in advance and has the right to modify these plans in the future.

In 2022 and 2021 the Company used December 31, 2022 and December 31, 2021, respectively, as the measurement date for all U.S. and international retirement and other benefit plans.

Net periodic benefit costs for the Company's defined benefit retirement plans and other benefit plans for 2022, 2021 and 2020 include the following components:

	Retirement Plans			Other Benefit Plans		
(Dollars in Millions)	2022	2021	2020	2022	2021	2020
Service cost	$ 1,327	1,421	1,380	320	309	287
Interest cost	911	770	955	105	81	133
Expected return on plan assets	(2,757)	(2,645)	(2,461)	(8)	(7)	(7)
Amortization of prior service cost	(184)	(181)	2	(5)	(31)	(31)
Recognized actuarial losses (gains)	655	1,257	891	121	151	142
Curtailments and settlements	1	1	23	—	—	—
Net periodic benefit cost (credit)	**$ (47)**	**623**	**790**	**533**	**503**	**524**

The service cost component of net periodic benefit cost is presented in the same line items on the Consolidated Statement of Earnings where other employee compensation costs are reported, including Cost of products sold, Research and development expense, and Selling, marketing and administrative expenses. All other components of net periodic benefit cost are presented as part of Other (income) expense, net on the Consolidated Statement of Earnings.

Unrecognized gains and losses for the U.S. pension plans are amortized over the average remaining future service for each plan. For plans with no active employees, they are amortized over the average life expectancy. The amortization of gains and losses for the other U.S. benefit plans is determined by using a 10% corridor of the greater of the market value of assets or the accumulated postretirement benefit obligation. Total unamortized gains and losses in excess of the corridor are amortized over the average remaining future service.

Prior service costs/benefits for the U.S. pension plans are amortized over the average remaining future service of plan participants at the time of the plan amendment. Prior service cost/benefit for the other U.S. benefit plans is amortized over the average remaining service to full eligibility age of plan participants at the time of the plan amendment.

The following table represents the weighted-average actuarial assumptions:

	Retirement Plans			Other Benefit Plans		
Worldwide Benefit Plans	**2022**	**2021**	**2020**	**2022**	**2021**	**2020**
Net Periodic Benefit Cost						
Service cost discount rate	2.46 %	2.14	2.82	2.59	2.09	3.04
Interest cost discount rate	2.80 %	2.34	3.13	2.64	2.33	3.08
Rate of increase in compensation levels	4.02 %	4.01	4.00	4.21	4.25	4.25
Expected long-term rate of return on plan assets	7.25 %	7.71	8.12			
Benefit Obligation						
Discount rate	5.01 %	2.49	2.14	5.42	2.68	2.23
Rate of increase in compensation levels	4.00 %	4.01	4.00	4.21	4.21	4.27

The Company’s discount rates are determined by considering current yield curves representing high quality, long-term fixed income instruments. The resulting discount rates are consistent with the duration of plan liabilities. The Company's methodology in determining service and interest cost uses duration specific spot rates along that yield curve to the plans' liability cash flows.

The expected rates of return on plan asset assumptions represent the Company's assessment of long-term returns on diversified investment portfolios globally. The assessment is determined using projections from external financial sources, long-term historical averages, actual returns by asset class and the various asset class allocations by market.

The following table displays the assumed healthcare cost trend rates, for all individuals:

Healthcare Plans	**2022**	**2021**
Healthcare cost trend rate assumed for next year	5.99 %	5.33 %
Rate to which the cost trend rate is assumed to decline (ultimate trend)	4.01 %	3.73 %
Year the rate reaches the ultimate trend rate	2047	2046

The following table sets forth information related to the benefit obligation and the fair value of plan assets at fiscal year-end 2022 and 2021 for the Company's defined benefit retirement plans and other post-retirement plans:

	Retirement Plans		Other Benefit Plans	
(Dollars in Millions)	**2022**	**2021**	**2022**	**2021**
Change in Benefit Obligation				
Projected benefit obligation — beginning of year	$ 41,582	43,300	4,878	5,028
Service cost	1,327	1,421	320	309
Interest cost	911	770	105	81
Plan participant contributions	67	67	—	—
Amendments	7	5	—	—
Actuarial (gains) losses[1]	(12,213)	(2,132)	(704)	(188)
Divestitures & acquisitions	—	(2)	—	—
Curtailments, settlements & restructuring	(7)	(7)	—	—
Benefits paid from plan	(1,228)	(1,157)	(393)	(348)
Effect of exchange rates	(815)	(683)	(9)	(4)
Projected benefit obligation — end of year	**$ 29,631**	**41,582**	**4,197**	**4,878**
Change in Plan Assets				
Plan assets at fair value — beginning of year	$ 41,930	38,195	102	90
Actual return (loss) on plan assets	(8,665)	4,439	(17)	17
Company contributions	270	969	386	343
Plan participant contributions	67	67	—	—
Settlements	(5)	(7)	—	—
Divestitures & acquisitions	—	(2)	—	—
Benefits paid from plan assets	(1,228)	(1,157)	(393)	(348)
Effect of exchange rates	(855)	(574)	—	—
Plan assets at fair value — end of year	**$ 31,514**	**41,930**	**78**	**102**
Funded status — end of year	**$ 1,883**	**348**	**(4,119)**	**(4,776)**
Amounts Recognized in the Company's Balance Sheet consist of the following:				
Non-current assets	$ 4,581	4,436	—	—
Current liabilities	(132)	(115)	(461)	(438)
Non-current liabilities	(2,566)	(3,973)	(3,658)	(4,338)
Total recognized in the consolidated balance sheet — end of year	**$ 1,883**	**348**	**(4,119)**	**(4,776)**
Amounts Recognized in Accumulated Other Comprehensive Income consist of the following:				
Net actuarial loss	$ 3,948	5,539	239	1,113
Prior service cost (credit)[1]	(1,417)	(1,610)	(7)	(13)
Unrecognized net transition obligation	—	—	—	—
Total before tax effects	**$ 2,531**	**3,929**	**232**	**1,100**
Accumulated Benefit Obligations — end of year	**$ 28,023**	**39,049**		

[1]The actuarial gain for retirement plans in 2022 and 2021 was primarily related to increases in discount rates.

(Dollars in Millions)	Retirement Plans 2022	Retirement Plans 2021	Other Benefit Plans 2022	Other Benefit Plans 2021
Amounts Recognized in Net Periodic Benefit Cost and Other Comprehensive Income				
Net periodic benefit cost (credit)	**$ (47)**	**623**	**533**	**503**
Net actuarial (gain) loss	(793)	(3,927)	(751)	(199)
Amortization of net actuarial loss	(655)	(1,257)	(121)	(151)
Prior service cost (credit)	7	5	—	—
Amortization of prior service (cost) credit	183	181	5	31
Effect of exchange rates	(140)	(136)	(1)	—
Total loss/(income) recognized in other comprehensive income, before tax	**$ (1,398)**	**(5,134)**	**(868)**	**(319)**
Total recognized in net periodic benefit cost and other comprehensive income	**$ (1,445)**	**(4,511)**	**(335)**	**184**

The Company plans to continue to fund its U.S. Qualified Plans to comply with the Pension Protection Act of 2006. International Plans are funded in accordance with local regulations. Additional discretionary contributions are made when deemed appropriate to meet the long-term obligations of the plans. For certain plans, funding is not a common practice, as funding provides no economic benefit. Consequently, the Company has several pension plans that are not funded.

In 2022, the Company contributed $119 million and $151 million to its U.S. and international pension plans, respectively.

The following table displays the funded status of the Company's U.S. Qualified & Non-Qualified pension plans and international funded and unfunded pension plans at December 31, 2022 and December 31, 2021, respectively:

	U.S. Plans				International Plans			
	Qualified Plans		Non-Qualified Plans		Funded Plans		Unfunded Plans	
(Dollars in Millions)	**2022**	**2021**	**2022**	**2021**	**2022**	**2021**	**2022**	**2021**
Plan Assets	$ 20,937	27,944	—	—	10,577	13,986	—	—
Projected Benefit Obligation	18,394	25,041	1,937	2,703	9,024	13,428	276	410
Accumulated Benefit Obligation	17,696	23,985	1,872	2,479	8,202	12,212	253	373
Over (Under) Funded Status								
Projected Benefit Obligation	$ 2,543	2,903	(1,937)	(2,703)	1,553	558	(276)	(410)
Accumulated Benefit Obligation	3,241	3,959	(1,872)	(2,479)	2,375	1,774	(253)	(373)

Plans with accumulated benefit obligations in excess of plan assets have an accumulated benefit obligation, projected benefit obligation and plan assets of $2.9 billion, $2.9 billion and $0.3 billion, respectively, at the end of 2022, and $3.9 billion, $4.2 billion and $0.3 billion, respectively, at the end of 2021.

The following table displays the projected future benefit payments from the Company's retirement and other benefit plans:

(Dollars in Millions)	2023	2024	2025	2026	2027	2028-2032
Projected future benefit payments						
Retirement plans	$ 1,445	1,457	1,532	1,609	1,708	10,034
Other benefit plans	$ 471	485	433	447	462	2,539

The following table displays the projected future minimum contributions to the unfunded retirement plans. These amounts do not include any discretionary contributions that the Company may elect to make in the future.

(Dollars in Millions)	2023	2024	2025	2026	2027	2028-2032
Projected future contributions	$ 123	128	136	141	146	816

Each pension plan is overseen by a local committee or board that is responsible for the overall administration and investment of the pension plans. In determining investment policies, strategies and goals, each committee or board considers factors including, local pension rules and regulations; local tax regulations; availability of investment vehicles (separate accounts, commingled accounts, insurance funds, etc.); funded status of the plans; ratio of actives to retirees; duration of liabilities; and other relevant factors including: diversification, liquidity of local markets and liquidity of base currency. A majority of the Company's pension funds are open to new entrants and are expected to be on-going plans. Permitted investments are primarily liquid and/or listed, with little reliance on illiquid and non-traditional investments such as hedge funds.

The Company's retirement plan asset allocation at the end of 2022 and 2021 and target allocations for 2023 are as follows:

	Percent of Plan Assets		Target Allocation
	2022	2021	2023
Worldwide Retirement Plans			
Equity securities	62 %	65 %	61 %
Debt securities	38	35	39
Total plan assets	**100 %**	**100 %**	**100 %**

Determination of Fair Value of Plan Assets

The Plan has an established and well-documented process for determining fair values. Fair value is based upon quoted market prices, where available. If listed prices or quotes are not available, fair value is based upon models that primarily use, as inputs, market-based or independently sourced market parameters, including yield curves, interest rates, volatilities, equity or debt prices, foreign exchange rates and credit curves.

While the Plan believes its valuation methods are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

Valuation Hierarchy

The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described in the table below with Level 1 having the highest priority and Level 3 having the lowest.

The Net Asset Value (NAV) is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Following is a description of the valuation methodologies used for the investments measured at fair value.

- *Short-term investment funds* — Cash and quoted short-term instruments are valued at the closing price or the amount held on deposit by the custodian bank. Other investments are through investment vehicles valued using the NAV provided by the administrator of the fund. The NAV is a quoted price in a market that is not active and classified as Level 2.
- *Government and agency securities* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified within Level 1 of the valuation hierarchy. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows. When quoted market prices for a security are not available in an active market, they are classified as Level 2.
- *Debt instruments* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified as Level 1. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows and are classified as Level 2. Level 3 debt instruments are priced based on unobservable inputs.
- *Equity securities* — Equity securities are valued at the closing price reported on the major market on which the individual securities are traded. Substantially all equity securities are classified within Level 1 of the valuation hierarchy.
- *Commingled funds* — These investment vehicles are valued using the NAV provided by the fund administrator. Assets in the Level 2 category have a quoted market price.

- *Other assets* — Other assets are represented primarily by limited partnerships. These investment vehicles are valued using the NAV provided by the fund administrator. Other assets that are exchange listed and actively traded are classified as Level 1, while inactively traded assets are classified as Level 2.

The following table sets forth the Retirement Plans' investments measured at fair value as of December 31, 2022 and December 31, 2021:

	Quoted Prices in Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs[1] (Level 3)		Investments Measured at Net Asset Value		Total Assets	
(Dollars in Millions)	**2022**	**2021**	**2022**	**2021**	**2022**	**2021**	**2022**	**2021**	**2022**	**2021**
Short-term investment funds	$ 33	102	13	1,033	—	—	—	—	46	1,135
Government and agency securities	—	—	5,863	7,016	—	—	—	—	5,863	7,016
Debt instruments	—	—	3,681	3,505	—	—	—	—	3,681	3,505
Equity securities	8,846	14,107	2	2	—	—	—	—	8,848	14,109
Commingled funds	—	—	4,362	5,496	56	105	6,106	8,708	10,524	14,309
Other assets	—	—	33	34	13	15	2,506	1,807	2,552	1,856
Investments at fair value	**$ 8,879**	**14,209**	**13,954**	**17,086**	**69**	**120**	**8,612**	**10,515**	**31,514**	**41,930**

[1] The activity for the Level 3 assets is not significant for all years presented.

The Company's Other Benefit Plans are unfunded except for U.S. commingled funds (Level 2) of $78 million and $102 million at December 31, 2022 and December 31, 2021, respectively.

The fair value of Johnson & Johnson Common Stock directly held in plan assets was $21 million (0.1% of total plan assets) at December 31, 2022 and $385 million (0.9% of total plan assets) at December 31, 2021.

11. Savings Plan

The Company has voluntary 401(k) savings plans designed to enhance the existing retirement programs covering eligible employees. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which he/she is eligible. Total Company matching contributions to the plans were $275 million, $256 million and $243 million in fiscal years 2022, 2021 and 2020, respectively.

12. Capital and Treasury Stock

Changes in treasury stock were:

(Amounts in Millions Except Treasury Stock Shares in Thousands)	Treasury Stock Shares	Treasury Stock Amount
Balance at December 29, 2019	487,336	$ 38,417
Employee compensation and stock option plans	(21,765)	(3,148)
Repurchase of common stock	21,760	3,221
Balance at January 3, 2021	487,331	38,490
Employee compensation and stock option plans	(17,399)	(2,847)
Repurchase of common stock	20,946	3,456
Balance at January 2, 2022	490,878	39,099
Employee compensation and stock option plans	(20,007)	(3,440)
Repurchase of common stock	35,375	6,035
Balance at January 1, 2023	506,246	$ 41,694

Aggregate shares of common stock issued were approximately 3,119,843,000 shares at the end of fiscal years 2022, 2021 and 2020.

Cash dividends paid were $4.45 per share in fiscal year 2022, compared with dividends of $4.19 per share in fiscal year 2021, and $3.98 per share in fiscal year 2020.

On January 3, 2023, the Board of Directors declared a regular cash dividend of $1.13 per share, payable on March 7, 2023 to shareholders of record as of February 21, 2023.

On September 14, 2022, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's shares of common stock. Share repurchases may be made at management's discretion from time to time on the open market or through privately negotiated transactions. The repurchase program has no time limit and may be suspended for periods or discontinued at any time. Through January 1, 2023, approximately $2.5 billion has been repurchased under the program.

13. Accumulated Other Comprehensive Income (Loss)

Components of other comprehensive income (loss) consist of the following:

(Dollars in Millions)	Foreign Currency Translation	Gain/(Loss) On Securities	Employee Benefit Plans	Gain/ (Loss) On Derivatives & Hedges	Total Accumulated Other Comprehensive Income (Loss)
December 29, 2019	$ (8,705)	—	(6,891)	(295)	(15,891)
Net 2020 changes	(233)	1	(66)	947	649
January 3, 2021	(8,938)	1	(6,957)	652	(15,242)
Net 2021 changes	(1,079)	(4)	4,255	(988)	2,184
January 2, 2022	(10,017)	(3)	(2,702)	(336)	(13,058)
Net 2022 changes	(1,796)	(24)	1,805	106	91
January 1, 2023	$ (11,813)	(27)	(897)	(230)	(12,967)

Amounts in accumulated other comprehensive income are presented net of the related tax impact. Foreign currency translation is not adjusted for income taxes where it relates to permanent investments in international subsidiaries. For additional details on comprehensive income see the Consolidated Statements of Comprehensive Income.

Details on reclassifications out of Accumulated Other Comprehensive Income:

Gain/(Loss) On Securities - reclassifications released to Other (income) expense, net.

Employee Benefit Plans - reclassifications are included in net periodic benefit cost. See Note 10 for additional details.

Gain/(Loss) On Derivatives & Hedges - reclassifications to earnings are recorded in the same account as the hedged transaction. See Note 6 for additional details.

14. International Currency Translation

For translation of its subsidiaries operating in non-U.S. Dollar currencies, the Company has determined that the local currencies of its international subsidiaries are the functional currencies except those in highly inflationary economies, which are defined as those which have had compound cumulative rates of inflation of 100% or more during the past three years, or where a substantial portion of its cash flows are not in the local currency. For the majority of the Company's subsidiaries the local currency is the functional currency.

In consolidating international subsidiaries, balance sheet currency effects are recorded as a component of accumulated other comprehensive income. The other current and non-current assets line within the Statement of Cash flows includes the impact of foreign currency translation. This equity account includes the results of translating certain balance sheet assets and liabilities at current exchange rates and some accounts at historical rates, except for those located in highly inflationary economies, (Argentina and Venezuela). Beginning in the fiscal second quarter of 2022, the Company also accounted for operations in Turkey as highly inflationary. The translation of balance sheet accounts for highly inflationary economies are reflected in the operating results.

A rollforward of the changes during fiscal years 2022, 2021 and 2020 for foreign currency translation adjustments is included in Note 13.

Net currency transaction gains and losses included in Other (income) expense were losses of $328 million, $236 million and $209 million in fiscal years 2022, 2021 and 2020, respectively.

15. Earnings Per Share

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal years ended January 1, 2023, January 2, 2022 and January 3, 2021:

(In Millions Except Per Share Amounts)	2022	2021	2020
Basic net earnings per share	$ 6.83	7.93	5.59
Average shares outstanding — basic	2,625.2	2,632.1	2,632.8
Potential shares exercisable under stock option plans	140.1	138.0	118.3
Less: shares repurchased under treasury stock method	(101.4)	(96.1)	(80.4)
Adjusted average shares outstanding — diluted	2,663.9	2,674.0	2,670.7
Diluted net earnings per share	$ 6.73	7.81	5.51

The diluted net earnings per share calculation for the fiscal years 2022 and 2021 included all shares related to stock options, as the exercise price of these options was less than the average market value of the Company's stock.

The diluted net earnings per share calculation for fiscal year 2020 excluded 18 million shares related to stock options, as the exercise price of these options was greater than the average market value of the Company's stock.

16. Common Stock, Stock Option Plans and Stock Compensation Agreements

At January 1, 2023, the Company had one stock-based compensation plan. The shares outstanding are for contracts under the Company's 2012 Long-Term Incentive Plan and the 2022 Long-Term Incentive Plan. The 2012 Long-Term Incentive Plan expired on April 26, 2022. All awards (stock options, restricted shares units and performance share units) granted subsequent to that date were under the 2022 Long-Term Incentive Plan. Under the 2022 Long-Term Incentive Plan, the Company may issue up to 150 million shares of common stock, of which up to 110 million shares of common stock may be issued subject to stock options or stock appreciation rights and up to 40 million shares of common stock may be issued subject to full value awards. Awards will generally be counted on a 1-for-1 basis against the share reserve, provided that if more than 40 million full value awards are granted, each full value award in excess of 40 million will be counted on a 5-for-1 basis against the share reserve. Shares available for future grants under the 2022 Long-Term Incentive Plan were 150 million at the end of fiscal year 2022.

The compensation cost that has been charged against income for these plans was $1,138 million, $1,135 million and $1,005 million for fiscal years 2022, 2021 and 2020, respectively. The total income tax benefit recognized in the income statement for share-based compensation costs was $196 million, $218 million and $210 million for fiscal years 2022, 2021 and 2020, respectively. The Company also recognized additional income tax benefits of $282 million, $223 million and $248 million for fiscal years 2022, 2021 and 2020, respectively, for which options were exercised or restricted shares were vested. The total unrecognized compensation cost was $939 million, $862 million and $804 million for fiscal years 2022, 2021 and 2020, respectively. The weighted average period for this cost to be recognized was 1.80 years, 1.78 years and 1.76 years for fiscal years 2022, 2021, and 2020, respectively. Share-based compensation costs capitalized as part of inventory were insignificant in all periods.

The Company settles employee benefit equity issuances with treasury shares. Treasury shares are replenished through market purchases throughout the year for the number of shares used to settle employee benefit equity issuances.

Stock Options

Stock options expire 10 years from the date of grant and vest over service periods that range from 6 months to 4 years. All options are granted at the average of the high and low prices of the Company's Common Stock on the New York Stock Exchange on the date of grant.

The fair value of each option award was estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the following table. For 2022, 2021, and 2020 grants, expected volatility represents a blended rate of 10-year weekly historical overall volatility rate, and a 5-week average implied volatility rate based on at-the-money traded Johnson & Johnson options with a life of 2 years. For all grants, historical data is used to determine the expected life of the option. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant.

The average fair value of options granted was $23.23, $20.86 and $16.42, in fiscal years 2022, 2021 and 2020, respectively. The fair value was estimated based on the weighted average assumptions of:

	2022	2021	2020
Risk-free rate	1.98 %	0.83 %	1.47 %
Expected volatility	18.00 %	18.59 %	15.33 %
Expected life (in years)	7.0	7.0	7.0
Expected dividend yield	2.70 %	2.50 %	2.60 %

A summary of option activity under the Plan as of January 1, 2023, January 2, 2022 and January 3, 2021, and changes during the years ending on those dates is presented below:

(Shares in Thousands)	Outstanding Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (Dollars in Millions)
Shares at December 29, 2019	111,637	$ 105.63	$ 4,478
Options granted	20,723	151.41	
Options exercised	(16,275)	86.05	
Options canceled/forfeited	(1,835)	137.62	
Shares at January 3, 2021	114,250	116.22	4,703
Options granted	18,525	164.62	
Options exercised	(13,248)	97.48	
Options canceled/forfeited	(2,166)	149.75	
Shares at January 2, 2022	117,361	125.36	5,364
Options granted	19,809	165.89	
Options exercised	(16,310)	100.15	
Options canceled/forfeited	(2,188)	160.56	
Shares at January 1, 2023	**118,672**	**$ 134.95**	**$ 4,949**

The total intrinsic value of options exercised was $1,228 million, $919 million and $1,021 million in fiscal years 2022, 2021 and 2020, respectively.

The following table summarizes stock options outstanding and exercisable at January 1, 2023:

(Shares in Thousands)	Outstanding			Exercisable	
Exercise Price Range	Options	Average Life[1]	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
$72.54-$100.48	17,221	1.5	$93.07	17,221	$93.07
$101.87-$115.67	22,039	3.6	$108.78	22,039	$108.78
$129.51-$141.06	24,870	5.7	$130.88	24,228	$130.85
$151.41-$164.62	35,465	7.6	$157.75	150	$156.21
$164.63-$165.89	19,077	9.1	$165.89	23	$165.89
	118,672	**5.8**	**$134.95**	**63,661**	**$113.06**

[1] Average contractual life remaining in years.

Stock options outstanding at January 2, 2022 and January 3, 2021 were 117,361 and an average life of 5.8 years and 114,250 and an average life of 6.0 years, respectively. Stock options exercisable at January 2, 2022 and January 3, 2021 were 62,742 at an average price of $104.42 and 61,289 at an average price of $96.97, respectively.

Restricted Share Units and Performance Share Units

The Company grants restricted share units which vest over service periods that range from 6 months to 3 years. The Company also grants performance share units, which are paid in shares of Johnson & Johnson Common Stock after the end of a three-year performance period. Performance shares were granted with two equally-weighted goals that directly align with or help drive long-term total shareholder return: adjusted operational earnings per share and relative total shareholder return. The number of shares actually earned at the end of the three-year period will vary, based only on actual performance, from 0% to 200% of the target number of performance share units granted.

A summary of the restricted share units and performance share units activity under the Plans as of January 1, 2023 is presented below:

(Shares in Thousands)	Outstanding Restricted Share Units	Outstanding Performance Share Units
Shares at January 2, 2022	14,122	2,312
Granted	5,154	753
Issued	(4,866)	(637)
Canceled/forfeited/adjusted	(794)	(71)
Shares at January 1, 2023	13,616	2,357

The average fair value of the restricted share units granted was $153.67, $152.62 and $139.58 in fiscal years 2022, 2021 and 2020, respectively, using the fair market value at the date of grant. The fair value of restricted share units was discounted for dividends, which are not paid on the restricted share units during the vesting period. The fair value of restricted share units issued was $591 million, $611 million and $650 million in 2022, 2021 and 2020, respectively.

The weighted average fair value of the performance share units granted was $170.46, $179.35 and $160.54 in fiscal years 2022, 2021 and 2020, calculated using the weighted average fair market value for each of the component goals at the date of grant.

The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. The fair value of performance share units issued was $94 million, $83 million and $91 million in fiscal years 2022, 2021 and 2020, respectively.

17. Segments of Business* and Geographic Areas

(Dollars in Millions)	Sales to Customers			% Change	
	2022	2021	2020	'22 vs. '21	'21 vs. '20
CONSUMER HEALTH[1]					
OTC					
U.S.	$ 2,782	2,594	2,460	7.3 %	5.4
International	3,249	3,034	2,761	7.1	9.9
Worldwide	6,031	5,627	5,221	7.2	7.8
Skin Health/Beauty					
U.S.	2,337	2,400	2,350	(2.6)	2.1
International	2,015	2,141	2,100	(5.9)	1.9
Worldwide	4,352	4,541	4,450	(4.2)	2.0
Oral Care					
U.S.	635	637	683	(0.3)	(6.7)
International	871	1,008	958	(13.6)	5.1
Worldwide	1,505	1,645	1,641	(8.5)	0.2
Baby Care					
U.S.	357	378	376	(5.5)	0.5
International	1,104	1,188	1,141	(7.1)	4.1
Worldwide	1,461	1,566	1,517	(6.7)	3.2
Women's Health					
U.S.	13	13	13	1.7	(1.6)
International	891	905	888	(1.5)	1.8
Worldwide	904	917	901	(1.5)	1.8
Wound Care/Other					
U.S.	475	495	480	(4.0)	3.1
International	224	243	240	(8.0)	1.7
Worldwide	700	739	720	(5.3)	2.6
TOTAL CONSUMER HEALTH					
U.S.	6,599	6,516	6,362	1.3	2.4
International	8,354	8,519	8,088	(1.9)	5.3
Worldwide	14,953	15,035	14,450	(0.5)	4.0

PHARMACEUTICAL[1]					
Immunology					
U.S.	11,036	10,843	10,175	1.8	6.6
International	5,899	5,907	4,880	(0.1)	21.0
Worldwide	16,935	16,750	15,055	1.1	11.3
REMICADE					
U.S.	1,417	2,019	2,508	(29.8)	(19.5)
U.S. Exports	204	236	346	(13.6)	(31.9)
International	722	935	893	(22.8)	4.8
Worldwide	2,343	3,190	3,747	(26.6)	(14.9)
SIMPONI / SIMPONI ARIA					
U.S.	1,166	1,127	1,155	3.5	(2.4)
International	1,017	1,148	1,088	(11.4)	5.5
Worldwide	2,184	2,276	2,243	(4.0)	1.4
STELARA					
U.S.	6,388	5,938	5,240	7.6	13.3
International	3,335	3,196	2,467	4.4	29.6
Worldwide	9,723	9,134	7,707	6.5	18.5
TREMFYA					
U.S.	1,844	1,503	926	22.7	62.3
International	824	624	421	32.0	48.2
Worldwide	2,668	2,127	1,347	25.4	57.9
OTHER IMMUNOLOGY					
U.S.	17	21	—	(18.4)	**
International	0	3	11	**	(73.3)
Worldwide	17	24	11	(28.2)	**
Infectious Diseases					
U.S.	1,680	2,249	1,735	(25.3)	29.7
International	3,769	3,576	1,808	5.4	97.8
Worldwide	5,449	5,825	3,543	(6.5)	64.4
COVID-19 VACCINE					
U.S.	120	634	—	(81.1)	**
International	2,059	1,751	—	17.6	**
Worldwide	2,179	2,385	—	(8.6)	**
EDURANT / rilpivirine					
U.S.	36	41	44	(10.8)	(7.6)
International	972	953	920	2.0	3.6
Worldwide	1,008	994	964	1.5	3.1
PREZISTA / PREZCOBIX / REZOLSTA / SYMTUZA					
U.S.	1,494	1,508	1,587	(1.0)	(4.9)
International	449	575	597	(21.9)	(3.6)
Worldwide	1,943	2,083	2,184	(6.7)	(4.6)
OTHER INFECTIOUS DISEASES					
U.S.	30	66	104	(55.5)	(36.0)
International	289	297	292	(2.6)	1.7
Worldwide	318	363	396	(12.3)	(8.3)

Neuroscience					
U.S.	3,570	3,347	3,091	6.7	8.3
International	3,323	3,641	3,435	(8.7)	6.0
Worldwide	6,893	6,988	6,526	(1.4)	7.1
CONCERTA / methylphenidate					
U.S.	151	172	183	(12.5)	(5.8)
International	493	495	439	(0.4)	12.8
Worldwide	644	667	622	(3.5)	7.3
INVEGA SUSTENNA / XEPLION / INVEGA TRINZA / TREVICTA					
U.S.	2,714	2,550	2,314	6.5	10.2
International	1,426	1,472	1,339	(3.1)	10.0
Worldwide	4,140	4,022	3,653	3.0	10.1
RISPERDAL CONSTA					
U.S.	257	287	296	(10.4)	(2.9)
International	228	305	346	(25.3)	(11.8)
Worldwide	485	592	642	(18.1)	(7.7)
OTHER NEUROSCIENCE					
U.S.	447	338	298	32.4	13.3
International	1,176	1,368	1,312	(14.1)	4.3
Worldwide	1,623	1,706	1,610	(4.9)	6.0
Oncology					
U.S.	6,930	5,958	5,092	16.3	17.0
International	9,052	8,590	7,275	5.4	18.1
Worldwide	15,983	14,548	12,367	9.9	17.6
DARZALEX					
U.S.	4,210	3,169	2,232	32.8	42.0
International	3,767	2,854	1,958	32.0	45.8
Worldwide	7,977	6,023	4,190	32.4	43.8
ERLEADA					
U.S.	968	813	583	19.2	39.3
International	913	478	176	**	* *
Worldwide	1,881	1,291	760	45.7	70.0
IMBRUVICA					
U.S.	1,390	1,747	1,821	(20.4)	(4.0)
International	2,394	2,622	2,307	(8.7)	13.6
Worldwide	3,784	4,369	4,128	(13.4)	5.8
ZYTIGA /abiraterone acetate					
U.S.	74	119	373	(37.8)	(68.1)
International	1,696	2,178	2,097	(22.1)	3.9
Worldwide	1,770	2,297	2,470	(22.9)	(7.0)
OTHER ONCOLOGY					
U.S.	289	110	83	**	31.7
International	283	458	738	(38.3)	(37.9)
Worldwide	571	568	821	0.6	(30.8)

Pulmonary Hypertension					
U.S.	2,346	2,365	2,133	(0.8)	10.9
International	1,071	1,085	1,015	(1.3)	6.9
Worldwide	3,417	3,450	3,148	(1.0)	9.6
OPSUMIT					
U.S.	1,132	1,147	1,008	(1.3)	13.7
International	651	672	631	(3.2)	6.6
Worldwide	1,783	1,819	1,639	(2.0)	11.0
UPTRAVI					
U.S.	1,104	1,056	955	4.5	10.5
International	218	181	138	20.4	31.1
Worldwide	1,322	1,237	1,093	6.9	13.1
OTHER					
U.S.	110	163	169	(32.3)	(3.7)
International	202	232	247	(12.8)	(5.9)
Worldwide	313	395	416	(20.8)	(5.0)
Cardiovascular / Metabolism / Other					
U.S.	3,042	3,192	3,509	(4.7)	(9.0)
International	845	927	1,025	(8.9)	(9.6)
Worldwide	3,887	4,119	4,534	(5.6)	(9.2)
XARELTO					
U.S.	2,473	2,438	2,345	1.4	4.0
International	—	—	—	—	—
Worldwide	2,473	2,438	2,345	1.4	4.0
INVOKANA/ INVOKAMET					
U.S.	193	308	564	(37.4)	(45.4)
International	255	254	231	0.1	9.9
Worldwide	448	563	795	(20.4)	(29.3)
OTHER[2]					
U.S.	376	446	600	(15.5)	(25.7)
International	590	673	794	(12.3)	(15.2)
Worldwide	966	1,119	1,394	(13.6)	(19.7)
TOTAL PHARMACEUTICAL					
U.S.	28,604	27,954	25,735	2.3	8.6
International	23,959	23,726	19,440	1.0	22.0
Worldwide	52,563	51,680	45,175	1.7	14.4

MEDTECH*(3)					
Interventional Solutions					
U.S.	2,169	1,836	1,452	18.2	26.4
International	2,131	2,135	1,594	(0.2)	34.0
Worldwide	4,300	3,971	3,046	8.3	30.4
Orthopaedics					
U.S.	5,321	5,126	4,779	3.8	7.3
International	3,267	3,462	2,984	(5.6)	16.0
Worldwide	8,587	8,588	7,763	0.0	10.6
HIPS					
U.S.	943	878	793	7.3	10.7
International	571	602	487	(5.1)	23.6
Worldwide	1,514	1,480	1,280	2.3	15.6
KNEES					
U.S.	851	787	743	8.2	5.9
International	508	538	427	(5.7)	26.1
Worldwide	1,359	1,325	1,170	2.6	13.3
TRAUMA					
U.S.	1,882	1,819	1,648	3.5	10.4
International	989	1,066	966	(7.2)	10.4
Worldwide	2,871	2,885	2,614	(0.5)	10.4
SPINE, SPORTS & OTHER					
U.S.	1,645	1,642	1,595	0.2	2.9
International	1,198	1,256	1,104	(4.6)	13.8
Worldwide	2,843	2,898	2,699	(1.9)	7.4
Surgery					
U.S.	3,897	3,867	3,249	0.8	19.0
International	5,793	5,945	4,983	(2.6)	19.3
Worldwide	9,690	9,812	8,232	(1.2)	19.2
ADVANCED					
U.S.	1,784	1,761	1,535	1.3	14.9
International	2,785	2,861	2,304	(2.6)	24.1
Worldwide	4,569	4,622	3,839	(1.1)	20.4
GENERAL					
U.S.	2,113	2,105	1,714	0.4	22.7
International	3,008	3,085	2,679	(2.5)	15.2
Worldwide	5,121	5,190	4,392	(1.3)	18.1
Vision					
U.S.	1,990	1,857	1,557	7.2	19.3
International	2,859	2,831	2,362	1.0	19.8
Worldwide	4,849	4,688	3,919	3.4	19.6
CONTACT LENSES / OTHER					
U.S.	1,522	1,398	1,213	8.9	15.2
International	2,022	2,043	1,781	(1.0)	14.7
Worldwide	3,543	3,440	2,994	3.0	14.9

SURGICAL					
U.S.	468	459	344	2.0	33.5
International	837	788	581	6.2	35.7
Worldwide	1,306	1,248	925	4.6	34.9
TOTAL MEDTECH					
U.S.	13,377	12,686	11,036	5.4	14.9
International	14,050	14,374	11,923	(2.3)	20.6
Worldwide	27,427	27,060	22,959	1.4	17.9
WORLDWIDE					
U.S.	48,580	47,156	43,133	3.0	9.3
International	46,363	46,619	39,451	(0.6)	18.2
Worldwide	$ 94,943	93,775	82,584	1.3 %	13.6

*Certain prior year amounts have been reclassified to conform to current year presentation
**Percentage greater than 100% or not meaningful
(1) Approximately $0.4 billion in both the fiscal 2021 and 2020, of certain international OTC products, primarily in China, were reclassified from the Pharmaceutical segment to the Consumer Health segment based on operational changes
(2) Inclusive of PROCRIT / EPREX which was previously disclosed separately
(3) Previously referred to as Medical Devices

	Income (Loss) Before Tax*			Identifiable Assets	
(Dollars in Millions)	**2022 (3)**	**2021 (4)**	**2020 (5)**	**2022**	**2021**
Consumer Health	$ 2,930	1,573	(852)	$ 24,068	25,081
Pharmaceutical	15,901	17,969	15,250	58,436	64,376
MedTech	4,607	4,373	3,044	70,956	53,372
Total	23,438	23,915	17,442	153,460	142,829
Less: Expense not allocated to segments (1)	624	1,072	945		
Less: Consumer Health separation costs	1,089	67			
General corporate (2)				33,918	39,189
Worldwide total	**$ 21,725**	**22,776**	**16,497**	**$ 187,378**	**182,018**

*Income before tax of approximately $0.2 billion and $0.2 billion in the fiscal years 2021 and 2020, respectively, has been reclassified as certain international OTC products, primarily in China, were reclassified from the Pharmaceutical segment to the Consumer Health segment based on operational changes

	Additions to Property, Plant & Equipment			Depreciation and Amortization		
(Dollars in Millions)	**2022**	**2021**	**2020**	**2022**	**2021**	**2020**
Consumer Health	$ 323	331	248	$ 658	759	785
Pharmaceutical	1,374	1,198	863	3,687	4,029	4,006
MedTech	2,120	1,933	1,980	2,302	2,286	2,140
Segments total	3,817	3,462	3,091	6,647	7,074	6,931
General corporate	192	190	256	323	316	300
Worldwide total	**$ 4,009**	**3,652**	**3,347**	**$ 6,970**	**7,390**	**7,231**

(Dollars in Millions)	Sales to Customers 2022	2021	2020	Long-Lived Assets [6] 2022	2021
United States	$ 48,580	47,156	43,133	$ 66,283	48,586
Europe	23,449	23,594	18,980	38,774	43,257
Western Hemisphere excluding U.S.	6,125	5,750	5,335	2,737	2,708
Asia-Pacific, Africa	16,789	17,275	15,136	4,431	5,035
Segments total	94,943	93,775	82,584	112,225	99,586
General corporate				1,134	1,014
Other non long-lived assets				74,019	81,418
Worldwide total	**$ 94,943**	**93,775**	**82,584**	**$ 187,378**	**182,018**

See Note 1 for a description of the segments in which the Company operates.

Export sales are not significant. In fiscal year 2022, the Company utilized three wholesalers distributing products for all three segments that represented approximately 16.5%, 13.0% and 12.0% of the total consolidated revenues. In fiscal year 2021, the Company had three wholesalers distributing products for all three segments that represented approximately 14.0%, 11.0% and 11.0% of the total consolidated revenues. In fiscal year 2020, the Company had three wholesalers distributing products for all three segments that represented approximately 16.0%, 12.0%, and 12.0% of the total consolidated revenues.

(1) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.

(2) General corporate includes cash, cash equivalents and marketable securities.

(3) Consumer Health includes:

- Litigation expense of $0.2 billion
- A restructuring related charge of $0.1 billion

Pharmaceutical includes:

- One-time COVID-19 Vaccine manufacturing exit related costs of $1.5 billion
- An intangible asset impairment charge of approximately $0.8 billion related to an in-process research and development asset, bermekimab (JnJ-77474462), an investigational drug for the treatment of Atopic Dermatitis (AD) and Hidradenitis Suppurativa (HS) acquired with the acquisition of XBiotech, Inc. in the fiscal year 2020. Additional information regarding efficacy of the AD and HS indications became available which led the Company to the decision to terminate the development of bermekimab for AD and HS
- Litigation expense of $0.1 billion
- Loss of $0.7 billion related to the change in the fair value of securities
- A restructuring related charge of $0.1 billion

MedTech includes:

- Litigation expense of $0.6 billion primarily for pelvic mesh related costs
- A restructuring related charge of $0.3 billion
- Acquisition and integration related costs of $0.3 billion primarily related to the acquisition of Abiomed
- A Medical Device Regulation charge of $0.3 billion

(4) Consumer Health includes:

- Litigation expense of $1.6 billion, primarily talc related costs
- A restructuring related charge of $0.1 billion

Pharmaceutical includes:

- Litigation expense of $0.6 billion, primarily related to Risperdal Gynecomastia
- Divestiture gains of $0.6 billion
- Gains of $0.5 billion related to the change in the fair value of securities
- A restructuring related charge of $0.1 billion

MedTech includes:

- A restructuring related charge of $0.3 billion
- An in-process research and development expense of $0.9 billion related to Ottava
- A Medical Device Regulation charge of $0.2 billion
- Litigation expense of $0.1 billion

(5) Consumer Health includes:

- Litigation expense of $3.9 billion, primarily talc related costs and certain settlements.

Pharmaceutical includes:

- Litigation expense of $0.8 billion, primarily related to the agreement in principle to settle opioid litigation
- A gain of $0.5 billion related to the change in the fair value of securities
- A restructuring related charge of $0.1 billion

MedTech includes:

- A contingent consideration reversal of $1.1 billion related to the timing of certain developmental milestones associated with the Auris Health acquisition.
- Litigation expense of $0.3 billion
- A restructuring related charge of $0.3 billion
- An in-process research and development expense of $0.2 billion
- A Medical Device Regulation charge of $0.1 billion

(6) Long-lived assets include property, plant and equipment, net for fiscal years 2022, and 2021 of $19,803 and $18,962, respectively, and intangible assets and goodwill, net for fiscal years 2022 and 2021 of $93,556 and $81,638, respectively.

18. Acquisitions and Divestitures

During the fiscal year 2022, certain businesses were acquired for $17.7 billion in cash and $1.1 billion of liabilities assumed. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition. The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $17.3 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

The fiscal year 2022 acquisitions primarily included Abiomed, Inc. (Abiomed). The remaining acquisitions were not material.

On December 22, 2022, the Company completed the acquisition of Abiomed, a leading, first-to-market provider of cardiovascular medical technology with a first-in-kind portfolio for the treatment of coronary artery disease and heart failure which also has an extensive innovation pipeline of life-saving technologies. The transaction broadens the Company's position as a growing cardiovascular innovator, advancing the standard of care in heart failure and recovery, one of healthcare's largest areas of unmet need. The transaction was accounted for as a business combination and the results of operations were included in the MedTech segment as of the date of the acquisition. The acquisition was completed through a tender offer for all outstanding shares. The consideration paid in the acquisition consisted of an upfront payment of $380.00 per share in cash, amounting to $17.1 billion, net of cash acquired, as well as a non-tradeable contingent value right ("CVR") entitling the holder to receive up to $35.00 per share in cash (which with respect to the CVRs total approximately $1.6 billion in the aggregate) if certain commercial and clinical milestones are achieved. The corresponding enterprise value (without taking into account the CVRs) of approximately $16.5 billion includes cash, cash equivalents and marketable securities acquired.

The milestones of the CVR consist of:

a. $17.50 per share, payable if net sales for Abiomed products exceeds $3.7 billion during Johnson & Johnson's fiscal second quarter of 2027 through fiscal first quarter of 2028, or if this threshold is not met during this period and is subsequently met during any rolling four quarter period up to the end of Johnson & Johnson's fiscal first quarter of 2029, $8.75 per share;
b. $7.50 per share payable upon FDA premarket application approval of the use of Impella® products in ST-elevated myocardial infarction (STEMI) patients without cardiogenic shock by January 1, 2028; and
c. $10.00 per share payable upon the first publication of a Class I recommendation for the use of Impella® products in high risk PCI or STEMI with or without cardiogenic shock within four years from their respective clinical endpoint publication dates, but in all cases no later than December 31, 2029.

The fair value of the acquisition was allocated to assets acquired of $19.9 billion (net of $0.3 billion cash acquired), primarily to goodwill for $10.9 billion, amortizable intangible assets for $6.6 billion, IPR&D for $1.1 billion, marketable

securities of $0.6 billion and liabilities assumed of $2.8 billion, which includes the fair value of the contingent consideration mentioned above for $0.7 billion and deferred taxes of $1.8 billion. The goodwill is primarily attributable to the commercial acceleration and expansion of the portfolio and is not expected to be deductible for tax purposes. The contingent consideration was recorded in Other Liabilities on the Consolidated Balance Sheet.

As the acquisition occurred in December 2022, the Company is still finalizing the allocation of the purchase price to the individual assets acquired and liabilities assumed. The allocation of the purchase price included in the current period balance sheet is based on the best estimate of management and is preliminary and subject to change. To assist management in the allocation, the Company engaged valuation specialists to prepare appraisals. The Company will finalize the amounts recognized as the information necessary to complete the analysis is obtained. The Company expects to finalize these amounts as soon as possible but no later than one year from the acquisition date.

The amortizable intangible assets were primarily comprised of already in-market products of the Impella® platform with an average weighted life of 14 years. The IPR&D assets were valued for technology programs for unapproved products. The value of the IPR&D was calculated using probability-adjusted cash flow projections discounted for the risk inherent in such projects. The probability of success factor ranged from 52% to 70%. The discount rate applied was 9.5%.

In 2022, the Company recorded acquisition related costs before tax of approximately $0.3 billion, which was recorded in Other (income)/expense.

During fiscal year 2021, the Company did not make any material acquisitions.

During fiscal year 2020, certain businesses were acquired for $7.3 billion in cash and $0.4 billion of liabilities assumed. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $7.5 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

The fiscal year 2020 acquisitions primarily included: all rights to the investigational compound bermekimab, which has multiple dermatological indications, along with certain employees from XBiotech Inc. (XBiotech), Momenta Pharmaceuticals, Inc. (Momenta), a company that discovers and develops novel therapies for immune-mediated diseases and the outstanding shares in Verb Surgical Inc., a company with significant robotics and data science capabilities.

During the fiscal first quarter of 2020, the Company completed the acquisition of all rights to the investigational compound bermekimab, which has multiple dermatological indications, along with certain employees from XBiotech Inc., for a purchase price of $0.8 billion. The fair value of the acquisition was allocated primarily to non-amortizable intangible assets, primarily IPR&D, for $0.8 billion applying a probability of success factor that ranged from 20% to 60% to reflect inherent development, regulatory and commercial risk for the different indications. The discount rate applied was approximately 16%. The transaction was accounted for as a business combination and included in the Pharmaceutical segment. In fiscal 2022, the Company recorded an intangible asset impairment charge of approximately $0.8 billion related to this in-process research and development asset.

Additionally, in the fiscal first quarter of 2020, the Company completed the acquisition of all outstanding shares in Verb Surgical Inc., a company with significant robotics and data science capabilities, including those shares previously held by Verily. The transaction was accounted for as a business combination and included in the MedTech segment. The fair value of the acquisition was allocated primarily to non-amortizable intangible assets, primarily IPR&D, for $0.4 billion, goodwill for $0.2 billion, other assets of $0.2 billion and liabilities assumed of $0.3 billion. The fair value of the Company's previously held equity investment in Verb Surgical Inc. was $0.4 billion.

On October 1, 2020, the Company completed the acquisition of Momenta for a purchase price of approximately $6.1 billion, net of cash acquired. The fair value of the acquisition was allocated primarily to non-amortizable intangible assets (IPR&D) of $6.0 billion, goodwill of $1.2 billion, other assets of $0.5 billion and liabilities of $1.6 billion. The assets acquired are intended to address substantial unmet medical need in maternal-fetal disorders, neuro-inflammatory disorders, rheumatology, dermatology and autoimmune hematology. Depending on the asset, probability of success factors ranging from 20% to 77% were used in the fair value calculation to reflect inherent development and regulatory risk of the IPR&D. The discount rate applied was approximately 13%. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not expected to be deductible for tax purposes. The transaction was accounted for as a business combination and included in the Pharmaceutical segment.

In accordance with U.S. GAAP standards related to business combinations, and goodwill and other intangible assets, supplemental pro forma information for fiscal years 2022, 2021 and 2020 is not provided, as the impact of the aforementioned acquisitions did not have a material effect on the Company’s results of operations.

Divestitures

During fiscal year 2022, the Company did not make any material divestitures.

During fiscal year 2021, in separate transactions, the Company divested two brands outside the U.S. within the Pharmaceutical segment. The Company recognized a pre-tax gain recorded in Other (income) expense, net, of approximately $0.6 billion.

During fiscal year 2020, the Company sold 11.8 million shares of Idorsia LTD (Idorsia), or its 8.3% ownership in the company at that time. The transaction resulted in gross proceeds of approximately CHF 337 million ($357 million) based on a sales price of CHF 28.55/share and resulted in an immaterial net loss. At the end of fiscal 2020, the Company had rights to approximately 38.7 million shares through a convertible loan with a principal amount of CHF 445 million (due June 2027). During fiscal year 2021, the Company converted CHF 110 million ($120 million) of this loan into approximately 9.6 million shares of Idorsia which were reflected at fair value as of January 2, 2022. During the fiscal third quarter of 2021, the Company's undrawn credit facility with Idorsia was terminated.

19. Legal Proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability; intellectual property; commercial; indemnification and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of their business.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred, and the amount of the loss can be reasonably estimated. As of January 1, 2023, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; ability to achieve comprehensive multi-party settlements; complexity of related cross-claims and counterclaims; and/or there are numerous parties involved. To the extent adverse awards, judgments or verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

In the Company’s opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company’s balance sheet, is not expected to have a material adverse effect on the Company’s financial position. However, the resolution of, or increase in accruals for, one or more of these matters in any reporting period may have a material adverse effect on the Company’s results of operations and cash flows for that period.

PRODUCT LIABILITY

The Company and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While the Company believes it has substantial defenses, it is not feasible to predict the ultimate outcome of litigation. From time to time, even if it has substantial defenses, the Company considers isolated settlements based on a variety of circumstances. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

The most significant of these cases include: the DePuy ASR XL Acetabular System and DePuy ASR Hip Resurfacing System; the PINNACLE Acetabular Cup System; pelvic meshes; RISPERDAL; body powders containing talc, primarily JOHNSON'S Baby Powder; ETHICON PHYSIOMESH Flexible Composite Mesh; ELMIRON; and TYLENOL. As of January 1, 2023, in the United States there were approximately 170 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to the DePuy ASR XL Acetabular System and DePuy ASR Hip Resurfacing System; 1,400 with respect to the PINNACLE Acetabular Cup System; 9,000 with respect to pelvic meshes; 1,100 with respect to RISPERDAL; 40,300 with respect to body powders containing talc; 2,100 with respect to ETHICON PHYSIOMESH Flexible Composite Mesh; 2,000 with respect to ELMIRON; and 170 with respect to TYLENOL. The number of pending lawsuits is expected to fluctuate as certain lawsuits are settled or dismissed and additional lawsuits are filed.

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR XL Acetabular System and DePuy ASR Hip Resurfacing System (ASR Hip) used in hip replacement surgery. Claims for personal injury have been made against DePuy and the Company. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada, Australia, Ireland, Germany, India and Italy. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR Hip plaintiffs to establish a program to settle claims with eligible ASR Hip patients in the United States who had surgery to replace their ASR Hips, known as revision surgery, as of August 2013. DePuy reached additional agreements in February 2015 and March 2017, which further extended the settlement program to include ASR Hip patients who had revision surgeries after August 2013 and prior to February 15, 2017. This settlement program has resolved more than 10,000 claims, thereby bringing to resolution significant ASR Hip litigation activity in the United States. However, lawsuits in the United States remain, and the settlement program does not address litigation outside of the United States. In Australia, a class action settlement was reached that resolved the claims of the majority of ASR Hip patients in that country. In Canada, the Company has reached agreements to settle the class actions filed in that country. The Company continues to receive information with respect to potential additional costs associated with this recall on a worldwide basis. The Company has established accruals for the costs associated with the United States settlement program and ASR Hip-related product liability litigation.

Claims for personal injury have also been made against DePuy Orthopaedics, Inc. and the Company (collectively, DePuy) relating to the PINNACLE Acetabular Cup System used in hip replacement surgery. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Most cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Texas (Texas MDL). Beginning on June 1, 2022, the Judicial Panel on Multidistrict Litigation ceased transfer of new cases into the Texas MDL, and there are now cases pending in federal court outside the Texas MDL. Litigation also has been filed in state courts and in countries outside of the United States. Prior to 2019, several adverse verdicts had been rendered against DePuy, one of which was reversed on appeal and remanded for retrial. During the first quarter of 2019, DePuy established a United States settlement program to resolve these cases. As part of the settlement program, adverse verdicts have been settled. The Company has established an accrual for product liability litigation associated with the PINNACLE Acetabular Cup System and the related settlement program.

Claims for personal injury have been made against Ethicon, Inc. (Ethicon) and the Company arising out of Ethicon's pelvic mesh devices used to treat stress urinary incontinence and pelvic organ prolapse. The Company continues to receive information with respect to potential costs and additional cases. Cases filed in federal courts in the United States had been organized as a multi-district litigation (MDL) in the United States District Court for the Southern District of West Virginia. In March 2021, the MDL Court entered an order closing the MDL. The MDL Court has remanded cases for trial to the jurisdictions where the case was originally filed and additional pelvic mesh lawsuits have been filed, and remain, outside of the MDL. The Company has settled or otherwise resolved the majority of the United States cases and the estimated costs associated with these settlements and the remaining cases are reflected in the Company's accruals. In addition, class actions and individual personal injury cases or claims seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices have been commenced in various countries outside of the United States, including claims and cases in the United Kingdom, the Netherlands, Belgium, France, Ireland, Italy, Spain and Slovenia and class actions in Israel, Australia, Canada and South Africa. In November 2019, the Federal Court of Australia issued a judgment regarding its findings with respect to liability in relation to the three Lead Applicants and generally in relation to the design, manufacture, pre and post-market assessments and testing, and supply and promotion of the devices in Australia used to treat stress urinary incontinence and pelvic organ prolapse. In September 2022, after exhausting its appeals, the Company reached an in-principle agreement to resolve the two pelvic mesh class actions in Australia, pending Federal Court approval. In November 2022, the application for approval of the settlement was filed, and a hearing on the settlement has been scheduled for the end of February 2023. The class actions in Canada were discontinued in 2020 as a result of a settlement of a group of cases and an agreement to resolve the Israeli class action was reached in May 2021. The parties in the Israeli class action are currently finalizing the terms of the settlement. A motion to approve the settlement was filed with the Court. The Company has established accruals with respect to product liability litigation associated with Ethicon's pelvic mesh products.

Following a June 2016 worldwide market withdrawal of ETHICON PHYSIOMESH Flexible Composite Mesh (Physiomesh), claims for personal injury have been made against Ethicon, Inc. (Ethicon) and the Company alleging personal injury arising out of the use of this hernia mesh device. Cases filed in federal courts in the United States have been organized as a multi-district litigation (MDL) in the United States District Court for the Northern District of Georgia. A multi-county litigation (MCL) also has been formed in New Jersey state court and assigned to Atlantic County for cases pending in New Jersey. In addition to the matters in the MDL and MCL, there are additional lawsuits pending in the United States District Court for the Southern District

of Ohio, which are part of the MDL for polypropylene mesh devices manufactured by C.R. Bard, Inc., and lawsuits pending in two New Jersey MCLs formed for Proceed/Proceed Ventral Patch and Prolene Hernia systems, and lawsuits pending outside the United States. In May 2021, Ethicon and lead counsel for the plaintiffs entered into a term sheet to resolve approximately 3,600 Physiomesh cases (covering approximately 4,300 plaintiffs) pending in the MDL and MCL at that time. A master settlement agreement (MSA) was entered into in September 2021 and includes 3,729 cases in the MDL and MCL. All deadlines and trial settings in those proceedings are currently stayed pending the completion of the settlement agreement. Of the cases subject to the MSA, 2,236 have been dismissed with prejudice. Post-settlement cases in the Physiomesh MDL and MCL are subject to docket control orders requiring early expert reports and discovery requirements. As of January 2023, there are approximately 208 active cases subject to these orders which are being reviewed and evaluated.

Claims have also been filed against Ethicon and the Company alleging personal injuries arising from the PROCEED Mesh and PROCEED Ventral Patch hernia mesh products. In March 2019, the New Jersey Supreme Court entered an order consolidating these cases pending in New Jersey as an MCL in Atlantic County Superior Court. Additional cases have been filed in various federal and state courts in the United States, and in jurisdictions outside the United States.

Ethicon and the Company also have been subject to claims for personal injuries arising from the PROLENE Polypropylene Hernia System. In January 2020, the New Jersey Supreme Court created an MCL in Atlantic County Superior Court to handle such cases. Cases involving this product have also been filed in other federal and state courts in the United States.

In October 2022, an agreement in principle, subject to various conditions, was reached to settle the majority of the pending cases involving Proceed, Proceed Ventral Patch, Prolene Hernia System and related multi-layered mesh products. All litigation activities in the two New Jersey MCLs are stayed pending resolution of the proposed settlement. Future cases that are filed in the New Jersey MCLs will be subject to docket control orders requiring early expert reports and discovery requirements.

The Company has established accruals with respect to product liability litigation associated with ETHICON PHYSIOMESH Flexible Composite Mesh, PROCEED Mesh and PROCEED Ventral Patch, and PROLENE Polypropylene Hernia System products.

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and the Company arising out of the use of RISPERDAL, and related compounds, indicated for the treatment of schizophrenia, acute manic or mixed episodes associated with bipolar I disorder and irritability associated with autism. Lawsuits primarily have been filed in state courts in Pennsylvania, California, and Missouri. Other actions are pending in various courts in the United States and Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has successfully defended a number of these cases but there have been verdicts against the Company, including a verdict in October 2019 of $8.0 billion of punitive damages related to one plaintiff, which the trial judge reduced to $6.8 million in January 2020. In September 2021, the Company entered into a settlement in principle with the counsel representing plaintiffs in this matter and in substantially all of the outstanding cases in the United States. The costs associated with this and other settlements are reflected in the Company's accruals.

Claims for personal injury arising out of the use of XARELTO, an oral anticoagulant, have been made against Janssen Pharmaceuticals, Inc. (JPI); the Company; and JPI's collaboration partner for XARELTO, Bayer Healthcare AG, and certain of its affiliates. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Eastern District of Louisiana. In addition, cases were filed in state courts across the United States. Many of these cases were consolidated into a state mass tort litigation in Philadelphia, Pennsylvania and in a coordinated proceeding in Los Angeles, California. Class action lawsuits also have been filed in Canada. In March 2019, JPI and the Company announced an agreement in principle to settle the XARELTO cases in the United States; the settlement agreement was executed in May 2019, the settlement became final in December 2019, and the settlement was funded in January 2020. This resolved the majority of cases pending in the United States. The Company has established accruals for its costs associated with the United States settlement program and XARELTO related product liability litigation.

A significant number of personal injury claims alleging that talc causes cancer were made against Johnson & Johnson Consumer Inc. and the Company arising out of the use of body powders containing talc, primarily JOHNSON'S Baby Powder. The number of these personal injury lawsuits, filed in state and federal courts in the United States as well as outside of the United States, continued to increase.

In talc cases that previously have gone to trial, the Company has obtained a number of defense verdicts, but there also have been verdicts against the Company, many of which have been reversed on appeal. In June 2020, the Missouri Court of Appeals reversed in part and affirmed in part a July 2018 verdict of $4.7 billion in *Ingham v. Johnson & Johnson, et al.,* No. ED 207476 (Mo. App.), reducing the overall award to $2.1 billion. An application for transfer of the case to the Missouri Supreme Court

was subsequently denied and in June 2021, a petition for certiorari, seeking a review of the *Ingham* decision by the United States Supreme Court, was denied. In June 2021, the Company paid the award, which, including interest, totaled approximately $2.5 billion. The facts and circumstances, including the terms of the award, were unique to the *Ingham* decision and not representative of other claims brought against the Company. The Company continues to believe that it has strong legal grounds to contest the other talc verdicts that it has appealed. Notwithstanding the Company's confidence in the safety of its talc products, in certain circumstances the Company has settled cases.

In October 2021, Johnson & Johnson Consumer Inc. (Old JJCI) implemented a corporate restructuring (the 2021 Corporate Restructuring). As a result of that restructuring, Old JJCI ceased to exist and three new entities were created: (a) LTL Management LLC, a North Carolina limited liability company (LTL or Debtor); (b) Royalty A&M LLC, a North Carolina limited liability company and a direct subsidiary of LTL (RAM); and (c) the Debtor's direct parent, Johnson & Johnson Consumer Inc., a New Jersey company (New JJCI). The Debtor received certain of Old JJCI's assets and became solely responsible for the talc-related liabilities of Old JJCI, including all liabilities related in any way to injury or damage, or alleged injury or damage, sustained or incurred in the purchase or use of, or exposure to, talc, including talc contained in any product, or to the risk of, or responsibility for, any such damage or injury, except for any liabilities for which the exclusive remedy is provided under a workers' compensation statute or act (the Talc-Related Liabilities).

In October 2021, notwithstanding the Company's confidence in the safety of its talc products, the Debtor filed a voluntary petition with the United States Bankruptcy Court for the Western District of North Carolina, Charlotte Division, seeking relief under chapter 11 of the Bankruptcy Code (the LTL Bankruptcy Case). As a result of the LTL Bankruptcy Case, the North Carolina Bankruptcy Court entered a temporary restraining order staying all litigation against LTL and Old JJCI. On November 15, 2021, the North Carolina Bankruptcy Court confirmed the scope of the stay, issuing a Preliminary Injunction (PI) prohibiting and enjoining the commencement and prosecution of talc-related claims against LTL, Old JJCI, New JJCI, the Company, other of their corporate affiliates, identified retailers, insurance companies, and certain other parties (the Protected Parties). The LTL Bankruptcy Case was transferred to the United States Bankruptcy Court for the District of New Jersey in November 2021, and that court extended the PI through the end of February 2022. Claimants filed motions to dismiss the LTL Bankruptcy Case and, following a multiple day hearing, the New Jersey Bankruptcy Court denied those motions by order issued in March 2022. The New Jersey Bankruptcy Court simultaneously issued another order extending the stay as to the Protected Parties. The claimants subsequently filed notices of appeal as to the denial of the motions to dismiss and the extension of the stay. In May 2022, the Third Circuit Court of Appeals granted the petitions to appeal. The briefing and oral argument on the appeal were completed in September 2022. On January 30, 2023, the Third Circuit reversed the Bankruptcy Court's ruling and remanded to the Bankruptcy Court to dismiss the LTL bankruptcy. LTL filed a petition for rehearing on the decision.

While the New Jersey Bankruptcy Court's order effectively stays all of the Company's talc-related personal injury litigation, LTL has agreed to lift the stay on a small number of appeals where appeal bonds have been filed.

The Company has agreed to provide funding to LTL for the payment of amounts the New Jersey Bankruptcy Court determines are owed by LTL and the establishment of a $2 billion trust in furtherance of this purpose. The Company has established a reserve for approximately $2 billion in connection with the aforementioned trust. After and as a result of the filing of the LTL Bankruptcy Case, the Company de-consolidated LTL, which is a related party. The impact of the de-consolidation is not material to the Company. The parties have not yet reached a resolution of all talc matters in the LTL Bankruptcy Case, and the Company is unable to estimate the possible loss or range of loss beyond the amount accrued.

A class action advancing claims relating to industrial talc was filed against the Company and others in New Jersey state court in May 2022 (the Edley Class Action). The Edley Class Action asserts, among other things, that the Company fraudulently defended past asbestos personal injury lawsuits arising from exposure to industrial talc mined, milled, and manufactured before January 6, 1989 by the Company's then wholly owned subsidiary, Windsor Minerals, Inc., which is currently a debtor in the Imerys Bankruptcy described hereafter. The Company removed the Edley Class Action to federal court in the District of New Jersey. In July 2022, Imerys filed a motion in the Imerys Bankruptcy to stay the Edley Class Action, which was denied in August 2022. In October 2022, the Company filed motions to dismiss and to deny certification of a class to pursue the Edley Class Action in the New Jersey District Court.

In February 2019, the Company's talc supplier, Imerys Talc America, Inc. and two of its affiliates, Imerys Talc Vermont, Inc. and Imerys Talc Canada, Inc. (collectively, Imerys) filed a voluntary petition under chapter 11 of the United States Code (the Bankruptcy Code) in the United States Bankruptcy Court for the District of Delaware (Imerys Bankruptcy). The Imerys Bankruptcy relates to Imerys's potential liability for personal injury from exposure to talcum powder sold by Imerys. In its bankruptcy, Imerys alleges it has claims against the Company for indemnification and rights to joint insurance proceeds. In May 2020, Imerys, its parent Imerys S.A., the Tort Claimants' Committee (TCC), and the Future Claimants' Representative (FCR) (collectively, the Plan Proponents) filed their Plan of Reorganization (the Plan) and the Disclosure Statement related

thereto. The Plan Proponents have since filed numerous amendments to the Plan and Disclosure Statement. A hearing on the Plan Proponent's Disclosure Statement was held in January 2021, and the Court entered an order approving the Disclosure Statement, allowing Imerys to proceed with soliciting votes on the Plan.

In March 2021, the Company voted to reject the Plan and opted out of the consensual releases in the Plan. In April 2021, the Plan Proponents announced the Plan had received the requisite number of accepting votes to confirm the Plan. The Company challenged certain improprieties with respect to portions of the vote and sought to disqualify those votes. In October 2021, the Bankruptcy Court issued a ruling deeming thousands of votes as withdrawn.

In October 2021, Imerys cancelled the confirmation hearing on the Plan. Imerys, the TCC, the FCR, certain of Imerys's insurers, and certain parties in the Cyprus Mines chapter 11 case (described below) (collectively the Mediation Parties) agreed to engage in mediation. The most recent term of the mediation ended on December 31, 2022.

In July 2021, Imerys commenced an adversary proceeding against the Company in the Imerys Bankruptcy (the Imerys Adversary Proceeding). The Imerys Adversary Proceeding sought, among other things, certain declarations with respect to the indemnification obligations allegedly owed by the Company to Imerys. The TCC and FCR simultaneously filed a motion for temporary restraining order and preliminary injunction seeking to enjoin the Company from undergoing a corporate restructuring that would separate the Company's talc liabilities from its other assets. The Bankruptcy Court denied the motion. The Company thereafter filed a motion to dismiss the adversary proceeding. The Bankruptcy Court has not yet decided the motion to dismiss. In October 2021, the Company filed a Notice of Bankruptcy Filing and Stay of Proceedings clarifying that the automatic stay arising upon the filing of the LTL Bankruptcy Case should apply to the Imerys Adversary Proceeding.

In June 2020, Cyprus Mines Corporation and its parent, Cyprus Amax Minerals Company (CAMC) (together, Cyprus), which had owned certain Imerys talc mines, filed an adversary proceeding against the Company and Imerys in the Imerys Bankruptcy seeking a declaration of indemnity rights under certain contractual agreements (the Cyprus Adversary Proceeding). The Company denies such indemnification is owed, and filed a motion to dismiss the adversary complaint. In February 2021, Cyprus filed a voluntary petition for relief under chapter 11 of the Bankruptcy Code and filed its Disclosure Statement and Plan (the Cyprus Plan). The Cyprus Plan contemplates a settlement with Imerys and talc claimants where Cyprus would make a monetary contribution to a trust established under the Imerys Plan in exchange for an injunction against talc claims asserted against it and certain protected parties. Cyprus has not yet sought approval of its Disclosure Statement and Plan. Cyprus, along with the TCC and FCR appointed in the Cyprus chapter 11 case, have agreed to participate in the mediation with the Mediation Parties. In October 2021, the Company filed a Notice of Bankruptcy Filing and Stay of Proceedings clarifying that the automatic stay arising upon the filing of the LTL Bankruptcy Case should apply to the Cyprus Adversary Proceeding. In June 2022, Cyprus commenced an Adversary Proceeding in its chapter 11 case seeking an order enforcing the automatic stay by enjoining parties from commencing or continuing "talc-related claims" against CAMC. In June 2022, the court entered a preliminary injunction order enjoining claimants from pursuing talc-related claims against CAMC through January 2023.

In February 2021, several of the Company's insurers involved in coverage litigation in New Jersey State Court (the Coverage Action) filed a motion in the Imerys Bankruptcy Court proceeding seeking a determination that the automatic stay does not apply to the Coverage Action and, in the alternative, seeking relief from the automatic stay to allow them to continue to litigate their claims in the Coverage Action. In March 2021, the Company filed a limited response and reservation of rights with respect to the motion. The Court entered an agreed order modifying the stay to allow the litigation in the Coverage Action to continue. In October 2021, LTL filed a Notice of Bankruptcy Filing and Stay of Proceedings clarifying that the automatic stay arising upon the filing of the LTL Bankruptcy Case should apply to the Coverage Action. In March 2022, the New Jersey Bankruptcy Court ruled that the LTL automatic stay applied to the Coverage Action.

In February 2018, a securities class action lawsuit was filed against the Company and certain named officers in the United States District Court for the District of New Jersey, alleging that the Company violated the federal securities laws by failing to disclose alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S Baby Powder, and that purchasers of the Company's shares suffered losses as a result. Plaintiff is seeking damages. In April 2019, the Company moved to dismiss the complaint and briefing on the motion was complete as of August 2019. In December 2019, the Court denied, in part, the motion to dismiss. In March 2020, the Company answered the complaint. In April 2021, briefing on Plaintiff's motion for class certification was completed. In July 2021, the Company filed a notice of supplemental authority in opposition to Plaintiff's motion for class certification, and Plaintiff filed a response. In December 2021, the Company filed a motion to supplement the class certification record, and in January 2022, Plaintiff responded. In March 2022, LTL asked the New Jersey Bankruptcy Court to stay the securities class action. In April 2022, Defendants filed a second motion to supplement the class certification record. In May 2022, the New Jersey Bankruptcy Court entered an order staying the securities class action. Plaintiff has appealed the Bankruptcy Court's order.

A lawsuit was brought against the Company in the Superior Court of California for the County of San Diego alleging violations of California's Consumer Legal Remedies Act (CLRA) relating to JOHNSON'S Baby Powder. In that lawsuit, the plaintiffs allege that the Company violated the CLRA by failing to provide required Proposition 65 warnings. In July 2019, the Company filed a notice of removal to the United States District Court for the Southern District of California and plaintiffs filed a second amended complaint shortly thereafter. In October 2019, the Company moved to dismiss the second amended complaint for failure to state a claim upon which relief may be granted. In response to those motions, plaintiffs filed a third amended complaint. In December 2019, the Company moved to dismiss the third amended complaint for failure to state a claim upon which relief may be granted. In April 2020, the Court granted the motion to dismiss but granted leave to amend. In May 2020, plaintiffs filed a Fourth Amended Complaint but indicated that they would be filing a motion for leave to file a fifth amended complaint. Plaintiffs filed a Fifth Amended Complaint in August 2020. The Company moved to dismiss the Fifth Amended Complaint for failure to state a claim upon which relief may be granted. In January 2021, the Court issued an Order and opinion ruling in the Company's favor and granting the motion to dismiss with prejudice. In February 2021, Plaintiffs filed a Notice of Appeal with the Ninth Circuit. Plaintiffs filed their opening brief in July 2021. The company filed its responsive brief in October 2021. In October 2021, Notice of Suggestion of Bankruptcy was filed with the Ninth Circuit. A bankruptcy stay was imposed in December 2021, and the Court held the reply deadline in abeyance. In February 2022, the Bankruptcy Court issued an order extending the stay. The appeal continues to be held in abeyance, with the Company being required to file periodic status updates.

In addition, the Company has received inquiries, subpoenas, and requests to produce documents regarding talc matters and the LTL Bankruptcy Case from various governmental authorities. The Company has produced documents and responded to inquiries, and will continue to cooperate with government inquiries.

Claims for personal injury have been made against a number of Johnson & Johnson companies, including Janssen Pharmaceuticals, Inc. and the Company, arising out of the use of INVOKANA, a prescription medication indicated to improve glycemic control in adults with Type 2 diabetes. In December 2016, lawsuits filed in federal courts in the United States were organized as a multi-district litigation in the United States District Court for the District of New Jersey. Cases have also been filed in state courts. Class action lawsuits have been filed in Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has settled or otherwise resolved many of the cases and claims in the United States and the costs associated with these settlements are reflected in the Company's accruals.

Claims for personal injury have been made against a number of Johnson & Johnson companies, including Janssen Pharmaceuticals, Inc. and the Company, arising out of the use of ELMIRON, a prescription medication indicated for the relief of bladder pain or discomfort associated with interstitial cystitis. These lawsuits, which allege that ELMIRON contributes to the development of permanent retinal injury and vision loss, have been filed in both state and federal courts across the United States. In December 2020, lawsuits filed in federal courts in the United States, including putative class action cases seeking medical monitoring, were organized as a multi-district litigation in the United States District Court for the District of New Jersey. In addition, cases have been filed in various state courts of New Jersey, which have been coordinated in a multi-county litigation in Bergen County, as well as the Court of Common Pleas in Philadelphia, which have been coordinated and granted mass tort designation. In addition, three class action lawsuits have been filed in Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has established accruals for defense and indemnity costs associated with ELMIRON related product liability litigation.

Claims for personal injury have been made against Johnson and Johnson Consumer Inc. (JJCI), arising out of the use of TYLENOL, an over-the-counter pain medication, alleging that prenatal exposure to acetaminophen is associated with the development of autism spectrum disorder and/or attention-deficit/hyperactivity disorder. In October 2022, lawsuits filed in federal courts in the United States were organized as a multi-district litigation in the United States District Court for the Southern District of New York. In addition, lawsuits have been filed in Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has established accruals for defense costs associated with TYLENOL related product liability litigation.

INTELLECTUAL PROPERTY

Certain subsidiaries of the Company are subject, from time to time, to legal proceedings and claims related to patent, trademark and other intellectual property matters arising out of their businesses. Many of these matters involve challenges to the coverage and/or validity of the patents on various products and allegations that certain of the Company's products infringe the patents of third parties. Although these subsidiaries believe that they have substantial defenses to these challenges and allegations with respect to all significant patents, there can be no assurance as to the outcome of these matters. A loss in any of these cases could adversely affect the ability of these subsidiaries to sell their products, result in loss of sales due to loss of market exclusivity,

require the payment of past damages and future royalties, and may result in a non-cash impairment charge for any associated intangible asset. Significant matters are described below.

MedTech

In August 2018, Intuitive Surgical, Inc. and Intuitive Surgical Operations, Inc. (collectively, Intuitive) filed a patent infringement suit against Auris Health, Inc. (Auris) in United States District Court for the District of Delaware. In the suit, Intuitive alleges willful infringement of U.S. Patent Nos. 6,522,906 ('906); 6,800,056 ('056); 8,142,447 ('447); and 9,452,276 ('276) based on Auris' MONARCH Platform. Auris filed IPR Petitions with the U.S. Patent and Trademark Office (USPTO) regarding the '056, '447, '276 and '906 patents. In December 2019, the USPTO denied review of the '056 patent. In February and March 2020, the USPTO instituted review of the '447, and '906 patents and denied review of the '276 patent. In March 2021, the USPTO ruled that the challenged claims of the '447 and '906 patents are not invalid. Auris appealed, and in April 2022, the United States Court of Appeals for the Federal Circuit vacated the decision that the '447 patent was not invalid and remanded the decision to the USPTO for further review. In May 2022, the United States Court of Appeals for the Federal Circuit confirmed the ruling that claim 53 of the '906 patent was not invalid, vacated the decision that the remaining claims of the '906 patent were not invalid and remanded the decision to the USPTO for further review. Auris filed a request for reexamination of the '276 patent in November 2021, and in January 2022, the USPTO granted the reexamination request. Trial is scheduled to begin in September 2023.

In August 2019, RSB Spine LLC (RSB Spine) filed a patent infringement suit against DePuy Synthes, Inc. in the United States District Court for the District of Delaware. In October 2019, RSB Spine amended the complaint to change the named defendants to DePuy Synthes Sales, Inc. and DePuy Synthes Products, Inc. In the suit, RSB Spine alleges willful infringement of U.S. Patent Nos. 6,984,234 ('234) and 9,713,537 ('537) by one or more of the following products: ZERO-P-VA Spacer, ZERO-P Spacer, ZERO-P NATURAL Plate, SYNFIX LR Spacer and SYNFIX Evolution System. RSB Spine seeks monetary damages and injunctive relief. In November 2019, the suit was consolidated for pre-trial purposes with other patent infringement suits brought by RSB Spine in the United States District Court for the District of Delaware against Life Spine, Inc., Medacta USA, Inc., and Precision Spine, Inc. In June 2022, DePuy filed potentially dispositive summary judgment motions that the '234 patent is invalid as anticipated and the '537 patent is not infringed. In November 2022, the Court granted DePuy's summary judgment motion that the '234 patent is invalid as anticipated and denied DePuy's motion that the '537 patent is not infringed. In December 2022, the Court conducted a jury trial on the '537 patent where the jury found that the '537 patent was not literally infringed, but that DePuy infringed under the doctrine of equivalents (DOE). The jury awarded RSB $12 million in damages subject to post-trial motions and appeals.

In October 2020, Rasmussen Instruments, LLC (Rasmussen) filed a patent infringement suit against DePuy Synthes Products, Inc., DePuy Synthes Sales, Inc. and Medical Device Business Services, Inc. (collectively, DePuy) in the United States District Court for the District of Massachusetts. Rasmussen alleges that DePuy willfully infringes U.S. Patent Nos. 9,492,180 ('180) and 10,517,583 ('583) by making and selling the Attune Balanced Sizer. In April 2021, Rasmussen sought permission to amend its infringement contentions to allege that DePuy also willfully infringes the '583 patent by making and selling the Attune Balancing Blocks. Rasmussen seeks treble damages for willful infringement. Trial concluded in March 2022, with the jury returning a verdict in favor of Rasmussen, finding willful infringement of the '180 patent, and awarding damages in the amount of $20 million. DePuy challenged the verdict in its post-trial motions. In July 2022, a hearing was held on the post-trial motions.

Pharmaceutical
Litigation Against Filers of Abbreviated New Drug Applications (ANDAs)

The following summarizes lawsuits the Company's subsidiaries have brought against generic companies that have filed ANDAs with the U.S. FDA or undertaken similar regulatory processes outside of the United States, seeking to market generic forms of products sold by various subsidiaries of the Company prior to expiration of the applicable patents covering those products. These ANDAs typically include allegations of non-infringement and invalidity of the applicable patents. The Inter Partes Review (IPR) process with the USPTO, created under the 2011 America Invents Act, is also being used at times by generic companies in conjunction with ANDAs and lawsuits, to challenge the applicable patents. In the event the Company's subsidiaries are not successful in an action, or the automatic statutory stay of the ANDAs expires before the United States District Court rulings are obtained, the generic companies involved would have the ability, upon approval of the U.S. FDA, to introduce generic versions of their products to the market, resulting in the potential for substantial market share and revenue losses for the applicable products, and which may result in a non-cash impairment charge in any associated intangible asset. In addition, from time to time, the Company's subsidiaries may settle these types of actions and such settlements can involve the introduction of generic versions of the products at issue to the market prior to the expiration of the relevant patents.

ZYTIGA

Beginning in January 2019, Janssen Inc., Janssen Oncology, Inc., and BTG International Ltd. (collectively, Janssen) initiated Statements of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations in Canada against Apotex Inc. (Apotex), Pharmascience Inc. (Pharmascience) and Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, DRL) in response to those parties' filing of Abbreviated New Drug Submissions (ANDS) seeking approval to market generic versions of ZYTIGA before the expiration of the Canadian Patent No. 2,661,422 ('422). The trial in these actions concluded in November 2020, and the Court issued a decision holding the '422 patent invalid in January 2021. In February 2021, Janssen appealed the decision. The appeal hearing took place in September 2022. In November 2022, Janssen's appeal was dismissed.

In April 2021, July 2021 and April 2022, respectively, Apotex, DRL and Pharmascience initiated Statements of Claim under Section 8 of the Patented Medicines (Notice of Compliance) Regulations against Janssen seeking damages in respect of those parties generic Zytiga tablets. Trials against Apotex and DRL are scheduled for June 2023. A trial date for the Pharmascience action has not been set.

XARELTO

Beginning in March 2021, Janssen Pharmaceuticals, Inc. (JPI) and Bayer Pharma AG and Bayer AG (collectively, Bayer) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of XARELTO (2.5 mg) before expiration of U.S. Patent No. 10,828,310 ('310). The following generic drug companies are named defendants: Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd.; Lupin Limited and Lupin Pharmaceuticals, Inc.; Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals U.S.A., Inc.; and Teva Pharmaceuticals USA, Inc. In October 2021, the court consolidated the Delaware lawsuits for all purposes, including trial. Trial for the consolidated Delaware lawsuits is scheduled to begin in May 2023.

In July 2021, JPI and Bayer filed a patent infringement lawsuit in the United States District Court for the Northern District of West Virginia against Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, Mylan) which filed an ANDA seeking approval to market a generic version of XARELTO (2.5 mg) before expiration of the '310 patent. In August 2021, JPI and Bayer filed a motion before the United States Judicial Panel on Multidistrict Litigation (the MDL panel) to transfer this lawsuit to the United States District Court for the District of Delaware for coordinated and consolidated pretrial proceedings. In December 2021, the MDL panel granted the motion. In August 2022, after receiving a second notice letter from Mylan regarding the same ANDA, JPI and Bayer filed a second patent infringement lawsuit in the United States District Court for the Northern District of West Virginia against Mylan. In September 2022, Mylan moved to dismiss the second lawsuit. In September 2022, the MDL panel transferred the second lawsuit to the District of Delaware. No trial date has been set for these two lawsuits. In October 2022, Mylan voluntarily withdrew its motion to dismiss.

In each of these lawsuits, JPI and Bayer are seeking an order enjoining defendants from marketing their generic version of XARELTO (2.5 mg) before the expiration of the '310 patent. In January 2023, the court issued an order staying the lawsuits until after a final written decision is issued in the Inter Partes Review proceedings on the '310 patent.

In February 2022, Mylan Pharmaceuticals Inc. filed a Petition for Inter Partes Review (IPR) with the United States Patent and Trademark Office (USPTO), seeking to invalidate the '310 patent. In August 2022, the Patent Trial and Appeal Board (PTAB) issued a decision instituting IPR.

In September 2022, InvaGen Pharmaceuticals, Inc. filed a Petition for IPR with the USPTO seeking to invalidate the '310 patent. Also in September 2022, Teva Pharmaceuticals USA, Inc. filed a Petition for IPR with the USPTO seeking to invalidate the '310 patent. In October 2022, the PTAB issued decisions instituting IPR in both proceedings and joining them with the earlier IPR proceeding filed by Mylan Pharmaceuticals Inc.

In September 2022, JPI, Bayer, and Bayer Intellectual Property GmbH (BIP) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against USV Private Limited (USV), who filed an ANDA seeking approval to market generic versions of XARELTO (2.5 mg, 10 mg, 15 mg, and 20 mg) before the expiration of the '310 patent and U.S. Patent No. 9,539,218 ('218). JPI, Bayer, and BIP are seeking an order enjoining USV from marketing its generic version of XARELTO (2.5 mg) before the expiration of the '310 patent, and its generic versions of XARELTO (10 mg, 15 mg, and 20 mg) before the expiration of the '218 patent. In November 2022, the MDL panel transferred this lawsuit to the United States District Court for the District of Delaware.

In September 2022, JPI, Bayer AG, and BIP initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Mankind Pharma Limited (Mankind), who filed an ANDA seeking approval to market generic versions of XARELTO (10 mg, 15 mg, and 20 mg) before the expiration of the ’218 patent. JPI, Bayer AG, and BIP are seeking an order enjoining Mankind from marketing its generic versions of XARELTO before the expiration of the ’218 patent.

In November 2022, JPI, Bayer, and BIP initiated a patent infringement lawsuit in the United States District Court for the District of Delaware against Epic Pharma, LLC (Epic), who filed an ANDA seeking approval to market generic versions of XARELTO (2.5 mg, 10 mg, 15 mg, and 20 mg) before the expiration of the ’310 patent and the ’218 patent. JPI, Bayer, and BIP are seeking an order enjoining Epic from marketing its generic version of XARELTO (2.5 mg) before the expiration of the ’310 patent, and its generic versions of XARELTO (10 mg, 15 mg, and 20 mg) before the expiration of the ’218 patent.

In December 2022, JPI and Bayer initiated a patent infringement lawsuit in the United States District Court for the District of Delaware against Apotex Inc. and Apotex Corp. (collectively, Apotex), who filed an ANDA seeking approval to market generic versions of XARELTO (2.5 mg) before the expiration of the ’310 patent. JPI and Bayer are seeking an order enjoining Apotex from marketing its generic version of XARELTO (2.5 mg) before the expiration of the ’310 patent.

OPSUMIT

In May 2020, Janssen Inc. (Janssen) and Actelion Pharmaceuticals Ltd (Actelion) initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Sandoz Canada Inc. (Sandoz) in Canada in response to Sandoz’s filing of an ANDS seeking approval to market a generic version of OPSUMIT 10 mg, before the expiration of Canadian Patent No. 2,659,770 (’770). Sandoz stipulated to infringement of the ’770 patent. Trial against Sandoz on the issue of validity concluded in February 2022, and in May 2022, the Court issued a decision in favor of Janssen and Actelion. In June 2022, Sandoz appealed the decision.

In May 2020, Janssen and Actelion initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex Inc. (Apotex) in Canada in response to Apotex’s filing of an ANDS seeking approval to market a generic version of OPSUMIT 10 mg, before the expiration of the ’770 patent. Apotex stipulated to validity of the ’770 patent. Trial against Apotex on the issue of infringement concluded in March 2022, and in May 2022, the Court issued a decision in favor of Janssen and Actelion. In June 2022, Apotex appealed the decision.

In January 2023, Janssen and Actelion initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Generic Medical Partners Inc. (GMP) in Canada in response to GMP’s filing of an ANDS seeking approval to market a generic version of OPSUMIT 10 mg, before the expiration of Canadian Patent Nos. 2,659,770 and 2,621,273.

In each of these Canadian actions, Janssen and Actelion are seeking an order enjoining the defendants from marketing their generic versions of OPSUMIT before the expiration of the relevant patents.

In January 2023, Actelion Pharmaceuticals Ltd and Actelion Pharmaceuticals US, Inc. (collectively, Actelion) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc. (collectively, Sun) who filed an ANDA seeking approval to market a generic version of OPSUMIT before the expiration of U.S. Patent Nos. 7,094,781 (’781) and 10,946,015 (’015). Actelion is seeking an order enjoining Sun from marketing their generic versions of OPSUMIT before the expiration of the ’781 and ’015 patents.

INVEGA SUSTENNA

In January 2018, Janssen Pharmaceutica NV and Janssen Pharmaceuticals, Inc. (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva Pharmaceuticals USA, Inc. (Teva), which filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of U.S. Patent No. 9,439,906 (’906). Trial concluded in October 2020. In October 2021, the court issued a decision in Janssen’s favor. Teva has appealed the decision.

In August 2019, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Mylan Laboratories Limited (Mylan), which filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of the ’906 patent. Pursuant to an agreement by the parties, judgment in favor of Janssen was entered in December 2021. Mylan appealed.

In December 2019, Janssen initiated a patent infringement lawsuit in the United States District Courts for the Districts of New Jersey and Delaware against Pharmascience Inc., Mallinckrodt PLC and Specgx LLC (collectively, Pharmascience), which filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of the ’906 patent.

In November 2021, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of Delaware against Tolmar, Inc., Tolmar Therapeutics, Inc., Tolmar Pharmaceuticals, Inc. and Tolmar Holding, Inc. (collectively, Tolmar), which filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of the ’906 patent. A trial is scheduled to begin in October 2023.

In February 2022, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Accord Healthcare, Inc., Accord Healthcare, Ltd. and Intas Pharmaceuticals, Ltd. (collectively, Accord), who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of the ’906 patent.

In each of these U.S. lawsuits, Janssen is seeking an order enjoining the defendant from marketing a generic version of INVEGA SUSTENNA before the expiration of the relevant patents.

In February 2018, Janssen Inc. and Janssen Pharmaceutica NV (collectively, Janssen Canada) initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Teva Canada Limited (Teva Canada) in response to Teva’s filing of an ANDS seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of Canadian Patent Nos. 2,309,629 (’629) and 2,655,335 (’335). Janssen subsequently discontinued the portion of the lawsuit relating to the ’629 patent. In May 2020, the Canadian Federal Court issued a Public Judgment and Reasons declaring that Teva Canada’s generic version of INVEGA SUSTENNA, if approved, would infringe certain claims of the ’335 patent and that the claims of the ’335 patent are not invalid. Teva Canada appealed.

In November 2020, Janssen Canada initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Pharmascience Inc. in response to Pharmascience Inc.’s filing of an ANDS seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of the ’335 patent. A summary trial on the issue of infringement took place in November 2021. In January 2022, the Court issued a decision in favor of Janssen on the issue of infringement. Pharmascience filed an appeal. In March 2022, Janssen Canada initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Pharmascience in response to Pharmascience’s filing of an ANDS seeking approval to market a generic version of an additional strength of INVEGA SUSTENNA before the expiration of the ’335 patent. The action has been consolidated with the November 2020 action for trial, which took place in July 2022. In August 2022, the Court issued a decision finding the claims of the’335 patent are not invalid. Pharmascience appealed.

In January 2021, Janssen Canada initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex Inc. (Apotex) in response to Apotex’s filing of an ANDS (original ANDS) seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of the ’335 patent. A summary trial on the issue of infringement took place in December 2021. In January 2022, the Court issued a decision in favor of Janssen on the issue of infringement. Apotex appealed.

In June 2022, Janssen Canada initiated Statements of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex in response to Apotex’s Notice of Allegation of invalidity with respect to the original ANDS and in response to Apotex’s filing of an ANDS seeking approval to market a generic version of an additional strength of INVEGA SUSTENNA before the expiration of the ’335 patent. A trial is scheduled to begin in March 2024.

In each of these Canadian lawsuits, Janssen Canada is seeking an order enjoining the defendant from marketing a generic version of INVEGA SUSTENNA before the expiration of the relevant patents.

INVEGA TRINZA

In September 2020, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV, and Janssen Research & Development, LLC (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Mylan Laboratories Limited, Mylan Pharmaceuticals Inc., and Mylan Institutional LLC (collectively, Mylan). Mylan filed an ANDA seeking approval to market generic versions of INVEGA TRINZA (546 mg) before expiration of U.S. Patent No. 10,143,693 (’693) relating to INVEGA TRINZA (546 mg).

In August 2021, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Mylan. Mylan filed an ANDA seeking approval to market generic versions of INVEGA TRINZA (819 mg) before expiration of the ’693 patent.

In October 2021, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Mylan. Mylan filed an ANDA seeking approval to market generic versions of INVEGA TRINZA (273 mg and 410 mg) before expiration of the ’693 patent.

In January 2022, the court consolidated the three cases into the case filed in September 2020. In each of these consolidated cases, Janssen is seeking an order enjoining Mylan from marketing its generic versions of INVEGA TRINZA before expiration of the ’693 patent. Trial was conducted in November and December 2022, and post-trial briefing is proceeding. Closing arguments will be held in March 2023.

IMBRUVICA

In March 2019, Pharmacyclics LLC (Pharmacyclics) and Janssen Biotech, Inc. (JBI) filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Alvogen Pine Brook LLC and Natco Pharma Ltd. (collectively, Alvogen), which filed an ANDA seeking approval to market generic versions of IMBRUVICA tablets, asserting infringement of U.S. Patent Nos. 7,514,444; 8,003,309; 8,476,284; 8,497,277; 8,697,711; 8,753,403; 8,754,090; 8,754,091; 8,952,015; 8,957,079; 9,181,257; 9,296,753; 9,655,857; 9,725,455; 10,010,507; 10,106,548; and 10,125,140. In June 2019, Pharmacyclics and JBI amended their complaint against Alvogen to further allege infringement of U.S. Patent No. 10,213,386.

Trial against Alvogen took place in October 2020. In August 2021, the District Court issued a decision in favor of Pharmacyclics and Janssen finding the asserted claims against Alvogen to be infringed and not invalid. In November 2022, the United States Court of Appeals for the Federal Circuit affirmed the District Court’s decision.

In September 2021, Pharmacyclics and Janssen Inc. (Janssen Canada) initiated Statements of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Natco Pharma (Canada) Inc. (Natco) in response to Natco’s filing of two ANDSs seeking approval to market generic versions of IMBRUVICA capsules before the expiration of Canadian Patent Nos. 2,663,116 (’116); 2,928,721 (’721); 2,800,913 (’913); 3,007,787 (’787); 3,007,788 (’788); 2,875,986 (’986); and 3,022,256 (’256). In this lawsuit, Pharmacyclics and Janssen Canada are seeking an order enjoining Natco from marketing its generic version of IMBRUVICA before the expiration of the relevant patents. Trial is scheduled to begin in July 2023.

In October 2022, Pharmacyclics and Janssen Canada initiated a second Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Natco in response to Natco’s filing of an ANDS seeking approval to market a generic version of IMBRUVICA capsules before the expiration of the ’116, ’721, ’913, ’787, and ’788 patents and Canadian Patent No. 2,851,808. In this lawsuit, Pharmacyclics and Janssen Canada are seeking an order enjoining Natco from marketing its generic version of IMBRUVICA capsules before the expiration of the relevant patents. Trial in this second action is scheduled to begin in August 2024.

In February 2023, Pharmacyclics and Janssen Canada initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Sandoz Canada Inc. (Sandoz) in response to Sandoz’s filing of an ANDS seeking approval to market a generic version of IMBRUVICA capsules before the expiration of the ’116, ’913, ’787, and ’788 patents. Also in February 2023, Pharmacyclics and Janssen initiated a Statement of Claim under Section 8.2 of the Patented Medicines (Notice of Compliance) Regulations against Sandoz asserting the ’721 and ’256 patents, which are also listed in Health Canada’s Patent Register for IMBRUVICA. In these lawsuits, Pharmacyclics and Janssen Canada are seeking an order enjoining Sandoz from marketing its generic version of IMBRUVICA capsules before the expiration of the relevant patents. A trial date for these actions has not been set.

SYMTUZA

In November 2021, Janssen Products, L.P. and Janssen Sciences Ireland Unlimited Company (collectively, Janssen) and Gilead Sciences, Inc. and Gilead Sciences Ireland UC (collectively, Gilead) initiated a patent infringement lawsuit in the United States District Court for the District of Delaware against Lupin Limited, Lupin Pharmaceuticals, Inc., MSN Laboratories Private Ltd., MSN Life Sciences Private Ltd., and MSN Pharmaceuticals Inc. (collectively, Lupin), which filed an ANDA seeking approval to market a generic version of SYMTUZA before the expiration of U.S. Patent Nos. 10,039,718 (’718) and 10,786,518 (’518). The trial is scheduled to begin in October 2023.

In October 2022, Janssen Products, L.P. and Janssen Sciences Ireland Unlimited Company (collectively, Janssen) and Gilead Sciences, Inc. and Gilead Sciences Ireland UC (collectively, Gilead) initiated a patent infringement lawsuit in the United States District Court for the District of Delaware against Apotex Inc. and Apotex Corp. (collectively, Apotex), which filed an ANDA seeking approval to market a generic version of SYMTUZA before the expiration of the ’718 and ’518 patents.

In each of these U.S. lawsuits, Janssen is seeking an order enjoining the defendant from marketing a generic version of SYMTUZA before the expiration of the relevant patents.

ERLEADA

In May 2022, Aragon Pharmaceuticals, Inc. and Janssen Biotech, Inc. (collectively, Janssen) and Sloan Kettering Institute for Cancer Research (SKI) initiated patent infringement lawsuits in United States District Court for the Districts of New Jersey and Delaware against Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, Lupin), which filed an ANDA seeking approval to market a generic version of ERLEADA before the expiration of U.S. Patent No. 9,481,663 ('663). In August 2022, Janssen and SKI filed a first amended complaint against Lupin adding U.S. Patent Nos. 9,884,054 ('054), 10,052,314 ('314), 10,702,508 ('508) and 10,849,888 ('888) to the suit. Janssen and SKI are seeking an order enjoining Lupin from marketing its generic version of ERLEADA before the expiration of the '663, '054, '314, '508, and '888 patents. In August 2022, Janssen and SKI voluntarily dismissed the Delaware complaint. The New Jersey action is proceeding.

In May 2022, Janssen and SKI initiated a patent infringement lawsuit in United States District Court for the District of New Jersey against Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA), Inc., and Zydus Lifesciences Limited (collectively, Zydus), which filed an ANDA seeking approval to market a generic version of ERLEADA before the expiration of the '663, '054, '314, '508, and '888 patents. Janssen and SKI are seeking an order enjoining Zydus from marketing its generic version of ERLEADA before the expiration of the '663, '054, '314, '508, and '888 patents.

In May 2022, Janssen, The Regents of the University of California (UC), and SKI initiated patent infringement lawsuits in United States District Court for the Districts of New Jersey and Delaware against Sandoz Inc. (Sandoz), which filed an ANDA seeking approval to market a generic version of ERLEADA before the expiration of the '663 patent and U.S. Patent Nos. 8,445,507 ('507), 8,802,689 ('689), 9,338,159 ('159), and 9,987,261 ('261). In August 2022, Janssen, UC, and SKI filed a first amended complaint against Sandoz adding the '054, '314, '508, and '888 patents to the suit. In August 2022, Janssen, UC, and SKI voluntarily dismissed the Delaware complaint. In December 2022, Janssen, UC, and SKI filed a second amended complaint against Sandoz withdrawing the '054, '314, '508, and '888 patents from the suit without prejudice. Janssen, UC, and SKI are seeking an order enjoining Sandoz from marketing its generic version of ERLEADA before the expiration of the '663, '507, '689, '159, and '261 patents. The New Jersey action is proceeding.

In May 2022, Janssen, UC, and SKI initiated patent infringement lawsuits in United States District Court for the Districts of New Jersey and Delaware against Eugia Pharma Specialities Limited, Aurobindo Pharma USA, Inc., and Auromedics Pharma LLC (collectively, Eugia), which filed an ANDA seeking approval to market a generic version of ERLEADA before the expiration of the '663, '507, '689, '159 and '261 patents. In September 2022, Janssen, UC, and SKI filed a first amended complaint against Eugia adding U.S. Patent Nos. 9,884,054 ('054), 10,052,314 ('314), 10,702,508 ('508) and 10,849,888 ('888) to the suit. In September 2022, Janssen, UC, and SKI voluntarily dismissed the Delaware complaint. Janssen, UC, and SKI are seeking an order enjoining Eugia from marketing its generic version of ERLEADA before the expiration of the '663,'507, '689, '159, '261, '054, '314, '508, and '888 patents. The New Jersey action is proceeding.

In May 2022, Janssen, UC, and SKI initiated patent infringement lawsuits in United States District Court for the Districts of New Jersey and Delaware against Hetero Labs Limited Unit V and Hetero USA, Inc. (collectively, Hetero), which filed an ANDA seeking approval to market a generic version of ERLEADA before the expiration of the '663, '507,'054, '314,'508, and '888 patents. Janssen, UC, and SKI are seeking an order enjoining Hetero from marketing its generic version of ERLEADA before the expiration of the '663, '507, '054, '314, '508 and '888 patents. In August 2022, Janssen, UC, and SKI voluntarily dismissed the Delaware complaint. The New Jersey action is proceeding.

UPTRAVI

In August 2022, Actelion Pharmaceuticals Ltd, and Janssen Inc. (collectively, Janssen) and Nippon Shinyaku Co. (Nippon Shinyaku) initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Sandoz Canada Inc. in response to Sandoz's filing of an ANDS seeking approval to market generic versions of UPTRAVI tablets before the expiration of Canadian Patent Nos. 2,731,370 and 2,764,475. In this lawsuit, Janssen and Nippon Shinyaku are seeking an order enjoining Sandoz from marketing its generic version of UPTRAVI before the expiration of the relevant patents. A trial is scheduled to begin in May 2024.

In November 2022, Actelion Pharmaceuticals US Inc. and Actelion Pharmaceuticals Ltd (collectively, Actelion) and Nippon Shinyaku Co., Ltd. (Nippon Shinyaku) initiated a patent infringement lawsuit in the United States District Court for the District of Delaware against Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals Inc. (collectively, Alembic) who filed an

ANDA seeking approval to market generic versions of UPTRAVI injection for intravenous use before expiration of U.S. Patent Nos. 8,791,122 ('122) and 9,284,280 ('280) relating to UPTRAVI. In this lawsuit, Actelion and Nippon Shinyaku are seeking an order enjoining Alembic from marketing a generic version of UPTRAVI before the expiration of the relevant patents. A trial date has not been set.

In February 2023, Actelion and Nippon Shinyaku initiated a patent infringement lawsuit in the United States District Court for the District of Delaware against Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, Lupin) who filed an ANDA seeking approval to market generic versions of UPTRAVI injection for intravenous use before expiration of the '122 and '280 patents relating to UPTRAVI. In this lawsuit, Actelion and Nippon Shinyaku are seeking an order enjoining Lupin from marketing a generic version of UPTRAVI before the expiration of the relevant patents. A trial date has not been set.

Other Litigation

In November 2021, Janssen Pharmaceutica N.V. (Janssen) provided to Alkermes Pharma Ireland Limited, Elan Pharma International Limited, and Elan Drug Delivery, Inc. three-months' notice of termination of a License Agreement by and among Elan Pharmaceutical Research Corp., d/b/a Nanosystems, Elan Pharma International Limited and Janssen, executed in March, 1999. In November 2021, Janssen also provided to Alkermes Pharma Ireland Limited three-months' notice of termination of a License Agreement between Elan Pharma International Limited and Janssen executed in July 2003. In April 2022, in response to these notices, Alkermes Pharma Ireland Limited (Alkermes) initiated arbitration in the International Institute for Conflict Prevention and Resolution. The parties exchanged opening briefs in July 2022 and responsive briefs in September 2022. In December 2022, the Arbitration Tribunal issued an Interim Decision finding that Janssen may terminate the agreements, but it may not continue to sell products developed during the term of the agreements without continuing to pay royalties to Alkermes.

GOVERNMENT PROCEEDINGS

Like other companies in the pharmaceutical, consumer health and medical devices industries, the Company and certain of its subsidiaries are subject to extensive regulation by national, state and local government agencies in the United States and other countries in which they operate. Such regulation has been the basis of government investigations and litigations. The most significant litigation brought by, and investigations conducted by, government agencies are listed below. It is possible that criminal charges and substantial fines and/or civil penalties or damages could result from government investigations or litigation.

Average Wholesale Price (AWP) Litigation

The Company and several of its pharmaceutical subsidiaries (the J&J AWP Defendants), along with numerous other pharmaceutical companies, were named as defendants in a series of lawsuits in state and federal courts involving allegations that the pricing and marketing of certain pharmaceutical products amounted to fraudulent and otherwise actionable conduct because, among other things, the companies allegedly reported an inflated Average Wholesale Price (AWP) for the drugs at issue. Payors alleged that they used those AWPs in calculating provider reimbursement levels. The plaintiffs in these cases included three classes of private persons or entities that paid for any portion of the purchase of the drugs at issue based on AWP, and state government entities that made Medicaid payments for the drugs at issue based on AWP. Many of these cases, both federal actions and state actions removed to federal court, were consolidated for pre-trial purposes in a multi-district litigation in the United States District Court for the District of Massachusetts, where all claims against the J&J AWP Defendants were ultimately dismissed. The J&J AWP Defendants also prevailed in a case brought by the Commonwealth of Pennsylvania. Other AWP cases have been resolved through court order or settlement. The case brought by Illinois was settled after trial. In New Jersey, a putative class action based upon AWP allegations is pending against Centocor, Inc. and Ortho Biotech Inc. (both now Janssen Biotech, Inc.), the Company and ALZA Corporation. All other cases have been resolved.

Opioid Litigation

Beginning in 2014 and continuing to the present, the Company and Janssen Pharmaceuticals, Inc. (JPI), along with other pharmaceutical companies, have been named in close to 3,500 lawsuits related to the marketing of opioids, including DURAGESIC, NUCYNTA and NUCYNTA ER. The suits also raise allegations related to previously owned active pharmaceutical ingredient supplier subsidiaries, Tasmanian Alkaloids Pty, Ltd. and Noramco, Inc. (both subsidiaries were divested in 2016). The majority of the cases have been filed by state and local governments. Similar lawsuits have also been filed by private plaintiffs and organizations, including but not limited to the following: individual plaintiffs on behalf of children born with Neonatal Abstinence Syndrome; hospitals; and health insurers/payors. To date, complaints against pharmaceutical manufacturers, including the Company and JPI, have been filed by the state Attorneys General in Arkansas, Florida, Idaho, Illinois, Kentucky, Louisiana, Mississippi, Missouri, Nevada, New Hampshire, New Jersey, New Mexico, New York, Ohio, Oklahoma, South Dakota, Texas, Washington and West Virginia. Complaints against the manufacturers also have been filed in state or federal court by city, county and local government agencies in every state but Alaska. The Government of Puerto Rico filed suit in Superior Court of San Juan.

The Company, JPI and other pharmaceutical companies had also received subpoenas or requests for information related to opioids marketing practices from the following state Attorneys General: Alaska, Indiana, Montana, New Hampshire, South Carolina, Tennessee, Texas and Washington. In September 2017, the Company and JPI were contacted by the Texas and Colorado Attorney General's Offices on behalf of approximately 38 states regarding a multi-state Attorney General investigation.

In 2019, the trial in the matter filed by the Oklahoma Attorney General resulted in a judgment against the Company and JPI in the amount of $465 million. The Company and JPI appealed the judgment, and in November 2021, the Oklahoma Supreme Court reversed the trial court's judgment and directed entry of judgment for Defendants. In October 2019 the Company and JPI announced a settlement of the first case set for trial in the MDL with two counties in Ohio. In April 2021, three California counties and the City of Oakland commenced a trial in California state court against the Company and JPI, and other affiliates, as well as three other pharmaceutical manufacturers. The trial concluded in October 2021, and in December 2021, the Court entered a final trial judgment in favor of Defendants on all claims. In February 2022, Plaintiffs' motion to set aside and vacate the judgment was denied. Plaintiffs appealed the judgment, but later filed a request to dismiss the appeal after electing to participate in the national settlement agreement.

In October 2019, the Company announced a proposed agreement in principle that would include the Company paying $4 billion as settlement of these matters that had not been tried or settled. In October 2020, the Company agreed to contribute up to an additional $1 billion to an all-in settlement amount that would resolve opioid lawsuits filed and future claims by states, cities, counties and tribal governments, for a total of $5 billion which has been accrued, subject to various conditions and an agreement being finalized. This agreement is not an admission of liability or wrong-doing. In July 2021, the Company announced that the terms of the agreement to settle the state and subdivision claims had been finalized and approximately half of the all-in settlement was expected to be paid by the end of fiscal year 2022, depending upon the level of participation by the states and their subdivisions. The terms provided a period of time for states to elect to participate in the agreement and, thereafter, a period for the subdivisions of the participating states to opt-in. Based on expected participation, the Company committed in advance to proceed with the settlement in five of the participating states (New York, Texas, Florida, Nevada, and New Mexico) and with tribal governments. By late February 2022, 45 states, five territories, the District of Columbia, and the vast majority of eligible subdivisions had elected to participate in the settlement, and the Company confirmed that the level of participation was sufficient to proceed with the agreement as to all participants. The agreement was effective in April 2022. Also in April 2022, the Company entered into settlement agreements with the states of Alabama and West Virginia and their participating subdivisions. In July 2022, the Company reached a settlement agreement with all litigating Oklahoma subdivisions, and in September 2022, the Company settled with the State of New Hampshire and its participating subdivisions. Consequently, by the end of the fiscal year 2022, the Company had settled the opioid claims advanced by all states except Washington.

There are approximately 60 cases remaining post-settlement in various state courts. There are approximately 570 remaining federal cases against the Company and JPI coordinated in a federal Multi-District Litigation (MDL) pending in the U.S. District Court for the Northern District of Ohio, and approximately 20 additional cases pending against the Company and JPI in other federal courts. In addition, the Province of British Columbia filed suit against the Company and its Canadian affiliate Janssen Inc., and many other industry members, in Canada, and is seeking to have that action certified as an opt in class action on behalf of other provincial/territorial and the federal governments in Canada. Additional proposed class actions have been filed in Canada against the Company and Janssen Inc., and many other industry members, by and on behalf of people who used opioids (for personal injuries), municipalities and First Nations bands. In October 2019, an antitrust complaint was filed by private plaintiffs in federal court in Tennessee and is pending transfer to the MDL. These actions allege a variety of claims related to opioid marketing practices, including false advertising, unfair competition, public nuisance, consumer fraud violations, deceptive acts and practices, false claims and unjust enrichment. The suits generally seek penalties and/or injunctive and monetary relief and, in some of the suits, the plaintiffs are seeking joint and several liability among the defendants. An adverse judgment in any of these lawsuits could result in the imposition of large monetary penalties and significant damages including, punitive damages, cost of abatement, substantial fines, equitable remedies and other sanctions.

In August 2019, the Company received a grand jury subpoena from the United States Attorney's Office for the Eastern District of New York for documents related to the Company's anti-diversion policies and procedures and distribution of its opioid medications, in what the Company understands to be part of a broader investigation into manufacturers' and distributors' monitoring programs and reporting under the Controlled Substances Act.

From June 2017 through December 2019, the Company's Board of Directors received a series of shareholder demand letters alleging breaches of fiduciary duties related to the marketing of opioids. The Board retained independent counsel to investigate the allegations in the demands, and in April 2020, independent counsel delivered a report to the Board recommending that the

Company reject the shareholder demands and take the steps that are necessary or appropriate to secure dismissal of related derivative litigation. The Board unanimously adopted the recommendations of the independent counsel's report.

In November 2019, one of the shareholders who sent a demand filed a derivative complaint against the Company as the nominal defendant and certain current and former directors and officers as defendants in the Superior Court of New Jersey. The complaint alleges breaches of fiduciary duties related to the marketing of opioids, and that the Company has suffered damages as a result of those alleged breaches. A series of additional derivative complaints making similar allegations against the same and similar defendants were filed in New Jersey state and federal courts in 2019 and 2020. By 2022, all but two state court cases had been voluntarily dismissed. In February 2022, the state court granted the Company's motion to dismiss one of the two cases, and the shareholder that brought the second case filed a notice of dismissal. The shareholder whose complaint was dismissed filed a motion for reconsideration. In May 2022, the state court held oral argument on the motion for reconsideration and subsequently denied the motion. The shareholder has appealed the state court's dismissal order.

Other

In August 2012, DePuy Orthopaedics, Inc., DePuy, Inc. (now known as DePuy Synthes, Inc.), and Johnson & Johnson Services, Inc. (collectively DePuy) received an informal request from the United States Attorney's Office for the District of Massachusetts and the Civil Division of the United States Department of Justice (the United States) for the production of materials relating to the DePuy ASR XL Hip device. In July 2014, the United States notified the United States District Court for the District of Massachusetts that it had declined to intervene in a *qui tam* case filed pursuant to the False Claims Act against the companies concerning the hip devices. In February 2016, the District Court granted the companies' motion to dismiss with prejudice, unsealed the *qui tam* complaint, and denied the *qui tam* relators' request for leave to file a further amended complaint. The *qui tam* relators appealed the case to the United States Court of Appeals for the First Circuit. In July 2017, the First Circuit affirmed the District Court's dismissal in part, reversed in part, and affirmed the decision to deny the relators' request to file a third amended complaint. In March 2021, DePuy filed its motion to strike and dismiss the relators' second amended complaint; the District Court denied DePuy's motion to strike and dismiss in July 2021. DePuy filed a motion for reconsideration of the District Court's July 2021 ruling. In November 2021, the District Court granted DePuy's motion for reconsideration and dismissed the case with prejudice. The District Court's order was unsealed in December 2021. The relators filed several post-dismissal motions, including a January 2022 omnibus motion for reconsideration, which the District Court denied. Following the District Court's order dismissing the case with prejudice, DePuy filed a December 2021 motion seeking the recovery of attorneys' fees and costs, which the District Court denied except as to costs. The Relators have appealed the District Court's dismissal of the case to the First Circuit. The briefing on the appeal is complete, the First Circuit held oral argument on December 6, 2022, and the First Circuit's decision remains pending.

In October 2012, the Company was contacted by the California Attorney General's office regarding a multi-state Attorney General investigation of the marketing of surgical mesh products for hernia and urogynecological purposes by the Company's subsidiary, Ethicon, Inc. (Ethicon). In May 2016, California and Washington filed civil complaints against the Company, Ethicon and Ethicon US, LLC alleging violations of their consumer protection statutes. Similar complaints were filed against the companies by the following states: Kentucky, Mississippi, West Virginia and Oregon. In April 2019, the Company and Ethicon settled the Washington case. In October 2019, the Company and Ethicon settled the multi-state investigation with 41 other states and the District of Columbia. In April 2020, the Company settled the West Virginia case. In October 2020, the Company settled with the Attorney General of Oregon. In November 2020, the Company settled with the Attorney General of Mississippi. Trial in the Kentucky matter is scheduled for June 2023. The California case started trial in July 2019 and concluded in September 2019. In January 2020, the Court in California issued a statement of decision, finding in favor of the State of California, and awarded civil penalties in the amount of $344 million. In April 2020, the Court in California denied the Company's motion for a new trial. In August 2020, the Court entered judgment with respect to the penalties of $344 million, but denied the Attorney General's request for injunctive relief. The Company appealed the penalty judgment. In April 2022, the Court of Appeals reduced the judgment to $302 million, but otherwise denied the appeal. In July 2022, the Supreme Court of California denied the Company's petition to review the Court of Appeals decision, and the Company recorded a charge to reflect the judgment in the second quarter of 2022. In November 2022, the Company petitioned the United States Supreme Court for review.

In June 2014, the Mississippi Attorney General filed a complaint in Chancery Court of The First Judicial District of Hinds County, Mississippi against the Company and Johnson & Johnson Consumer Companies, Inc. (now known as Johnson & Johnson Consumer Inc.) (collectively, JJCI). The complaint alleges that JJCI violated the Mississippi Consumer Protection Act by failing to disclose alleged health risks associated with female consumers' use of talc contained in JOHNSON'S Baby Powder and JOHNSON'S Shower to Shower (a product divested in 2012) and seeks injunctive and monetary relief. The Company and JJCI moved for summary judgment on the grounds that the State's claim was barred by preemption, which the trial court denied. The Mississippi Supreme Court granted the Company and JJCI's request to file an interlocutory appeal of the denial of the motion for summary judgment in late 2019. Briefing and oral argument were completed. Thereafter, the Court

rejected the interlocutory appeal in April 2021 and remanded the matter to the trial court. In August 2021, JJCI filed a Petition for Writ of Certiorari in the United States Supreme Court as to the Mississippi Supreme Court's ruling of April 2021. In December 2021 the United States Supreme Court denied the Petition for Writ of Certiorari. After the Mississippi Supreme Court remanded the matter to the trial court, the State moved for a trial setting. JJCI objected to any trial setting as barred by the stay arising from the LTL Bankruptcy Case, referenced above, while the State argued that the stay did not apply. In January 2022, the Court granted the State's motion for trial setting and directed the parties to consult with the Court administrator to secure a trial date. In February 2022, the trial court set the case for trial to begin in February 2023. However, given the efforts to resolve talc-related claims in the LTL Bankruptcy Case, the Company and the State agreed to a temporary stay of discovery until May 2022. The temporary stay expired in May 2022. LTL thereafter moved to enjoin prosecution of the case in the LTL Bankruptcy Case. In October 2022, the bankruptcy court issued an order staying the case. The State filed an appeal to the Third Circuit concerning the stay order.

In January 2020, the State of New Mexico filed a consumer protection case alleging that the Company deceptively marketed and sold its talcum powder products by making misrepresentations about the safety of the products and the presence of carcinogens, including asbestos. The State of New Mexico filed an Amended Complaint in March 2020. The Company moved to dismiss certain of the claims in the Amended Complaint, which was granted. The Company then filed a motion for partial judgment on the pleadings in December 2020, which was denied. In March 2022, the New Mexico court denied the Company's motion to compel the State of New Mexico to engage in discovery of state agencies and denied the Company's request for interlocutory appeal of that decision. The Company then filed a Petition for Writ of Superintending Control and a Request for a Stay to the New Mexico Supreme Court on the issue of the State of New Mexico's discovery obligations. In April 2022, in view of the efforts to resolve talc-related claims in the LTL Bankruptcy Case, the Company and the State agreed to a 60-day stay of all matters except for the pending writ before the New Mexico Supreme Court, which expired in June 2022. Thereafter, the Company moved to enjoin prosecution of the case in the LTL Bankruptcy Case. In October 2022, the bankruptcy court issued an order staying the case. In December 2022, the State filed an appeal to the Third Circuit concerning the stay order. Separately, in September 2022, the New Mexico Supreme Court granted the Company's request for a stay pending further briefing on the scope of the State of New Mexico's discovery obligations.

Forty-two states and the District of Columbia have commenced a joint investigation into the Company's marketing of its talcum powder products. At this time, the multi-state group has not asserted any claims against the Company. Five states have issued Civil Investigative Demands seeking documents and other information. The Company has produced documents to Arizona, North Carolina, Texas, and Washington and entered into confidentiality agreements. The Company has not received any follow up requests from those states. In March 2022, each of the forty-two states (including Mississippi and New Mexico) agreed to mediation of their claims in the LTL Bankruptcy Case. In July 2022, New Mexico and Mississippi indicated they would no longer voluntarily submit to further mediation in the LTL Bankruptcy and would proceed with their respective cases in state court. LTL moved the New Jersey Bankruptcy Court for an order staying further proceedings in those two actions, which the Bankruptcy Court granted in October 2022. In December 2022, the Bankruptcy Court allowed New Mexico and Mississippi to file a direct appeal of its stay.

In July 2016, the Company and Janssen Products, LP were served with a qui tam complaint pursuant to the False Claims Act filed in the United States District Court for the District of New Jersey alleging the off-label promotion of two HIV products, PREZISTA and INTELENCE, and anti-kickback violations in connection with the promotion of these products. The complaint was filed under seal in December 2012. The federal and state governments have declined to intervene, and the lawsuit is being prosecuted by the relators. The Court denied summary judgment on all claims in December 2021. Daubert motions were granted in part and denied in part in January 2022, and the case is proceeding to trial.

In March 2017, Janssen Biotech, Inc. (JBI) received a Civil Investigative Demand from the United States Department of Justice regarding a False Claims Act investigation concerning management and advisory services provided to rheumatology and gastroenterology practices that purchased REMICADE or SIMPONI ARIA. In August 2019, the United States Department of Justice notified JBI that it was closing the investigation. Subsequently, the United States District Court for the District of Massachusetts unsealed a qui tam False Claims Act complaint, which was served on the Company. The Department of Justice had declined to intervene in the qui tam lawsuit in August 2019. The Company filed a motion to dismiss, which was granted in part and denied in part. Discovery is underway.

In April and September 2017, the Company received subpoenas from the United States Attorney for the District of Massachusetts seeking documents broadly relating to pharmaceutical copayment support programs for DARZALEX, OLYSIO, REMICADE, SIMPONI, STELARA and ZYTIGA. The subpoenas also seek documents relating to Average Manufacturer Price and Best Price reporting to the Center for Medicare and Medicaid Services related to those products, as well as rebate payments to state Medicaid agencies. The Company has provided documents in response to the subpoenas.

In June 2017, the Company received a subpoena from the United States Attorney's Office for the District of Massachusetts seeking information regarding practices pertaining to the sterilization of DePuy Synthes, Inc. (DePuy) spinal implants at three hospitals in Boston as well as interactions of employees of Company subsidiaries with physicians at these hospitals. The Company and DePuy fully cooperated with the government's investigation. In January 2023, the Company, DePuy Synthes, Inc., and DePuy Synthes Sales Inc. entered into a settlement agreement with the United States resolving the matter for an immaterial amount.

In July 2018, the Public Prosecution Service in Rio de Janeiro and representatives from the Brazilian antitrust authority CADE inspected the offices of more than 30 companies including Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda. The authorities appear to be investigating allegations of possible anti-competitive behavior and possible improper payments in the medical device industry. The Company continues to respond to inquiries regarding the Foreign Corrupt Practices Act from the United States Department of Justice and the United States Securities and Exchange Commission.

From time to time, the Company has received requests from a variety of United States Congressional Committees to produce information relevant to ongoing congressional inquiries. It is the policy of Johnson & Johnson to cooperate with these inquiries by producing the requested information.

GENERAL LITIGATION

Beginning in September 2017, multiple purported class actions were filed on behalf of indirect purchasers of REMICADE against the Company and Janssen Biotech, Inc. (collectively, Janssen) alleging that Janssen has violated federal antitrust laws through its contracting strategies for REMICADE. The cases were consolidated for pre-trial purposes as *In re REMICADE Antitrust Litigation* in United States District Court for the Eastern District of Pennsylvania. This case was settled in February 2022. The final approval hearing is scheduled for February 2023.

In June 2019, the United States Federal Trade Commission (FTC) issued a Civil Investigative Demand to the Company and Janssen Biotech, Inc. (collectively, Janssen) in connection with its investigation of whether Janssen's REMICADE contracting practices violate federal antitrust laws. The Company has produced documents and information responsive to the Civil Investigative Demand. Janssen is in ongoing discussions with the FTC staff regarding its inquiry.

In February 2022, the United States Federal Trade Commission (FTC) issued Civil Investigative Demands to Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) in connection with its investigation of whether advertising practices for REMICADE violate federal law. Janssen has produced documents and information responsive to the Civil Investigative Demands. Janssen is in ongoing discussions with the FTC staff regarding the inquiry.

In June 2022, Genmab A/S filed a Notice for Arbitration with International Institute for Conflict Prevention and Resolution (CPR) against Janssen Biotech, Inc. seeking milestones and an extended royalty term for Darzalex FASPRO. Janssen filed its Notice of Defense in July 2022. Genmab and Janssen have cross-moved for early disposition of the arbitration. Argument was had in January 2023.

In October 2017, certain United States service members and their families brought a complaint against a number of pharmaceutical and medical devices companies, including Johnson & Johnson and certain of its subsidiaries in United States District Court for the District of Columbia, alleging that the defendants violated the United States Anti-Terrorism Act. The complaint alleges that the defendants provided funding for terrorist organizations through their sales practices pursuant to pharmaceutical and medical device contracts with the Iraqi Ministry of Health. In July 2020, the District Court dismissed the complaint. In January 2022, the United States Court of Appeals for the District of Columbia Circuit reversed the District Court's decision. In February 2022, defendants petitioned for rehearing en banc.

In October 2018, two separate putative class actions were filed against Actelion Pharmaceutical Ltd., Actelion Pharmaceuticals U.S., Inc., and Actelion Clinical Research, Inc. (collectively Actelion) in United States District Court for the District of Maryland and United States District Court for the District of Columbia. The complaints allege that Actelion violated state and federal antitrust and unfair competition laws by allegedly refusing to supply generic pharmaceutical manufacturers with samples of TRACLEER. TRACLEER is subject to a Risk Evaluation and Mitigation Strategy required by the Food and Drug Administration, which imposes restrictions on distribution of the product. In January 2019, the plaintiffs dismissed the District of Columbia case and filed a consolidated complaint in the United States District Court for the District of Maryland. In October 2019, the Court granted Actelion's motion to dismiss the amended complaint. In April 2021, the United States Court of Appeals for the Fourth Circuit reversed and remanded. Discovery is ongoing.

In May 2019, a class action antitrust complaint was filed against Janssen R&D Ireland (Janssen) and Johnson & Johnson in the United States District Court for the Northern District of California. The complaint alleges that Janssen violated federal and state

antitrust and consumer protection laws by agreeing to exclusivity provisions in its agreements with Gilead concerning the development and marketing of combination antiretroviral therapies (cART) to treat HIV. The complaint also alleges that Gilead entered into similar agreements with Bristol-Myers Squibb and Japan Tobacco. In March 2020, the Court granted in part and denied in part defendants' motions to dismiss. Plaintiffs filed an amended complaint in April 2020. Defendants moved to dismiss the amended complaint. In July 2020, the Court granted in part and denied in part the renewed motion to dismiss. In December 2021, several insurance companies and other payers filed individual "Opt-Out" complaints containing allegations similar to the original complaint. In September 2022, the Court granted in part and denied in part plaintiff's motion for class certification. In January 2023, the Court granted in part and denied in part defendants' motion for summary judgment. Trial is scheduled for May 2023.

In October 2019, Innovative Health, LLC filed a complaint against Biosense Webster, Inc. (BWI) in the United States District Court for the Middle District of California. The complaint alleges that certain of BWI's business practices and contractual terms violate the antitrust laws of the United States and the State of California by restricting competition in the sale of High Density Mapping Catheters and Ultrasound Catheters. In January 2020, BWI filed a motion to dismiss the complaint. In August 2020, the Court granted in part and denied in part BWI's motion to dismiss. In December 2021, BWI filed a motion for summary judgment. In March 2022, the Court granted BWI's motion for summary judgment. In April 2022, Innovative appealed this ruling to the United States Court of Appeals for the Ninth Circuit.

In November 2019, the Company received a demand for indemnification from Pfizer Inc. (Pfizer), pursuant to the 2006 Stock and Asset Purchase Agreement between the Company and Pfizer. Also in November 2019, Johnson & Johnson Inc. received notice reserving rights to claim indemnification from Sanofi Consumer Health, Inc. (Sanofi), pursuant to the 2016 Asset Purchase Agreement between Johnson & Johnson Inc. and Sanofi. In January 2020, Johnson & Johnson received a demand for indemnification from Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer Ingelheim), pursuant to the 2006 Asset Purchase Agreement among the Company, Pfizer, and Boehringer Ingelheim. In November 2022, Johnson & Johnson received a demand for indemnification from GlaxoSmithKline LLC (GSK), pursuant to the 2006 Stock and Asset Purchase Agreement between the Company and Pfizer, and certain 1993, 1998, and 2002 agreements between Glaxo Wellcome and Warner-Lambert entities. The notices seek indemnification for legal claims related to over-the-counter ZANTAC (ranitidine) products. Plaintiffs in the underlying actions allege that ZANTAC and other over-the-counter ranitidine medications contain unsafe levels of NDMA (N-nitrosodimethylamine) and can cause and/or have caused various cancers in patients using the products, and seek injunctive and monetary relief. The Company and Johnson & Johnson Inc. have also been named in putative class actions filed in Canada with similar allegations regarding ZANTAC or ranitidine use. Johnson & Johnson Inc. was also named as a defendant along with other manufacturers in various personal injury actions in Canada related to ZANTAC products. Johnson & Johnson Inc. has provided Sanofi notice reserving rights to claim indemnification pursuant to the 2016 Asset Purchase Agreement related to the class actions and personal injury actions.

In October 2020, Fortis Advisors LLC (Fortis), in its capacity as representative of the former stockholders of Auris Health Inc. (Auris), filed a complaint against the Company, Ethicon Inc., and certain named officers and employees (collectively, Ethicon) in the Court of Chancery of the State of Delaware. The complaint alleges breach of contract, fraud, and other causes of action against Ethicon in connection with Ethicon's acquisition of Auris in 2019. The complaint seeks damages and other relief. In December 2021, the Court granted in part and denied in part defendants' motion to dismiss certain causes of action. All claims against the individual defendants were dismissed. The trial is scheduled for January 2024.

In June 2022, Janssen Pharmaceuticals, Inc. filed a Demand for Arbitration against Emergent Biosolutions Inc. et al ("EBSI") with the American Arbitration Association, alleging that EBSI breached the parties' Manufacturing Services Agreement for the Company's COVID-19 vaccine. In July 2022, Emergent filed its answering statement and counterclaims.

In October 2022, Janssen Pharmaceuticals, Inc. filed a Demand for Arbitration against Merck Sharp & Dohme Corp. with the American Arbitration Association pursuant to the Parties' agreements relating to production of drug substance and drug product for the Company's COVID-19 vaccine. Also in October 2022, Merck filed its answer and counterclaims.

Beginning in May 2021, multiple putative class actions were filed in state and federal courts (California, Florida, New York, and New Jersey) against various Johnson & Johnson entities alleging violations of state consumer fraud statutes based on nondisclosure of alleged benzene contamination of certain Neutrogena and Aveeno sunscreen products and the affirmative promotion of those products as "safe"; and, in at least one case, alleging a strict liability manufacturing defect and failure to warn claims, asserting that the named plaintiffs suffered unspecified injuries as a result of alleged exposure to benzene. The Judicial Panel on Multi-District Litigation has consolidated all pending actions, except one product liability case and one case pending in New Jersey state court, in the United States District Court for the Southern District of Florida, Fort Lauderdale Division. In October 2021, the Company reached an agreement in principle for the settlement of a nationwide class, encompassing the claims of the consolidated actions, subject to approval by the Florida federal Court. In December 2021,

plaintiffs in the consolidated actions filed a motion for preliminary approval of a nationwide class settlement. The settlement was preliminarily approved by the court in March 2022.

The Company (subsequently substituted by Johnson & Johnson Consumer Inc. (JJCI)) along with more than 120 other companies, is a defendant in a cost recovery and contribution action brought by Occidental Chemical Corporation in June 2018 in the United States District Court for the District of New Jersey, related to the clean-up of a section of the Lower Passaic River in New Jersey.

The Company or its subsidiaries are also parties to various proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the cost of past and/or future remediation.

20. Restructuring

In the fiscal second quarter of 2018, the Company announced plans to implement a series of actions across its Global Supply Chain that are intended to focus resources and increase investments in the critical capabilities, technologies and solutions necessary to manufacture and supply its product portfolio, enhance agility and drive growth. The Global Supply Chain actions include expanding the use of strategic collaborations and bolstering initiatives to reduce complexity, improve cost-competitiveness, enhance capabilities and optimize the Supply Chain network. In fiscal year 2022, the Company recorded a pre-tax charge of $0.5 billion, which is included on the following lines of the Consolidated Statement of Earnings, $0.3 billion in restructuring, $0.1 billion in other (income) expense and $0.1 billion in cost of products sold. Total project costs of approximately $2.2 billion have been recorded since the restructuring was announced. The program was completed in the fiscal fourth quarter of 2022.

The following table summarizes the severance charges and the associated spending under these initiatives through the fiscal year ended 2022:

(Dollars in Millions)	Severance	Asset Write-offs/Sales	Other[2]	Total
Reserve balance, January 3, 2021	$ 135	—	9	144
2021 activity	(23)	—	16	(7)
Reserve balance, January 2, 2022	112	—	25	137
Current year activity:				
Charges	—	15	448	463
Cash settlements	(37)	44 [3]	(439)	(432)
Settled non cash	—	(59)		(59)
Reserve balance, January 1, 2023[1]	$ 75	—	34	109

[1] Although the restructuring program has been completed in the fiscal year 2022, the Company expects that severance charges will continue beyond that date. The reserve balance as of January 1, 2023 is recorded in the Employee Related Obligation account in the Consolidated Balance Sheet.
[2] Other includes project expense such as salaries for employees supporting these initiatives and consulting expenses.
[3] Represents gain on sale of assets

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Johnson & Johnson

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Johnson & Johnson and its subsidiaries (the "Company") as of January 1, 2023 and January 2, 2022, and the related consolidated statements of earnings, of comprehensive income, of equity and of cash flows for each of the three fiscal years in the period ended January 1, 2023, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of January 1, 2023, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of January 1, 2023 and January 2, 2022, and the results of its operations and its cash flows for each of the three fiscal years in the period ended January 1, 2023 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of January 1, 2023, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As described in Management's Report on Internal Control Over Financial Reporting, management has excluded Abiomed, Inc., ("Abiomed") from its assessment of internal control over financial reporting as of January 1, 2023, because it was acquired by the Company in a business combination during 2022. We have also excluded Abiomed from our audit of internal control over financial reporting. Abiomed is a wholly-owned subsidiary whose total assets and total sales excluded from management's assessment and our audit of internal control over financial reporting represent less than 1% of each of the related consolidated financial statement amounts as of and for the fiscal year ended January 1, 2023.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

U.S. Pharmaceutical Rebate Reserves – Managed Care, Medicare and Medicaid

As described in Note 1 to the consolidated financial statements, the Company recognizes revenue from product sales when obligations under the terms of a contract with the customer are satisfied. Rebates and discounts provided to customers are accounted for as variable consideration and recorded as a reduction in sales. The liability for such rebates and discounts is recognized within Accrued Rebates, Returns, and Promotions on the consolidated balance sheet. A significant portion of the liability related to rebates is from the sale of pharmaceutical goods within the U.S., primarily the Managed Care, Medicare and Medicaid programs, which amounted to $9.6 billion as of January 1, 2023. For significant rebate programs, which include the U.S. Managed Care, Medicare and Medicaid rebate programs, rebates and discounts estimated by management are based on contractual terms, historical experience, patient outcomes, trend analysis, and projected market conditions in the U.S. pharmaceutical market.

The principal considerations for our determination that performing procedures relating to U.S. pharmaceutical rebate reserves - Managed Care, Medicare and Medicaid is a critical audit matter are the significant judgment by management due to the significant measurement uncertainty involved in developing these reserves and the high degree of auditor judgment, subjectivity and audit effort in performing procedures and evaluating the assumptions related to contractual terms, historical experience, patient outcomes, trend analysis, and projected market conditions in the U.S. pharmaceutical market.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to U.S. pharmaceutical rebate reserves - Managed Care, Medicare and Medicaid, including controls over the assumptions used to estimate these rebates. These procedures also included, among others, (i) developing an independent estimate of the rebates by utilizing third party information on price and market conditions in the U.S. pharmaceutical market, the terms of the specific rebate programs, and the historical experience and trend analysis of actual rebate claims paid; (ii) testing rebate claims processed by the Company, including evaluating those claims for consistency with the contractual and mandated terms of the Company's rebate arrangements; and (iii) comparing the independent estimates to management's estimates.

Litigation Contingencies – Talc

As described in Notes 1 and 19 to the consolidated financial statements, the Company records accruals for loss contingencies associated with legal matters, including talc, when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. To the extent adverse awards, judgments, or verdicts have been rendered against the Company, management does not record an accrual until a loss is determined to be probable and can be reasonably estimated. For these matters, management is unable to estimate the possible loss or range of loss beyond the amounts accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors, including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; ability to achieve comprehensive multi-party settlements; complexity of related cross-claims and counterclaims; and/or there are numerous parties involved. Management continues to believe that the Company has strong legal grounds to contest the talc verdicts it has appealed. Notwithstanding management's confidence in the safety of the Company's talc products, in certain circumstances the Company has settled cases. In October 2021, Johnson & Johnson Consumer Inc. (Old JJCI), a wholly-owned subsidiary of Johnson & Johnson, implemented a corporate restructuring and created a subsidiary, LTL Management LLC (LTL), which became solely responsible for the talc-related liabilities, and another subsidiary, New JJCI, which became responsible for the remaining business of Old JJCI. LTL filed a voluntary petition, seeking relief under chapter 11 of the Bankruptcy Code. As a result of the LTL bankruptcy case, the Court entered a temporary restraining order staying all litigation against LTL and Old JJCI. On November 15, 2021, the North Carolina Bankruptcy Court confirmed the scope of the stay, issuing a Preliminary Injunction (PI) prohibiting and enjoining the commencement and prosecution of talc-related claims against LTL, Old JJCI, New JJCI, Johnson & Johnson, other of their corporate affiliates, identified retailers, insurance companies, and certain other parties. The LTL Bankruptcy Case was transferred to the United States Bankruptcy Court for the District of New Jersey in November 2021, and that court extended the PI through the end of

February 2022. Claimants filed motions to dismiss the LTL Bankruptcy Case and, following a multiple day hearing, the New Jersey Bankruptcy Court denied those motions by order issued in March 2022. The New Jersey Bankruptcy Court simultaneously issued another order extending the stay as to the Protected Parties. The claimants subsequently filed notices of appeal as to the denial of the motions to dismiss and the extension of the stay. In May 2022,the Third Circuit Court of Appeals granted the petitions to appeal. The briefing and oral argument on the appeal were completed in September 2022. On January 30, 2023, the Third Circuit reversed the Bankruptcy Court's ruling and remanded to the Bankruptcy Court to dismiss the LTL bankruptcy. LTL has filed a petition for rehearing on the decision.

The principal considerations for our determination that performing procedures relating to the talc litigation is a critical audit matter are the significant judgment by management when assessing the likelihood of a loss being incurred and when determining whether a reasonable estimate of the loss or range of loss for the future and existing talc claims can be made, which in turn led to a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating management's assessment of the loss contingencies associated with this litigation.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's evaluation of the talc litigation, including controls over determining whether a loss is probable and whether the amount of loss can be reasonably estimated, as well as financial statement disclosures. These procedures also included, among others, (i) gaining an understanding of the Company's process around the accounting and reporting for the talc litigation; (ii) discussing the status of significant known actual and potential litigation and the ongoing LTL bankruptcy proceedings with the Company's in-house legal counsel, as well as external counsel when deemed necessary; (iii) obtaining and evaluating the letters of audit inquiry with internal and external legal counsel for significant litigation; (iv) evaluating the reasonableness of management's assessment regarding whether an unfavorable outcome is reasonably possible or probable and reasonably estimable; and (v) evaluating the sufficiency of the Company's litigation contingencies disclosures.

/s/ PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 16, 2023

We have served as the Company's auditor since at least 1920. We have not been able to determine the specific year we began serving as auditor of the Company.

Management's Report on Internal Control Over Financial Reporting

Under Section 404 of the Sarbanes-Oxley Act of 2002, management is required to assess the effectiveness of the Company's internal control over financial reporting as of the end of each fiscal year and report, based on that assessment, whether the Company's internal control over financial reporting is effective.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is designed to provide reasonable assurance as to the reliability of the Company's financial reporting and the preparation of external financial statements in accordance with generally accepted accounting principles.

Internal controls over financial reporting, no matter how well designed, have inherent limitations. Therefore, internal control over financial reporting determined to be effective can provide only reasonable assurance with respect to financial statement preparation and may not prevent or detect all misstatements. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management has assessed the effectiveness of the Company's internal control over financial reporting as of January 1, 2023. In making this assessment, the Company used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework (2013)." These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. The Company's assessment included extensive documenting, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

The Company acquired Abiomed, Inc. (Abiomed), in a business combination in December 2022. Abiomed's total assets, excluding intangible assets and goodwill, and total sales represented less than 1% of each of the related consolidated financial statement amounts as of and for the fiscal year ended January 1, 2023. As the acquisition occurred in the fiscal year 2022, the scope of the Company's assessment of the design and effectiveness of internal control over financial reporting for the fiscal year 2022 excluded the above mentioned acquisition. This exclusion is in accordance with the SEC's general guidance that an assessment of a recently acquired business may be omitted from the scope in the year of acquisition.

Based on the Company's processes and assessment, as described above, management has concluded that, as of January 1, 2023, the Company's internal control over financial reporting was effective.

The effectiveness of the Company's internal control over financial reporting as of January 1, 2023 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which appears herein.

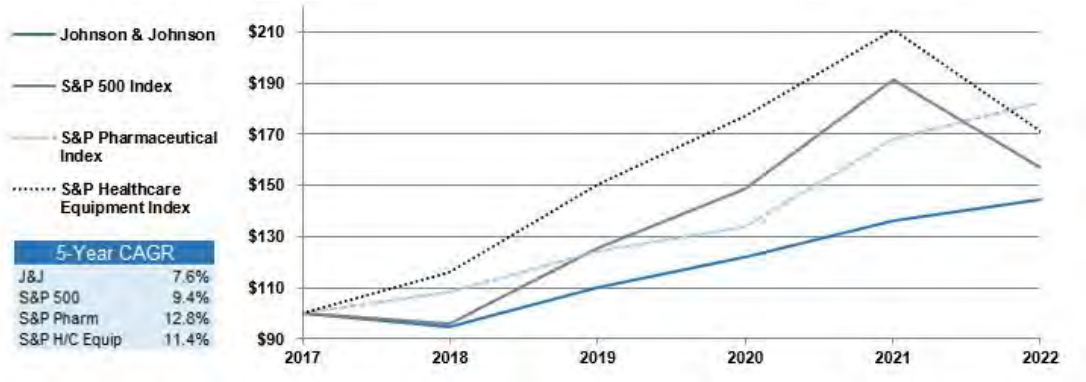
/s/ J. Duato
Joaquin Duato
Chairman, Board of Directors
Chief Executive Officer

/s/ Joseph J. Wolk
Joseph J. Wolk
Executive Vice President, Chief Financial Officer

Shareholder Return Performance Graphs

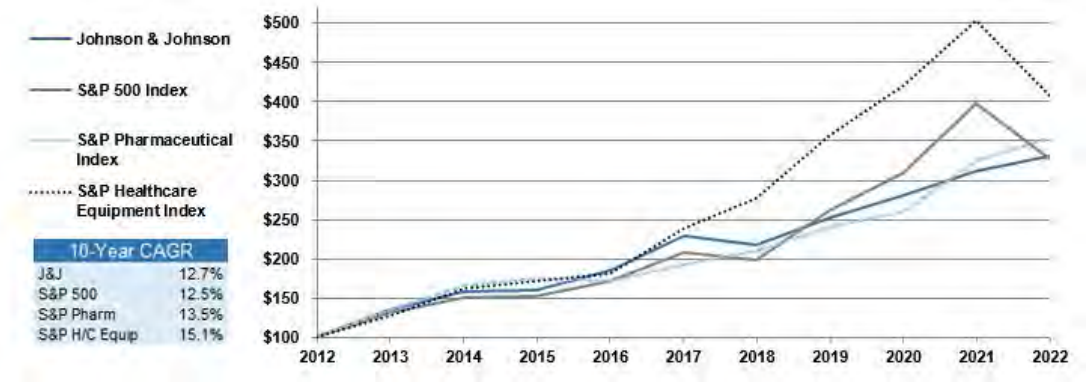
Set forth below are line graphs comparing the cumulative total shareholder return on the Company's Common Stock for periods of five years and ten years ending January 1, 2023, against the cumulative total return of the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Healthcare Equipment Index. The graphs and tables assume that $100 was invested on December 31, 2017 and December 31, 2012 in each of the Company's Common Stock, the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Healthcare Equipment Index and that all dividends were reinvested.

5 Year Shareholder Return Performance J&J vs. Indices



	2017	2018	2019	2020	2021	2022
Johnson & Johnson	$100.00	$94.86	$110.24	$122.20	$136.19	$144.32
S&P 500 Index	$100.00	$95.61	$125.70	$148.81	$191.48	$156.77
S&P Pharmaceutical Index	$100.00	$108.09	$124.40	$133.76	$168.21	$182.43
S&P Healthcare Equipment Index	$100.00	$116.24	$150.32	$176.83	$211.05	$171.25

10 Year Shareholder Return Performance J&J vs. Indices



	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Johnson & Johnson	$100.00	$134.62	$157.95	$159.78	$184.26	$229.23	$217.46	$252.71	$280.13	$312.20	$330.83
S&P 500 Index	$100.00	$132.37	$150.47	$152.53	$170.76	$208.02	$198.87	$261.47	$309.54	$398.32	$326.12
S&P Pharmaceutical Index	$100.00	$135.23	$165.27	$174.84	$172.10	$193.74	$209.41	$241.01	$259.15	$325.89	$353.44
S&P Healthcare Equipment Index	$100.00	$127.69	$161.24	$170.87	$181.95	$238.17	$276.85	$358.03	$421.16	$502.66	$407.86

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures. At the end of the period covered by this Report, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Joaquin Duato, Chairman and Chief Executive Officer, and Joseph J. Wolk, Executive Vice President, Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Duato and Wolk concluded that, as of the end of the period covered by this Report, the Company's disclosure controls and procedures were effective.

Reports on Internal Control Over Financial Reporting. The information called for by this item is incorporated herein by reference to "Management's Report on Internal Control Over Financial Reporting", and the attestation regarding internal controls over financial reporting included in the "Report of Independent Registered Public Accounting Firm" included in Item 8 of this Report.

Changes in Internal Control Over Financial Reporting. During the fiscal quarter ended January 1, 2023, there were no changes in the Company's internal control over financial reporting identified in connection with the evaluation required under Rules 13a-15 and 15d-15 under the Exchange Act that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting. The Company continues to monitor and assess the effectiveness of the design and operation of its disclosure controls and procedures.

The Company is implementing a multi-year, enterprise-wide initiative to integrate, simplify and standardize processes and systems for the human resources, information technology, procurement, supply chain and finance functions. These are enhancements to support the growth of the Company's financial shared service capabilities and standardize financial systems. This initiative is not in response to any identified deficiency or weakness in the Company's internal control over financial reporting. In response to this initiative, the Company has and will continue to align and streamline the design and operation of its financial control environment.

Item 9B. OTHER INFORMATION

Not applicable.

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information called for by this item is incorporated herein by reference to the discussion of the Audit Committee under the caption "Item 1. Election of Directors - Board Committees"; and the material under the captions "Item 1. Election of Directors" and, if applicable, "Stock Ownership and Section 16 Compliance – Delinquent Section 16(a) Reports" in the Proxy Statement; and the material under the caption "Executive Officers of the Registrant" in Part I of this Report.

The Company's Code of Business Conduct, which covers all employees (including the Chief Executive Officer, Chief Financial Officer and Controller), meets the requirements of the SEC rules promulgated under Section 406 of the Sarbanes-Oxley Act of 2002. The Code of Business Conduct is available on the Company's website at *www.jnj.com/code-of-business-conduct*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code of Business Conduct or any waiver of the Code granted to the Chief Executive Officer, the Chief Financial Officer or the Controller will be posted on the Company's website at *www.investor.jnj.com/gov.cfm* within five business days (and retained on the website for at least one year).

In addition, the Company has adopted a Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers. The Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers

is available on the Company's website at *www.investor.jnj.com/gov/boardconduct.cfm*, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code or any waiver of the Code granted to any member of the Board of Directors or any executive officer will be posted on the Company's website at *www.investor.jnj.com/gov.cfm* within five business days (and retained on the website for at least one year).

Item 11. EXECUTIVE COMPENSATION

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1. Election of Directors – Director Compensation," and "Item 2. Compensation & Benefits Committee Report," "Compensation Discussion and Analysis" and "Executive Compensation Tables" in the Proxy Statement.

The material incorporated herein by reference to the material under the caption "Compensation & Benefits Committee Report" in the Proxy Statement shall be deemed furnished, and not filed, in this Report and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, as a result of this furnishing, except to the extent that the Company specifically incorporates it by reference.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information called for by this item is incorporated herein by reference to the material under the caption "Item 1. Stock Ownership and Section 16 Compliance" in the Proxy Statement; and Note 16 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements in Item 8 of this Report.

Equity Compensation Plan Information

The following table provides certain information as of January 1, 2023 concerning the shares of the Company's Common Stock that may be issued under existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights	Weighted Average Exercise Price of Outstanding Options and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans[2][3]
Equity Compensation Plans Approved by Security Holders[1]	134,644,525	$118.94	149,652,710
Equity Compensation Plans Not Approved by Security Holders	-	-	-
Total	134,644,525	$118.94	149,652,710

(1) Included in this category are the following equity compensation plans which have been approved by the Company's shareholders: 2012 Long-Term Incentive Plan and 2022 Long-Term Incentive Plan.

(2) This column excludes shares reflected under the column "Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights."

(3) The 2012 Long-Term Incentive Plan expired April 26, 2022. All options and restricted shares granted subsequent to that date were under the 2022 Long-Term Incentive Plan.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information called for by this item is incorporated herein by reference to the material under the captions "Item 1. Election of Directors - Director Independence" and "Related Person Transactions" in the Proxy Statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information called for by this item is incorporated herein by reference to the material under the caption "Item 3. Ratification of Appointment of Independent Registered Public Accounting Firm" in the Proxy Statement.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this report:

1. *Financial Statements*

   Consolidated Balance Sheets at end of Fiscal Years 2022 and 2021

   Consolidated Statements of Earnings for Fiscal Years 2022, 2021 and 2020

   Consolidated Statements of Comprehensive Income for Fiscal Years 2022, 2021 and 2020

   Consolidated Statements of Equity for Fiscal Years 2022, 2021 and 2020

   Consolidated Statements of Cash Flows for Fiscal Years 2022, 2021 and 2020

   Notes to Consolidated Financial Statements

   Report of Independent Registered Public Accounting Firm

   All schedules are omitted because they are not applicable or the required information is included in the financial statements or notes.

2. *Exhibits* Required *to be Filed by Item 601 of Regulation S-K*

   The information called for by this item is incorporated herein by reference to the Exhibit Index in this Report.

Item 16. FORM 10-K SUMMARY

Registrants may voluntarily include a summary of information required by Form 10-K under this Item 16. The Company has elected not to include such summary information.

SIGNATURES

Pursuant to the requirements of Section 13 of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

JOHNSON & JOHNSON
(Registrant)

Date: February 16, 2023

By /s/ J. Duato
J. Duato, Chairman of the Board
and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ J. Duato J. Duato	Chairman of the Board Chief Executive Officer (Principal Executive Officer)	February 16, 2023
/s/ J. J. Wolk J. J. Wolk	Chief Financial Officer (Principal Financial Officer)	February 16, 2023
/s/ R. J. Decker Jr. R. J. Decker Jr.	Controller and Chief Accounting Officer (Principal Accounting Officer)	February 16, 2023
/s/D. Adamczyk D. Adamczyk	Director	February 16, 2023
/s/ M. C. Beckerle M. C. Beckerle	Director	February 16, 2023
/s/ D. S. Davis D. S. Davis	Director	February 16, 2023
/s/ I. E. L. Davis I. E. L. Davis	Director	February 16, 2023
/s/ J. A. Doudna J. A. Doudna	Director	February 16, 2023

Signature	Title	Date
/s/ M. A. Hewson M. A. Hewson	Director	February 16, 2023
/s/ H. Joly H. Joly	Director	February 16, 2023
/s/ M. B. McClellan M. B. McClellan	Director	February 16, 2023
/s/ A. M. Mulcahy A. M. Mulcahy	Director	February 16, 2023
/s/ A. E. Washington A. E. Washington	Director	February 16, 2023
/s/ M. A. Weinberger M. A. Weinberger	Director	February 16, 2023
/s/ N.Y. West N. Y. West	Director	February 16, 2023

EXHIBIT INDEX

Reg. S-K Exhibit Table Item No.	Description of Exhibit
2(i)	Agreement and Plan of Merger, dated as of October 31, 2022, by and among Johnson & Johnson, Athos Merger Sub, Inc. and ABIOMED, Inc. – Incorporated herein by reference to Exhibit 2.1 of the Registrant's Form 8-K Current Report filed November 1, 2022.†
3(i)	Restated Certificate of Incorporation effective February 19, 2016 — Incorporated herein by reference to Exhibit 3(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.
3(ii)	Certificate of Amendment to the Certificate of Incorporation of Johnson & Johnson effective April 30, 2020 — Incorporated herein by reference to Exhibit 3.1 of the Registrant's Form 8-K Current Report filed April 29, 2020.
3(iii)	By-Laws of the Company, as amended effective June 9, 2020 — Incorporated herein by reference to Exhibit 3.1 of the Registrant's Form 8-K Current Report filed June 10, 2020.
4(a)	Upon the request of the Securities and Exchange Commission, the Registrant will furnish a copy of all instruments defining the rights of holders of long-term debt of the Registrant.
4(b)	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 — Incorporated herein by reference to Exhibit 4.1 of the Registrant's Form 8-K Current Report filed August 12, 2020.
10(a)	2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 4 of the Registrant's S-8 Registration Statement filed on May 10, 2005 (file no. 333-124785).*
10(b)	Form of Stock Option Certificate under the 2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 8-K Current Report filed January 13, 2012.*
10(c)	2012 Long-Term Incentive Plan — Incorporated herein by reference to Appendix A of the Registrant's Proxy Statement filed on March 15, 2017.*
10(d)	Form of Stock Option Certificate, Restricted Share Unit Certificate and Performance Share Unit Certificate under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.2, 10.3 and 10.4 of the Registrant's Form 10-Q Quarterly Report for the quarter ended April 1, 2012.*
10(e)	Global NonQualified Stock Option Award Agreement, Global Restricted Share Unit Award Agreement and Global Performance Share Unit Award Agreement under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.1, 10.2 and 10.3 of the Registrant's Form 10-Q Quarterly Report for the quarter ended April 1, 2018.*
10(f)	Johnson & Johnson Executive Incentive Plan (Amended as of November 28, 2018) — Incorporated herein by reference to Exhibit 10(a) of the Registrant's Form 10-Q Quarterly Report for the quarter ended March 31, 2019.*
10(g)	Domestic Deferred Compensation (Certificate of Extra Compensation) Plan — Incorporated herein by reference to Exhibit 10(g) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2003.*
10(h)	Amendments to the Certificate of Extra Compensation Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(i)	2009 Certificates of Long-Term Performance Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 27, 2009.*
10(j)	Amended and Restated Deferred Fee Plan for Directors (Amended as of January 17, 2012) — Incorporated herein by reference to Exhibit 10(k) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 1, 2012.*
10(k)	The Johnson & Johnson Executive Income Deferral Plan Amended and Restated Effective January 1, 2010 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*
10(l)	The Johnson & Johnson Excess Savings Plan (amended and restated as of January 1, 2022) — Filed with this document.*
10(m)	Excess Benefit Plan of Johnson & Johnson and Affiliated Companies (amended and restated as of January 1, 2020)— incorporated by reference to Exhibit 10(n) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2021.*
10(n)**	Executive Life Plan Agreement — Incorporated herein by reference to Exhibit 10(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 1993.*
10(o)	Executive Life Plan Agreement Closure Letter — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended March 29, 2015.*
10(p)	2022 Long-Term Incentive Plan — Incorporated by reference to Appendix A of the Registrant's Proxy Statement filed on March 16, 2022.*

Reg. S-K Exhibit Table Item No.	Description of Exhibit
10(q)	Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies, Amended and Restated as of October 1, 2014 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 28, 2014.*
10(r)	First Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended June 28, 2015.*
10(s)	Second Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10(x) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.*
10(t)	Contingent Value Rights Agreement, dated as of December 22, 2022, by and between Johnson & Johnson and American Stock Transfer & Trust Company, LLC – Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 8-K Current Report filed December 22, 2022.†
21	Subsidiaries — Filed with this document.
23	Consent of Independent Registered Public Accounting Firm — Filed with this document.
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
32.1	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
32.2	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
Exhibit 101:	
EX-101.INS	Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
EX-101.SCH	Inline XBRL Taxonomy Extension Schema
EX-101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
EX-101.LAB	Inline XBRL Taxonomy Extension Label Linkbase
EX-101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
EX-101.DEF	Inline XBRL Taxonomy Extension Definition Document
Exhibit 104:	Cover Page Interactive Data File—the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

* Management contract or compensatory plan.

** Paper filing.

† Certain exhibits and schedules have been omitted pursuant to Item 601(b)(2)(ii) or 601(b)(10)(iv) of Regulation S-K, as applicable.

A copy of any of the Exhibits listed above will be provided without charge to any shareholder submitting a written request specifying the desired exhibit(s) to the Secretary at the principal executive offices of the Company. Pursuant to Item 601(b)(4)(iii)(A) of Regulation S-K, the Company has not filed as exhibits to this Form 10-K certain long-term debt instruments, including indentures, under which the total amount of securities authorized does not exceed 10% of the total assets of the Company and its subsidiaries on a consolidated basis. The Company hereby agrees to furnish a copy of any such instrument to the SEC upon request.

Exhibit “J20”

This is Exhibit “J20” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

2023 Annual Report

Johnson & Johnson

Our Credo

We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to provide value, reduce our costs and maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our business partners must have an opportunity to make a fair profit.

We are responsible to our employees who work with us throughout the world. We must provide an inclusive work environment where each person must be considered as an individual. We must respect their diversity and dignity and recognize their merit. They must have a sense of security, fulfillment and purpose in their jobs. Compensation must be fair and adequate and working conditions clean, orderly and safe. We must support the health and well-being of our employees and help them fulfill their family and other personal responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide highly capable leaders and their actions must be just and ethical.

We are responsible to the communities in which we live and work and to the world community as well. We must help people be healthier by supporting better access and care in more places around the world. We must be good citizens — support good works and charities, better health and education, and bear our fair share of taxes. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.

Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programs developed, investments made for the future and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realize a fair return.

Johnson&Johnson

Dear shareholders,

2023 was a defining moment in Johnson & Johnson's 138-year history.

It was a year of transformation and growth that has positioned our company to be a leader in global healthcare for decades to come.

With the successful separation of our consumer health business, we entered a new era – one exclusively focused on tackling the world's toughest health challenges through scientific innovation and technology.

We remain the world's largest, most diversified healthcare products company, and Johnson & Johnson is now moving forward as a more focused and agile organization, with a stronger growth and margin profile.

Operating as a company focused on delivering innovative medicines and medical technologies has strengthened our position as an innovation powerhouse. Today, we are innovating for patients across a spectrum of healthcare solutions in ways no other company can, and our impact is significant.

Performance and priorities

In 2023, we delivered strong and sustained performance with 9.0% operational sales growth*, excluding the COVID-19 vaccine. Adjusted net earnings were $25.4 billion*. Adjusted diluted net earnings per share was $9.92*, an increase of 11.1% from 2022.

We maintained a healthy balance sheet and robust credit rating, underscoring the stability of our financial position, and executed against all our capital allocation priorities. We remain a top investor in innovation, funding $15.1 billion in R&D, or almost 18% of 2023 sales – an all-time high for the company.

We committed over $3 billion to external growth opportunities in the last 12 months, including the acquisitions of Ambrx and Laminar, and more than 50 smaller, early-stage licensing deals and partnerships. We increased our dividend for the 61st consecutive year and completed the share repurchase program initiated in 2022, returning a total of over $14 billion to shareholders.

Innovative Medicine

We are leading where medicine is going, and for the 12th consecutive year we reported above-market growth for our Innovative Medicine business. This strong performance was fueled by growth in key brands such as DARZALEX, ERLEADA, STELARA and TREMFYA, and the acceleration of recently launched products, including CARVYKTI, SPRAVATO, TALVEY and TECVAYLI.

We made significant advances in our pipeline, with FDA approvals for AKEEGA and TALVEY, and positive Phase III data readouts for 11 in-line and pipeline medicines. We initiated Phase III clinical development programs for milvexian and our targeted oral peptide, JNJ-2113, and received FDA Breakthrough Therapy Designation for TAR-200 for the treatment of bladder cancer. Milvexian also received FDA Fast Track designations in atrial fibrillation, stroke, and acute coronary syndrome.

With 19 U.S. and EU filings across Innovative Medicine in 2023, we have high expectations for the year ahead.

MedTech

Innovating at the intersection of biology and technology, our MedTech businesses delivered over $30 billion in sales, with sales growth across Orthopaedics, Surgery, Interventional Solutions, and Vision.

We progressed 20+ MedTech pipeline programs that each have an expected net present value of greater than $100 million, and launched 15 major products. To increase access for patients and deliver clinical differentiation, we produced more than 200 scientific publications.

We built on our commitment to interventional cardiology with our successful integration of Abiomed and our acquisition of Laminar, a company focused on eliminating the left atrial appendage to prevent stroke in AFib patients.

Profoundly impacting health for humanity

Science and technology will advance human health more in the next decade than in the last century. It will lead to more effective and personalized treatments, earlier intervention, and smarter, less invasive healthcare. One example is in lung cancer, where doctors can use our robotic bronchoscopy to make a diagnosis, perform surgery with our smart instruments, and treat with our bispecific antibody. In so many ways, we are just getting started.

We are energized by our future and our evolution at Johnson & Johnson, and we remain grounded in our purpose and guiding principles. For more than 80 years, Our Credo has reminded us of our responsibilities to the people we serve: patients, doctors and nurses, employees, communities, and investors.

Our Credo values are as strong as ever. I see them in action every day working with my colleagues—a team of over 130,000 incredible individuals that includes more than 26,000 employees working in R&D, innovation, and engineering, and approximately 6,000 data scientists and digital experts embedded across our businesses globally.

The people of Johnson & Johnson are my greatest source of inspiration and the foundation of my confidence in the future of our business. Fueled by our shared belief that health is everything, and our commitment to investing in transformative science and breakthrough technology, Johnson & Johnson is poised to lead the next wave of innovation. I look forward to seeing what we accomplish together in 2024 and beyond.

Sincerely,

Joaquin Duato

Joaquin Duato
Chairman and CEO

Delivering for Our Credo stakeholders

9%

operational sales growth*[1]

$85.2 billion

in consolidated sales

61st

consecutive year of increased dividends

$15.1 billion

invested in R&D

13,000+

employee promotions to new roles

80

years of Our Credo

800,000

courses of SIRTURO® delivered to fight multi-drug resistant tuberculosis since 2014

>$5 billion

global impact spend with small and diverse suppliers

6

consecutive years of recognition with a CDP A-List rating for our leadership in climate action

$3 billion

invested in externally sourced innovation

40,000

operating room and hospital staff trained in resource-limited settings

* Non-GAAP Measure: Operational sales growth excludes the effect of translational currency. Adjusted net earnings and adjusted diluted net earnings per share excludes special items and intangible asset amortization expense. See Non-GAAP reconciliation in this Annual Report.

1. Excluding the Covid-19 vaccine.

Key drivers for long-term competitive growth

At our 2023 Enterprise Business Review, we presented the Company's overarching innovation strategy, diverse and robust pipelines, and expected long-term financial outlook:

5 - 7%

compound annual growth rate for the Enterprise between 2025-2030[2,3]

5 - 7%

compound annual growth rate in our Innovative Medicine business between 2025-2030[2,3]

10+

innovative medicines by 2030 with potential for $5+ billion in peak year sales[4]

15+

innovative medicines by 2030 with potential for $1-5 billion in peak year sales[4]

2022 - 2027

MedTech growth in the upper range of the market 5-7%[5]

1/3rd

of MedTech sales to be generated by new products[6] in 2027

2. Represents operational sales; Non-GAAP financial measure; excludes the impact of translational currency.
3. Based on risk-adjusted sales projection.
4. Peak non-risk adjusted operational sales, including partner sales.
5. MedTech Market WAMGR reflects the following sources: Internal estimates, Fitch, HRI, GlobalData, and DRG.
6. Products launched within last five years.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☑ ANNUAL REPORT PURSUANT TO SECTION 13 OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023
or

☐ Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
for the transition period from to

Commission file number 1-3215

Johnson & Johnson

(Exact name of registrant as specified in its charter)

New Jersey	22-1024240
(State of incorporation)	(I.R.S. Employer Identification No.)
One Johnson & Johnson Plaza New Brunswick, New Jersey	08933
(Address of principal executive offices)	(Zip Code)

One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
(Address of principal executive offices)
Registrant's telephone number, including area code: (732) 524-0400

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, Par Value $1.00	JNJ	New York Stock Exchange
0.650% Notes Due May 2024	JNJ24C	New York Stock Exchange
5.50% Notes Due November 2024	JNJ24BP	New York Stock Exchange
1.150% Notes Due November 2028	JNJ28	New York Stock Exchange
1.650% Notes Due May 2035	JNJ35	New York Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☑ No ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $430 billion.

On February 9, 2024, there were 2,408,767,228 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III: Portions of the registrant's proxy statement for its 2024 annual meeting of shareholders filed within 120 days after the close of the registrant's fiscal year (the "Proxy Statement"), are incorporated by reference to this report on Form 10-K (this "Report").

Item

Cautionary note regarding forward-looking statements

This Annual Report on Form 10-K and Johnson & Johnson's other publicly available documents contain "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Management and representatives of Johnson & Johnson and its subsidiaries (the Company) also may from time to time make forward-looking statements. Forward-looking statements do not relate strictly to historical or current facts and reflect management's assumptions, views, plans, objectives and projections about the future. Forward-looking statements may be identified by the use of words such as "plans," "expects," "will," "anticipates," "estimates" and other words of similar meaning in conjunction with, among other things: discussions of future operations; expected operating results and financial performance; impact of planned acquisitions and dispositions; impact and timing of restructuring initiatives, including associated cost savings and other benefits; the Company's strategy for growth; product development activities; regulatory approvals; market position and expenditures.

Because forward-looking statements are based on current beliefs, expectations and assumptions regarding future events, they are subject to uncertainties, risks and changes that are difficult to predict and many of which are outside of the Company's control. Investors should realize that if underlying assumptions prove inaccurate, or known or unknown risks or uncertainties materialize, the Company's actual results and financial condition could vary materially from expectations and projections expressed or implied in its forward-looking statements. Investors are therefore cautioned not to rely on these forward-looking statements. Risks and uncertainties include, but are not limited to:

Risks related to product development, market success and competition

- Challenges and uncertainties inherent in innovation and development of new and improved products and technologies on which the Company's continued growth and success depend, including uncertainty of clinical outcomes, additional analysis of existing clinical data, obtaining regulatory approvals, health plan coverage and customer access, and initial and continued commercial success;
- Challenges to the Company's ability to obtain and protect adequate patent and other intellectual property rights for new and existing products and technologies in the United States and other important markets;
- The impact of patent expirations, typically followed by the introduction of competing generic, biosimilar or other products and resulting revenue and market share losses;
- Increasingly aggressive and frequent challenges to the Company's patents by competitors and others seeking to launch competing generic, biosimilar or other products and increased receptivity of courts, the United States Patent and Trademark Office and other decision makers to such challenges, potentially resulting in loss of market exclusivity and rapid decline in sales for the relevant product sooner than expected;
- Competition in research and development of new and improved products, processes and technologies, which can result in product and process obsolescence;
- Competition to reach agreement with third parties for collaboration, licensing, development and marketing agreements for products and technologies;
- Competition based on cost-effectiveness, product performance, technological advances and patents attained by competitors; and
- Allegations that the Company's products infringe the patents and other intellectual property rights of third parties, which could adversely affect the Company's ability to sell the products in question and require the payment of money damages and future royalties.

Risks related to product liability, litigation and regulatory activity

- Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the United States Food and Drug Administration (U.S. FDA) (or international counterparts), declining sales, reputational damage, increased litigation expense and share price impact;
- The impact, including declining sales and reputational damage, of significant litigation or government action adverse to the Company, including product liability claims and allegations related to pharmaceutical marketing practices and contracting strategies;
- The impact of an adverse judgment or settlement and the adequacy of reserves related to legal proceedings, including patent litigation, product liability, personal injury claims, securities class actions, government investigations, employment and other legal proceedings;

- Increased scrutiny of the healthcare industry by government agencies and state attorneys general resulting in investigations and prosecutions, which carry the risk of significant civil and criminal penalties, including, but not limited to, debarment from government business;
- Failure to meet compliance obligations in compliance agreements with governments or government agencies, which could result in significant sanctions;
- Potential changes to applicable laws and regulations affecting United States and international operations, including relating to: approval of new products; licensing and patent rights; sales and promotion of healthcare products; access to, and reimbursement and pricing for, healthcare products and services; environmental protection; and sourcing of raw materials;
- Compliance with local regulations and laws that may restrict the Company's ability to manufacture or sell its products in relevant markets, including requirements to comply with medical device reporting regulations and other requirements such as the European Union's Medical Devices Regulation;
- Changes in domestic and international tax laws and regulations, increasing audit scrutiny by tax authorities around the world and exposures to additional tax liabilities potentially in excess of existing reserves; and
- The issuance of new or revised accounting standards by the Financial Accounting Standards Board and regulations by the Securities and Exchange Commission.

Risks related to the Company's strategic initiatives, healthcare market trends and the realization of benefits from the separation of the Company's Consumer Health Business

- Pricing pressures resulting from trends toward healthcare cost containment, including the continued consolidation among healthcare providers and other market participants, trends toward managed care, the shift toward governments increasingly becoming the primary payors of healthcare expenses, significant new entrants to the healthcare markets seeking to reduce costs and government pressure on companies to voluntarily reduce costs and price increases;
- Restricted spending patterns of individual, institutional and governmental purchasers of healthcare products and services due to economic hardship and budgetary constraints;
- Challenges to the Company's ability to realize its strategy for growth including through externally sourced innovations, such as development collaborations, strategic acquisitions, licensing and marketing agreements, and the potential heightened costs of any such external arrangements due to competitive pressures;
- The potential that the expected strategic benefits and opportunities from any planned or completed acquisition or divestiture by the Company may not be realized or may take longer to realize than expected;
- The potential that the expected benefits and opportunities related to past and ongoing restructuring actions may not be realized or may take longer to realize than expected;
- The Company's ability to divest the Company's remaining ownership interest in Kenvue Inc. (Kenvue) and realize the anticipated benefits from the separation; and
- Kenvue's ability to succeed as a standalone publicly traded company.

Risks related to economic conditions, financial markets and operating internationally

- The risks associated with global operations on the Company and its customers and suppliers, including foreign governments in countries in which the Company operates;
- The impact of inflation and fluctuations in interest rates and currency exchange rates and the potential effect of such fluctuations on revenues, expenses and resulting margins;
- Potential changes in export/import and trade laws, regulations and policies of the United States and other countries, including any increased trade restrictions or tariffs and potential drug reimportation legislation;
- The impact on international operations from financial instability in international economies, sovereign risk, possible imposition of governmental controls and restrictive economic policies, and unstable international governments and legal systems;
- The impact of global public health crises and pandemics;

- Changes to global climate, extreme weather and natural disasters that could affect demand for the Company's products and services, cause disruptions in manufacturing and distribution networks, alter the availability of goods and services within the supply chain, and affect the overall design and integrity of the Company's products and operations;
- The impact of global or economic changes or events, including global tensions and war; and
- The impact of armed conflicts and terrorist attacks in the United States and other parts of the world, including social and economic disruptions and instability of financial and other markets.

Risks related to supply chain and operations

- Difficulties and delays in manufacturing, internally, through third-party providers or otherwise within the supply chain, that may lead to voluntary or involuntary business interruptions or shutdowns, product shortages, withdrawals or suspensions of products from the market, and potential regulatory action;
- Interruptions and breaches of the Company's information technology systems or those of the Company's vendors, which could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action;
- Reliance on global supply chains and production and distribution processes that are complex and subject to increasing regulatory requirements that may adversely affect supply, sourcing and pricing of materials used in the Company's products; and
- The potential that the expected benefits and opportunities related to restructuring actions may not be realized or may take longer to realize than expected, including due to any required approvals from applicable regulatory authorities.

Investors also should carefully read the risk factors described in Item 1A of this Annual Report on Form 10-K for a description of certain risks that could, among other things, cause the Company's actual results to differ materially from those expressed in its forward-looking statements. Investors should understand that it is not possible to predict or identify all such factors and should not consider the risks described above and in Item 1A to be a complete statement of all potential risks and uncertainties. The Company does not undertake to publicly update any forward-looking statement that may be made from time to time, whether as a result of new information or future events or developments.

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Part I

Item 1. Business

General

Johnson & Johnson and its subsidiaries (the Company) have approximately 131,900 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the healthcare field. Johnson & Johnson is a holding company, with operating companies conducting business in virtually all countries of the world. The Company's primary focus is products related to human health and well-being. Johnson & Johnson was incorporated in the State of New Jersey in 1887.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Company's two business segments: Innovative Medicine (previously referred to as Pharmaceutical) and MedTech. Within the strategic parameters provided by the Committee, senior management groups at U.S. and international operating companies are each responsible for their own strategic plans and the day-to-day operations of those companies. Each subsidiary within the business segments is, with limited exceptions, managed by residents of the country where located.

Segments of business

Following the completion of the separation of the Consumer Health business (Kenvue) in August 2023, the Company is now organized into two business segments: Innovative Medicine and MedTech. Additional information required by this item is incorporated herein by reference to the narrative and tabular descriptions of segments and operating results under: Item 7. Management's discussion and analysis of results of operations and financial condition of this Report; and Note 17 Segments of business and geographic areas of the notes to consolidated financial statements included in Item 8 of this Report.

Innovative Medicine

The Innovative Medicine segment is focused on the following therapeutic areas: Immunology (e.g., rheumatoid arthritis, psoriatic arthritis, inflammatory bowel disease and psoriasis), Infectious Diseases (e.g., HIV/AIDS), Neuroscience (e.g., mood disorders, neurodegenerative disorders and schizophrenia), Oncology (e.g., prostate cancer, hematologic malignancies, lung cancer and bladder cancer), Cardiovascular and Metabolism (e.g., thrombosis, diabetes and macular degeneration) and Pulmonary Hypertension (e.g., Pulmonary Arterial Hypertension). Medicines in this segment are distributed directly to retailers, wholesalers, distributors, hospitals and healthcare professionals for prescription use. Key products in the Innovative Medicine segment include: REMICADE (infliximab), a treatment for a number of immune-mediated inflammatory diseases; SIMPONI (golimumab), a subcutaneous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis and moderately active to severely active ulcerative colitis; SIMPONI ARIA (golimumab), an intravenous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis and active ankylosing spondylitis and active polyarticular juvenile idiopathic arthritis (pJIA) in people 2 years of age and older; STELARA (ustekinumab), a treatment for adults and children with moderate to severe plaque psoriasis, for adults with active psoriatic arthritis, for adults with moderately to severely active Crohn's disease and treatment of moderately to severely active ulcerative colitis; TREMFYA (guselkumab), a treatment for adults with moderate to severe plaque psoriasis and active psoriatic arthritis; EDURANT (rilpivirine), PREZISTA (darunavir) and PREZCOBIX/REZOLSTA (darunavir/cobicistat), antiretroviral medicines for the treatment of human immunodeficiency virus (HIV) in combination with other antiretroviral products and SYMTUZA (darunavir/cobicistat/emtricitabine/tenofovir alafenamide), a once-daily single tablet regimen for the treatment of HIV; CONCERTA (methylphenidate HCl) extended-release tablets CII, a treatment for attention deficit hyperactivity disorder; INVEGA SUSTENNA/XEPLION (paliperidone palmitate), for the treatment of schizophrenia and schizoaffective disorder in adults; INVEGA TRINZA/TREVICTA (paliperidone palmitate), for the treatment of schizophrenia in patients after they have been adequately treated with INVEGA SUSTENNA for at least four months; SPRAVATO (Esketamine), a nasal spray, used along with an oral antidepressant, to treat adults with treatment-resistant depression (TRD) and depressive symptoms in adults with major depressive disorder (MDD) with suicidal thoughts or actions; CARVYKTI (ciltacabtagene autoleucel), a chimeric antigen receptor (CAR)-T-cell therapy for the treatment of patients with relapsed/refractory multiple myeloma; ZYTIGA (abiraterone

acetate), a treatment for patients with prostate cancer; ERLEADA (apalutamide), a next-generation androgen receptor inhibitor for the treatment of patients with prostate cancer; IMBRUVICA (ibrutinib), a treatment for certain B-cell malignancies, or blood cancers and chronic graft versus host disease; DARZALEX (daratumumab), a treatment for multiple myeloma; DARZALEX FASPRO (daratumumab and hyaluronidase-fihj), a treatment for multiple myeloma and light chain (AL) Amyloidosis; XARELTO (rivaroxaban), an oral anticoagulant for the prevention of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery, to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, and for the treatment and reduction of risk of recurrence of DVT and PE to reduce the risk of major cardiovascular events in patients with coronary artery disease (CAD) and peripheral artery disease (PAD), for the treatment and secondary prevention of thromboembolism in pediatric patients, and for thromboprophylaxis in pediatric patients following the Fontan procedure; OPSUMIT (macitentan) as monotherapy or in combination, indicated for the long-term treatment of pulmonary arterial hypertension (PAH); UPTRAVI (selexipag), the only approved oral and intravenous, selective IP receptor agonist targeting a prostacyclin pathway in PAH. Many of these medicines were developed in collaboration with strategic partners or are licensed from other companies and maintain active lifecycle development programs.

MedTech

The MedTech segment includes a broad portfolio of products used in the Interventional Solutions, Orthopaedics, Surgery and Vision categories. Interventional Solutions include electrophysiology products (Biosense Webster) to treat heart rhythm disorders, the heart recovery portfolio (Abiomed) which includes technologies to treat severe coronary artery disease requiring high-risk PCI or AMI cardiogenic shock, and Neurovascular care (Cerenovus) that treats hemorrhagic and ischemic stroke. The Orthopaedics portfolio (DePuy Synthes) includes products and enabling technologies that support Hips, Knees, Trauma, and Spine, Sports & Other. The Surgery portfolios include advanced and general surgery technologies (Ethicon), as well as solutions that focus on breast aesthetics (Mentor), and Ear, Nose and Throat (Acclarent) procedures. Johnson & Johnson Vision products include ACUVUE Brand contact lenses and TECNIS intraocular lenses for cataract surgery. These products are distributed to wholesalers, hospitals and retailers, and used predominantly in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

Geographic areas

Johnson & Johnson and its subsidiaries (the Company) have approximately 131,900 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the healthcare field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The products made and sold in the international business include many of those described above under Segments of Business – Innovative Medicine and MedTech. However, the principal markets, products and methods of distribution in the international business vary with the country and the culture. The products sold in international business include those developed in the U.S. and by subsidiaries abroad.

Investments and activities in some countries outside the U.S. are subject to higher risks than comparable U.S. activities because the investment and commercial climate may be influenced by financial instability in international economies, restrictive economic policies and political and legal system uncertainties.

Raw materials

Raw materials essential to the Company's business are generally readily available from multiple sources. Where there are exceptions, the temporary unavailability of those raw materials would not likely have a material adverse effect on the financial results of the Company.

Patents

The Company's subsidiaries have made a practice of obtaining patent protection on their products and processes where possible. They own, or are licensed under, a significant number of patents in the U.S. and other countries relating to their products, product uses, formulations and manufacturing processes, which in the aggregate are believed to be of material importance to the Company in the operation of its businesses. The Company’s subsidiaries face patent challenges from third parties, including challenges seeking to manufacture and market generic and biosimilar versions of the Company's key

pharmaceutical products prior to expiration of the applicable patents covering those products. Significant legal proceedings and claims involving the Company's patent and other intellectual property are described in Note 19 Legal proceedings—Intellectual property of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Sales of the Company's largest product, STELARA (ustekinumab) accounted for approximately 12.8% of the Company's total revenues for fiscal 2023. Accordingly, the patents related to this product are believed to be material to the Company. Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson, owns patents specifically related to STELARA. The latest expiring United States composition of matter patent expired in 2023. As a result of settlements and other agreements with third parties, the Company does not anticipate the launch of a biosimilar version of STELARA before January 1, 2025 in the United States. The latest expiring European composition of matter patent (Supplementary Protection Certificate) expires in 2024.

Sales of the Company's second largest product, collectively DARZALEX (daratumumab) and DARZALEX FASPRO (daratumumab and hyaluronidase-fihj), accounted for approximately 11.4% of the Company's total revenues for fiscal 2023. Accordingly, the patents related to this product are believed to be material to the Company. Genmab A/S owns two patent families related to DARZALEX, and Janssen Biotech, Inc. has an exclusive license to those patent families. The two patent families both expire in the United States in 2029, and in Europe, compound patent protection in select countries extends to 2031/2032. Janssen Biotech, Inc. owns a separate patent portfolio related to DARZALEX FASPRO.

Trademarks

The Company's subsidiaries have made a practice of selling their products under trademarks and of obtaining protection for these trademarks by all available means. These trademarks are protected by registration in the U.S. and other countries where such products are marketed. The Company considers these trademarks in the aggregate to be of material importance in the operation of its businesses.

Seasonality

Worldwide sales do not reflect any significant degree of seasonality; however, spending has typically been heavier in the fourth quarter of each year than in other quarters. This reflects increased spending decisions, principally for research and development activity.

Competition

In all of their product lines, the Company's subsidiaries compete with companies both locally and globally. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, both internally and externally sourced, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products, as well as protecting the underlying intellectual property of the Company's product portfolio, is important to the Company's success in all areas of its business. The competitive environment requires substantial investments in continuing research.

Environment

The Company is subject to a variety of environmental laws and regulations in the United States and other jurisdictions. The Company believes that its operations comply in all material respects with applicable environmental laws and regulations. The Company's compliance with these requirements is not expected to have a material effect upon its capital expenditures, cash flows, earnings or competitive position.

Regulation

The Company's businesses are subject to varying degrees of governmental regulation in the countries in which operations are conducted, and the general trend is toward increasingly stringent regulation and enforcement. The Company is subject to costly and complex U.S. and foreign laws and governmental regulations and any adverse regulatory action may materially adversely affect the Company's financial condition and business operations. In the U.S., the pharmaceutical product and medical technology industries have long been subject to regulation by various federal and state agencies, primarily as to product safety, efficacy, manufacturing, advertising, labeling and safety reporting. The exercise of broad regulatory powers by the U.S. Food and Drug Administration (the U.S. FDA) continues to result in increases in the amounts of testing and documentation required for U.S. FDA approval of new drugs and devices and a corresponding increase in the expense of product introduction. Similar trends are also evident in major markets outside of the U.S.

The new medical device regulatory framework and the evolving privacy, data localization, and emerging cyber security laws and regulations around the world are examples of such increased regulation. Within the U.S., an increasing number of U.S. States have enacted comprehensive privacy laws and federal regulators (e.g., the U.S. FDA, FTC and HHS) continue to stress the intersection of health and privacy as a compliance and enforcement priority. In the EU, multiple directives and laws (including NIS2, EHDS, the Data Act, the Cyber Resilience Act, and the AI Act) are rapidly changing privacy and cybersecurity compliance requirements while introducing new enforcement risks. In addition, China has introduced broad personal information protection and data security regulations, with more anticipated, thereby increasing China's scrutiny of company compliance and data transfer practices. With other jurisdictions enacting similar privacy laws, local data protection authorities will force greater accountability on the collection, access and use of personal data in the healthcare industry. These laws can also restrict transfers of data across borders, potentially impacting how data-driven health care solutions are developed and deployed globally in a compliant manner. Moreover, as a result of the broad scale release and availability of Artificial Intelligence (AI) technologies such as generative AI, a global trend towards more comprehensive and nuanced regulation (e.g., White House's Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence; the EU AI Act) to ensure the ethical use, privacy, and security of AI is underway that includes standards for transparency, accountability, and fairness, which will require compliance developments or enhancements.

The regulatory agencies under whose purview the Company operates have administrative powers that may subject it to actions such as product withdrawals, recalls, seizure of products and other civil and criminal sanctions. In some cases, the Company's subsidiaries may deem it advisable to initiate product recalls regardless of whether it has been required or directed to.

The U.S. FDA and regulatory agencies around the globe are also increasing their enforcement activities. If the U.S. FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our pharmaceutical products or medical technologies are ineffective or pose an unreasonable health risk, the U.S. FDA could ban such products, detain or seize adulterated or misbranded products, order a recall, repair, replacement, or refund of such products, refuse to grant pending applications for marketing authorization or require certificates of foreign governments for exports, and/or require us to notify health professionals and others that the products present unreasonable risks of substantial harm to the public health. The U.S. FDA may also assess civil or criminal penalties against us, our officers or employees and impose operating restrictions on a company-wide basis, or enjoin and/or restrain certain conduct resulting in violations of applicable law. The U.S. FDA may also recommend prosecution to the U.S. Department of Justice. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and limit our ability to obtain future clearances or approvals, and could result in a substantial modification to our business practices and operations. Equivalent enforcement mechanisms exist in different countries in which we conduct business.

The costs of human healthcare have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. In the U.S., attention has been focused by states, regulatory agencies and Congress on prices, profits, overutilization and the quality and costs of healthcare generally. Laws and regulations have been enacted to require adherence to strict compliance standards and prevent fraud and abuse in the healthcare industry. There is increased focus on interactions and financial relationships between healthcare companies and healthcare providers. Various state and federal transparency laws and regulations require disclosures of payments and other transfers of value made to certain healthcare practitioners, including physicians, teaching hospitals, and certain non-physician practitioners. Federal and foreign laws governing international business practices require strict compliance with anti-bribery standards and certain prohibitions with respect to payments to any foreign government official. Payors and Pharmacy Benefit Managers (PBMs) are a potent force in the marketplace, and increased attention is being paid to the impact of PBM practices on healthcare cost and access in the U.S.

Our business has been and continues to be affected by federal and state legislation that alters the pricing, coverage, and reimbursement landscape. At the federal level, in August 2022, President Biden signed into law the Inflation Reduction Act

(IRA), which includes provisions that effectively authorize the government to establish prices for certain high-spend single-source drugs and biologics reimbursed by the Medicare program, starting in 2026 for Medicare Part D drugs and 2028 for Medicare Part B drugs. On August 29, 2023, the Centers for Medicare & Medicaid Services ("CMS") published the first "Selected Drug" list, which includes XARELTO and STELARA as well as IMBRUVICA, which is developed in collaboration and co-commercialized in the U.S. with Pharmacyclics LLC, an AbbVie company. The Selected Drug list also included other medicines targeting disease states that are prevalent in the Medicare population. There remains uncertainty, however, regarding how the federal government will establish prices for the selected products, as the IRA specifies a ceiling price but not a minimum price. In any event, we anticipate that the selected products will be subjected to a government-established price for the Medicare population.

The IRA also contains provisions that impose rebates if certain prices increase at a rate that outpaces the rate of inflation, beginning October 1, 2022, for Medicare Part D drugs and January 1, 2023, for Medicare Part B drugs. Separate IRA provisions redesign the Medicare Part D benefit in various ways, including by shifting a greater portion of costs to manufacturers within certain coverage phases and replacing the Part D coverage gap discount program with a new manufacturer discounting program. Failure to comply with IRA provisions may subject manufacturers to various penalties, including civil monetary penalties.

In July 2023, Janssen Pharmaceuticals, Inc. (Janssen) filed litigation against the U.S. Department of Health and Human Services as well as the Centers for Medicare and Medicaid Services challenging the constitutionality of the Inflation Reduction Act's (IRA) Medicare Drug Price Negotiation Program. The litigation requests a declaration that the IRA violates Janssen's rights under the First Amendment and the Fifth Amendment to the Constitution and therefore that Janssen is not subject to the IRA's mandatory pricing scheme. The impact of the IRA on our business and the broader pharmaceutical industry remains uncertain, as litigation filed by Janssen and other pharmaceutical companies remains ongoing and CMS has yet to publicly announce the maximum fair price for each of the selected drugs.

Additionally, we expect continued scrutiny on drug pricing and government price reporting from Congress, agencies, and other bodies at the federal and state levels, which may result in additional regulations or other mechanisms to increase pricing transparency and controls.

There are a number of additional bills pending in Congress and healthcare reform proposals at the state level that would affect drug pricing, including in the Medicare and Medicaid programs. This changing legal landscape has both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of federal and state law, and potential modification or repeal of these laws, will ultimately affect the industry. The IRA and any other federal or state legislative change could affect the pricing and market conditions for our products.

In addition, business practices in the healthcare industry have come under increased scrutiny, particularly in the U.S., by government agencies and state attorneys general, and resulting investigations and prosecutions carry the risk of significant civil and criminal penalties. Of note is the increased enforcement activity by data protection authorities in various jurisdictions, particularly in the European Union, where significant fines have been levied on companies for data breaches, violations of privacy requirements, and unlawful cross-border data transfers. In the U.S., the Federal Trade Commission has stepped up enforcement of data privacy with several significant settlements (including settlements concerning the downstream sharing of personal information and use and disclosure of personal health data) and there have been a material increase in class-action lawsuits linked to the collection and use of biometric data and use of tracking technologies.

Further, the Company relies on global supply chains, and production and distribution processes, that are complex, and subject to increasing regulatory requirements that may affect sourcing, supply and pricing of materials used in the Company's products. These processes also are subject to complex and lengthy regulatory approvals.

Employees and human capital management

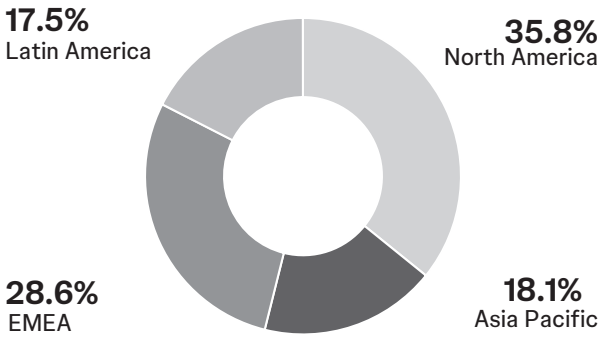
As of December 31, 2023, the number of employees was approximately:

	2023
Employees[1]	134,400
Full-time equivalent (FTE) positions[2]	131,900

1 "Employee" is defined as an individual working full-time or part-time, excluding fixed term employees, interns and co-op employees. Employee data may not include full population from more recently acquired companies and individuals on long-term disability are excluded. Contingent workers, contractors and subcontractors are also excluded.

2 FTE represents the total number of full-time equivalent positions and does not reflect the total number of individual employees as some work part-time.

Employees by region (in percentages)



Strategy

The Company believes that its employees are critical to its continued success and are an essential element of its long-term strategy. Management is responsible for ensuring that its policies and processes reflect and reinforce the Company's desired corporate culture, including policies and processes related to strategy, risk management, and ethics and compliance. The Company's human capital management strategy is built on three fundamental focus areas:

- Attracting and recruiting the best talent
- Developing and retaining talent
- Empowering and inspiring talent

Underpinning these focus areas are ongoing efforts to cultivate and foster a culture built on diversity, equity and inclusion (DEI), innovation, health, well-being and safety, where the Company's employees are encouraged to succeed both professionally and personally while helping the Company achieve its business goals.

Culture and employee engagement

At the Company, employees are guided by Our Credo which sets forth the Company's responsibilities to patients, consumers, customers, healthcare professionals, employees, communities and shareholders. Employees worldwide must adhere to the Company's Code of Business Conduct which sets basic requirements and serves as a foundation for the Company policies, procedures and guidelines, all of which provide additional guidance on expected employee behaviors in every market where it operates. The Company conducts global surveys that offer its employees the ability to provide feedback and valuable insight to help address potential human resources risks and identify opportunities to improve. In 2023, 94% of global employees across 76 countries participated in Our Credo Survey which was offered in 36 languages.

Growth and development

To lead in the changing healthcare landscape, it is crucial that the Company continue to attract and retain top talent. In 2023, the Company's voluntary turnover rate was 7%. The Company believes that its employees must be equipped with the right knowledge and skills and be provided with opportunities to grow and develop in their careers. Accordingly, professional development programs and educational resources are available to all employees. The Company's objective is to foster a learning culture that helps shape each person's unique career path while creating a robust pipeline of talent to deliver on the Company's long-term strategies. In furtherance of this objective, the Company deploys a global approach to ensure development is for everyone, regardless of where they are on their career journey. To prioritize learning, the Company recently held Johnson & Johnson's first Global Learning Day. Employees were encouraged to set aside a full day to explore skill-building courses across five areas: leadership, business skills, digital upskilling, DEI, and well-being, on J&J Learn, the Company's new learning platform.

Diversity, equity, and inclusion (DEI)

The Company is committed to workplace diversity and to cultivating, fostering, and advancing a culture of equity and inclusion. The Company's evidenced-based global enterprise Diversity, Equity and Inclusion strategy recognizes how DEI accelerates the Company's ability to meet the changing needs of the communities the Company serves in, as outlined in Our Credo. The Company's DEI Vision is: *Be yourself, change the world*. The Company's DEI Mission is: *Make diversity, equity and inclusion how we work everyday*. The Company's enterprise DEI Strategy is aligned to the DEI Vision and Mission and rests on four core pillars:

- Build a workforce of individuals with diverse backgrounds, cultures, abilities and perspectives
- Foster a culture of inclusion where every individual belongs
- Transform talent and business processes to achieve equitable opportunities for all
- Drive innovation and growth with our business to serve diverse markets around the world

The Company's DEI strategy is guided by internal and external insights, global best practices and continual employee feedback and recognizes that while diversity changes by location, inclusion is the same everywhere.

Compensation and benefits

As part of the Company's total rewards philosophy, the Company offers competitive compensation and benefits to attract and retain top talent. The Company is committed to fairness and equitable treatment in its compensation and benefits for employees at all levels. The Company observes legal minimum wage provisions and exceeds them where possible. The Company's total rewards offerings include an array of programs to support its employees' well-being, including annual performance incentive opportunities, pension and retirement savings programs, health and welfare benefits, paid time off, leave programs, flexible work schedules and employee assistance programs. In recognition of the Company's commitment to help employees balance their personal and professional responsibilities, the Company enhanced its caregiver, bereavement, and volunteer paid leave benefits, effective July 2023.

Health, wellness and safety

The Company's investment in employee health, well-being and safety is built on its conviction that advancing health for humanity starts with advancing the health of its employees. With the right awareness, focus, practices and tools, the Company ensures that all its employees around the world, as well as temporary contractors and visitors to the Company's sites, can work safely. The Company has continuously expanded health and well-being programs throughout the Company and across the globe, incorporating new thinking and technologies to keep its offerings best-in-class and to help employees achieve their personal health goals. The programs and practices the Company advances for total health—physical, mental, emotional and financial—ensure employee health protection for emerging health risks. The Company continues to address our employees needs through J&J Flex, a hybrid model that empowers the Company's office-based employees to find the right productivity and balance of in-person and remote work.

Available information

The Company's main corporate website address is www.jnj.com. The Company makes its SEC filings available on the Company's website at www.investor.jnj.com/financials/sec-filings, as soon as reasonably practicable after having been electronically filed or furnished to the SEC. The Company's SEC filings are also available at the SEC's website at www.sec.gov.

Investors and the public should note that the Company also announces information at www.factsaboutourprescriptionopioids.com, www.factsabouttalc.com and www.LLTManagementInformation.com. We use these websites to communicate with investors and the public about our products, litigation and other matters. It is possible that the information we post to these websites could be deemed to be material information. Therefore, we encourage investors and others interested in the Company to review the information posted to these websites in conjunction with www.jnj.com, the Company's SEC filings, press releases, public conference calls and webcasts.

In addition, the Amended and Restated Certificate of Incorporation, By-Laws, the written charters of the Audit Committee, the Compensation & Benefits Committee, the Nominating & Corporate Governance Committee, the Regulatory Compliance & Sustainability Committee, the Science & Technology Committee and any special committee of the Board of Directors and the Company's Principles of Corporate Governance, Code of Business Conduct (for employees), Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers, and other corporate governance materials, are available at www.investor.jnj.com/governance/corporate-governance-overview on the Company's website and will be provided without charge to any shareholder submitting a written request, as provided above. The information on www.jnj.com, www.factsaboutourprescriptionopioids.com, www.factsabouttalc.com and www.LLTManagementInformation.com is not, and will not be deemed, a part of this Report or incorporated into any other filings the Company makes with the SEC.

Item 1A. Risk factors

An investment in the Company's common stock or debt securities involves risks and uncertainties. The Company seeks to identify, manage and mitigate risks to our business, but uncertainties and risks are difficult to predict and many are outside of the Company's control and cannot therefore be eliminated. In addition to the other information in this report and the Company's other filings with the SEC, investors should consider carefully the factors set forth below. Investors should be aware that it is not possible to predict or identify all such factors and that the following is not meant to be a complete discussion of all potential risks or uncertainties. If known or unknown risks or uncertainties materialize, the Company's business, results of operations or financial condition could be adversely affected, potentially in a material way.

Risks related to our business, industry and operations

The Company's businesses operate in highly competitive product markets and competitive pressures could adversely affect the Company's earnings.

The Company faces substantial competition in its two operating segments and in all geographic markets. The Company's businesses compete with companies of all sizes on the basis of cost-effectiveness, technological innovations, intellectual property rights, product performance, real or perceived product advantages, pricing and availability and rate of reimbursement. The Company also competes with other market participants in securing rights to acquisitions, collaborations and licensing agreements with third parties. Competition for rights to product candidates and technologies may result in significant investment and acquisition costs and onerous agreement terms for the Company. Competitors' development of more effective or less costly products, and/or their ability to secure patent and other intellectual property rights and successfully market products ahead of the Company, could negatively impact sales of the Company's existing products as well as its ability to bring new products to market despite significant prior investment in the related product development. The Company may also experience operational and financial risk in connection with acquisitions if we are unable to fully identify potential risks and liabilities associated with acquired businesses or products, successfully integrate operations and employees, and successfully identify and realize synergies with existing businesses while containing acquisition-related strain on our management, operations and financial resources.

For the Company's Innovative Medicine businesses, loss of patent exclusivity for a product often is followed by a substantial reduction in sales as competitors gain regulatory approval for generic and other competing products and enter the market. Similar competition can be triggered by the loss of exclusivity for a biological product. For the Company's MedTech businesses, technological innovation, product quality, reputation and customer service are especially important to competitiveness. Development by other companies of new or improved products, processes and technologies could threaten to make the Company's products or technologies less desirable, less economical or obsolete. The Company's business and operations will be negatively impacted if we are unable to introduce new products or technological advances that are safe, more effective, more effectively marketed or otherwise outperform those of our competitors.

Interruptions and delays in manufacturing operations could adversely affect the Company's business, sales and reputation.

The Company's manufacturing of products requires the timely delivery of sufficient amounts of complex, high-quality components and materials. The Company's subsidiaries operate 61 manufacturing facilities as well as sourcing from thousands of suppliers around the world. The Company has in the past, and may in the future, face unanticipated interruptions and delays in manufacturing through its internal or external supply chain. Manufacturing disruptions can occur for many reasons including regulatory action, production quality deviations or safety issues, labor disputes, labor shortages, site-specific incidents (such as fires), natural disasters such as hurricanes and other severe weather events, raw material shortages, political unrest, terrorist attacks and epidemics or pandemics. Such delays and difficulties in manufacturing can result in product shortages, declines in sales and reputational impact as well as significant remediation and related costs associated with addressing the shortage.

The Company relies on third parties to manufacture and supply certain of our products. Any failure by or loss of a third-party manufacturer or supplier could result in delays and increased costs, which may adversely affect our business.

The Company relies on third parties to manufacture and supply certain of our raw materials, component parts and products. We depend on these third-party manufacturers to allocate to us a portion of their manufacturing capacity sufficient to meet our needs, to produce products of acceptable quality and at acceptable manufacturing yields and to deliver those products to us on a timely basis and at acceptable prices. However, we cannot guarantee that these third-party manufacturers will be able to meet our near-term or long-term manufacturing requirements, which could result in lost sales and have an adverse effect on our business.

Other risks associated with our reliance on third parties to manufacture these products include reliance on the third party for regulatory compliance and quality assurance, misappropriation of the Company's intellectual property, limited ability to manage our inventory, possible breach of the manufacturing agreement by the third party and the possible termination or nonrenewal of the manufacturing agreement by the third party at a time that is costly or inconvenient for us. Moreover, if any of our third-party manufacturers suffers any damage to facilities, loses benefits under material agreements, experiences power outages, encounters financial difficulties, is unable to secure necessary raw materials from its suppliers or suffers any other reduction in efficiency, the Company may experience significant business disruption. In the event of any such disruption, the Company would need to seek and source other qualified third-party manufacturers, likely resulting in further delays and increased costs which could affect our business adversely.

Counterfeit versions of our products could harm our patients and have a negative impact on our revenues, earnings, reputation and business.

Our industry continues to be challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Third parties may illegally distribute and sell counterfeit versions of our products, which do not meet our rigorous manufacturing and testing standards. To distributors and patients, counterfeit products may be visually indistinguishable from the authentic version. Counterfeit medicines pose a risk to patient health and safety because of the conditions under which they are manufactured – often in unregulated, unlicensed, uninspected and unsanitary sites – as well as the lack of regulation of their contents.

The industry's failure to mitigate the threat of counterfeit medicines could adversely impact our business and reputation by impacting patient confidence in our authentic products, potentially resulting in lost sales, product recalls, and an increased threat of litigation. In addition, diversion of our products from their authorized market into other channels may result in reduced revenues and negatively affect our profitability.

Global health crises, pandemics, epidemics, or other outbreaks could adversely disrupt or impact certain aspects of the Company's business, results of operations and financial condition.

We are subject to risks associated with global health crises, epidemics, pandemics and other outbreaks (such incident(s), a health crisis or health crises). For example, the COVID-19 pandemic adversely impacted certain aspects of the Company's business, results of operations and financial condition, including lower sales and reduced customer demand and usage of certain of our products. The spread of any health crises may cause the Company to modify its business practices, and take further actions as may be required by government authorities or as the Company determines are in the best interests of our patients, customers, employees and business partners under such circumstances. While the Company has robust business continuity plans in place across our global supply chain network designed to help mitigate the impact of health crises, these efforts may not completely prevent our business from being adversely affected in the event of a health crisis. Health crises could adversely impact the Company's operations, including, among other things, our manufacturing operations, supply chain, third-party suppliers, sales and marketing, and clinical trial operations. Any of these factors could adversely affect the Company's business, financial results, and global economic conditions generally.

Risks related to government regulation and legal proceedings

Global sales in the Company's Innovative Medicine and MedTech segments may be negatively impacted by healthcare reforms and increasing pricing pressures.

Sales of the Company's Innovative Medicine and MedTech products are significantly affected by reimbursements by third-party payors such as government healthcare programs, private insurance plans and managed care organizations. As part of various efforts to contain healthcare costs, these payors are putting downward pressure on prices at which products will be reimbursed. In the U.S., increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, in part due to continued consolidation among healthcare providers, could result in further pricing pressures. In addition, recent legislation and ongoing political scrutiny on pricing, coverage and reimbursement could result in additional pricing pressures. Specifically, the Inflation Reduction Act of 2022 (IRA) may subject certain products to government-established pricing, potentially impose rebates, and subject manufacturers who fail to adhere to the government's interpretations of the law to penalties. Further, increased third-party utilization of the 340B Federal Drug Discount Program from expanded interpretations of the statute may have a negative impact on the Company's financial performance. Outside the U.S., numerous major markets, including the EU, United Kingdom, Japan and China, have pervasive government involvement in funding healthcare and, in that regard, directly or indirectly impose price controls, limit access to, or reimbursement for, the Company's products, or reduce the value of its intellectual property protection.

We are subject to an increasing number of costly and complex governmental regulations in the countries in which operations are conducted which may materially adversely affect the Company's financial condition and business operations.

As described in Item 1. Business, the Company is subject to an increasing number of extensive government laws and regulations, investigations and legal action by national, state and local government agencies in the U.S. and other countries in which it operates. For example, changes to the U.S. FDA's timing or requirements for approval or clearance of our products may have a negative impact on our ability to bring new products to market. New laws and regulations may also impose deadlines on the Company, or its third-party suppliers, manufacturers or other partners and providers, for which there may be insufficient time to implement changes to comply with such new regulations and may result in manufacturing delays or other supply chain constraints. If the Company is unable to identify ways to mitigate these delays or constraints, there may be an adverse effect on sales and access to our products.

The Company is subject to significant legal proceedings that can result in significant expenses, fines and reputational damage.

In the ordinary course of business, Johnson & Johnson and its subsidiaries are subject to numerous claims and lawsuits involving various issues such as product liability, patent disputes and claims that their product sales, marketing and pricing practices violate various antitrust, unfair trade practices and/or consumer protection laws. The Company's more significant legal proceedings are described in Note 19 Legal proceedings under Notes to the Consolidated Financial Statements included in Item 8 of this Report. Litigation, in general, and securities, derivative action, class action and multi-district litigation, in particular, can be expensive and disruptive. Some of these matters may include thousands of plaintiffs, may involve parties seeking large and/or indeterminate amounts, including punitive or exemplary damages, and may remain unresolved for several years. For example, the Company is a defendant in numerous lawsuits arising out of the use of body powders containing talc, primarily JOHNSON'S Baby Powder, and the Company's sale, manufacturing and marketing of opioids. While the Company believes it has substantial defenses in these matters, it is not feasible to predict the ultimate outcome of litigation. The Company could in the future be required to pay significant amounts as a result of settlements or judgments in these matters, potentially in excess of accruals, including matters where the Company could be held jointly and severally liable among other defendants. The resolution of, or increase in accruals for, one or more of these matters in any reporting period could have a material adverse effect on the Company's results of operations and cash flows for that period. The Company does not purchase third-party product liability insurance; however, the Company utilizes a wholly owned captive insurance company subject to certain limits.

Product reliability, safety and effectiveness concerns can have significant negative impacts on sales and results of operations, lead to litigation and cause reputational damage.

Concerns about product safety, whether raised internally or by litigants, regulators or consumer advocates, and whether or not based on scientific evidence, can result in safety alerts, product recalls, governmental investigations, regulatory action on the part of the U.S. FDA (or its counterpart in other countries), private claims and lawsuits, payment of fines and settlements, declining sales and reputational damage. These circumstances can also result in damage to brand image, brand equity and consumer trust in the Company's products. Product recalls have in the past, and could in the future, prompt government investigations and inspections, the shutdown of manufacturing facilities, continued product shortages and related sales declines, significant remediation costs, reputational damage, possible civil penalties and criminal prosecution.

The Company faces significant regulatory scrutiny, which imposes significant compliance costs and exposes the Company to government investigations, legal actions and penalties.

The rapid increase in new government laws and regulations imposes significant compliance costs to the Company and a failure of the Company to timely implement changes to comply with these new laws may expose the Company to investigations, legal actions or penalties. Regulatory issues regarding compliance with current Good Manufacturing Practices (cGMP) (and comparable quality regulations in foreign countries) by manufacturers of drugs and devices can lead to fines and penalties, product recalls, product shortages, interruptions in production, delays in new product approvals and litigation. In addition, the marketing, pricing and sale of the Company's products are subject to regulation, investigations and legal actions including under the Federal Food, Drug, and Cosmetic Act, the Medicaid Rebate Program, federal and state false claims acts, state unfair trade practices acts and consumer protection laws. Scrutiny of healthcare industry business practices by government agencies and state attorneys general in the U.S., and any resulting investigations and prosecutions, carry risk of significant civil and criminal penalties including, but not limited to, debarment from participation in government healthcare programs. Any such debarment could have a material adverse effect on the Company's business and results of operations. The most significant current investigations and litigation brought by government agencies are described in Note 19 Legal proceedings—Government proceedings under Notes to the Consolidated Financial Statements included in Item 8 of this Report.

Changes in tax laws or exposures to additional tax liabilities could negatively impact the Company's operating results.

Changes in tax laws or regulations around the world, including in the U.S. and as led by the Organization for Economic Cooperation and Development, such as the recent enactment by certain EU and non-EU countries, and the anticipated enactment by additional countries, of a global minimum tax, could negatively impact the Company's effective tax rate and results of operations. A change in statutory tax rate or certain international tax provisions in any country would result in the revaluation of the Company's deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is enacted. This change would result in an expense or benefit recorded to the Company's Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries where it operates. Changes to tax laws or regulations may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted.

See Note 8 Income taxes under Notes to the Consolidated Financial Statements included in Item 8 of this Report for additional information.

The Company conducts business and files tax returns in numerous countries and is addressing tax audits and disputes with many tax authorities. In connection with various government initiatives, companies are required to disclose more information to tax authorities on operations around the world, which may lead to greater audit scrutiny of profits earned in other countries. The Company regularly assesses the likely outcomes of its tax audits and disputes to determine the appropriateness of its tax reserves. However, any tax authority could take a position on tax treatment that is contrary to the Company's expectations, which could result in tax liabilities in excess of reserves.

Risks related to our intellectual property

The Company faces increased challenges to intellectual property rights central to its business.

The Company owns or licenses a significant number of patents and other proprietary rights relating to its products and manufacturing processes. These rights are essential to the Company's businesses and materially important to the Company's results of operations. Public policy, both within and outside the U.S., has become increasingly unfavorable toward intellectual property rights. The Company cannot be certain that it will obtain adequate patent protection for new products and technologies in the United States and other important markets or that such protections, once granted, will last as long as originally anticipated.

Competitors routinely challenge the validity or extent of the Company's owned or licensed patents and proprietary rights through litigation, interferences, oppositions and other proceedings, such as inter partes review (IPR) proceedings before the United States Patent & Trademark Office (USPTO). These proceedings absorb resources and can be protracted as well as unpredictable. In addition, challenges that the Company's products infringe the patents of third parties could result in an injunction and/or the need to pay past damages and future royalties and adversely affect the competitive position and sales of the products in question.

The Company has faced increasing patent challenges from third parties seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the U.S., manufacturers of generic versions of innovative human pharmaceutical products may challenge the validity, or claim non-infringement, of innovator products through the Abbreviated New Drug Application, or ANDA, process with the U.S. FDA and related ANDA litigation. The Biologics Price Competition and Innovation Act (BPCIA), enacted in 2010, which created a new regulatory pathway for the approval by the U.S. FDA of biosimilar alternatives to innovator-developed biological products, also created mechanisms for biosimilar applicants to challenge the patents on the innovator biologics. The IPR process with the USPTO is also being used by competitors to challenge patents asserted in litigation.

In the event the Company is not successful in defending its patents against such challenges, or upon the "at-risk" launch by the generic or biosimilar firm of its product, the Company can lose a major portion of revenues for the referenced product in a very short period of time. Current legal proceedings involving the Company's patents and other intellectual property rights are described in Note 19 Legal proceedings—Intellectual property under Notes to the Consolidated Financial Statements included in Item 8 of this Report.

Risks related to product development, regulatory approval and commercialization

Significant challenges or delays in the Company's innovation, development and implementation of new products, technologies and indications could have an adverse impact on the Company's long-term success.

The Company's continued growth and success depends on its ability to innovate and develop new and differentiated products and services that address the evolving healthcare needs of patients, providers and consumers. Development of successful products and technologies is also necessary to offset revenue losses when the Company's existing products lose market share due to various factors such as competition and loss of patent exclusivity. New products introduced within the past five years accounted for approximately 25% of 2023 sales. The Company cannot be certain when or whether it will be able to develop, license or otherwise acquire companies, products and technologies, whether particular product candidates will be granted regulatory approval, and, if approved, whether the products will be commercially successful.

The Company pursues product development through internal research and development as well as through collaborations, acquisitions, joint ventures and licensing or other arrangements with third parties. In all of these contexts, developing new products, particularly pharmaceutical and biotechnology products and medical devices, requires significant investment of resources over many years. Only a very few biopharmaceutical research and development programs result in commercially viable products. The process depends on many factors including the ability to: discern patients' and healthcare providers' future needs; develop promising new compounds, strategies and technologies; achieve successful clinical trial results; secure effective intellectual property protection; obtain regulatory approvals on a timely basis; and, if and when they reach the market, successfully differentiate the Company's products from competing products and approaches to treatment. New products or enhancements to existing products may not be accepted quickly or significantly in the marketplace due to product and price competition, changes in customer preferences or healthcare purchasing patterns, resistance by healthcare providers or uncertainty over third-party reimbursement. Even following initial regulatory approval, the success of a product can be adversely impacted by safety and efficacy findings in larger real-world patient populations, as well as market entry of competitive products.

The Company leverages the use of data science, machine learning and other forms of AI and emerging technologies across varying parts of its business and operations, and the introduction and incorporation of AI may result in unintended consequences or other new or expanded risks and liabilities. AI technology is continuously evolving, and the AI technologies we develop and adopt may become obsolete earlier than planned. Our investments in these technologies may not result in the benefits we anticipate or enable us to obtain or maintain a competitive advantage. The application of machine learning and AI in our business is emerging and evolving alongside new laws and regulations that may entail significant costs or ultimately limit our ability to continue the use of these technologies. These technologies also carry inherent risks related to data privacy and security further described below.

Risks related to financial and economic market conditions

The Company faces a variety of financial, economic, legal, social and political risks associated with conducting business internationally.

The Company's extensive operations and business activity throughout the world are accompanied by certain financial, economic, legal, social and political risks, including those listed below.

Foreign currency exchange: In fiscal 2023, approximately 45% of the Company's sales occurred outside of the U.S., with approximately 24% in Europe, 5% in the Western Hemisphere, excluding the U.S., and 16% in the Asia-Pacific and Africa region. Changes in non-U.S. currencies relative to the U.S. dollar impact the Company's revenues and expenses. While the Company uses financial instruments to mitigate the impact of fluctuations in currency exchange rates on its cash flows, unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the U.S. dollar may result in significant favorable or unfavorable translation effects when the operating results of the Company's non-U.S. business activity are translated into U.S. dollars.

Inflation and currency devaluation risks: The Company faces challenges in maintaining profitability of operations in economies experiencing high inflation rates. Specifically, the Company has accounted for operations in Argentina, Turkey and Venezuela as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. While the Company strives to maintain profit margins in these areas through cost reduction programs, productivity improvements and periodic price increases, it might experience operating losses as a result of continued inflation. In addition, the impact of currency devaluations in

countries experiencing high inflation rates or significant currency exchange fluctuations could negatively impact the Company's operating results.

Illegal importation of pharmaceutical products: The illegal importation of pharmaceutical products from countries where government price controls or other market dynamics result in lower prices may adversely affect the Company's sales and profitability in the U.S. and other countries in which the Company operates. With the exception of limited quantities of prescription drugs for personal use, foreign imports of pharmaceutical products are illegal under current U.S. law. However, the volume of illegal imports continues to rise as the ability of patients and other customers to obtain the lower-priced imports has grown significantly.

Anti-bribery and other regulations: The Company is subject to various federal and foreign laws that govern its international business practices with respect to payments to government officials. Those laws include the U.S. Foreign Corrupt Practices Act (FCPA), which prohibits U.S. publicly traded companies from promising, offering, or giving anything of value to foreign officials with the corrupt intent of influencing the foreign official for the purpose of helping the Company obtain or retain business or gain any improper advantage. The Company's business is heavily regulated and therefore involves significant interaction with foreign officials. Also, in many countries outside the U.S., the healthcare providers who prescribe human pharmaceuticals are employed by the government and the purchasers of human pharmaceuticals are government entities; therefore, the Company's interactions with these prescribers and purchasers are subject to regulation under the FCPA. In addition to the U.S. application and enforcement of the FCPA, various jurisdictions in which the Company operates have laws and regulations, including the U.K. Bribery Act 2010, aimed at preventing and penalizing corrupt and anticompetitive behavior. Enforcement activities under these laws could subject the Company to additional administrative and legal proceedings and actions, which could include claims for civil penalties, criminal sanctions, and administrative remedies, including exclusion from healthcare programs.

Other financial, economic, legal, social and political risks. Other risks inherent in conducting business globally include:

- local and regional economic environments and policies in the markets that we serve, including interest rates, monetary policy, inflation, economic growth, recession, commodity prices, and currency controls or other limitations on the ability to expatriate cash;
- protective economic policies taken by governments, such as trade protection measures, increased antitrust reporting requirements and enforcement activity, and import/export licensing requirements;
- compliance with local regulations and laws including, in some countries, regulatory requirements restricting the Company's ability to manufacture or sell its products in the relevant market;
- diminished protection of intellectual property and contractual rights in certain jurisdictions;
- potential nationalization or expropriation of the Company's foreign assets;
- political or social upheavals, economic instability, repression, or human rights issues; and
- geopolitical events, including natural disasters, disruptions to markets due to war, armed conflict, terrorism, epidemics or pandemics.

Due to the international nature of the Company's business, geopolitical or economic changes or events, including global tensions and war, could adversely affect our business, results of operations or financial condition.

As described above, the Company has extensive operations and business activity throughout the world. Global tensions, conflict and/or war among any of the countries in which we conduct business or distribute our products may result in foreign currency volatility, decreased demand for our products in affected countries, and challenges to our global supply chain related to increased costs of materials and other inputs for our products and suppliers. Most recently, we have experienced, and expect to continue to experience, impacts to the Company's business resulting from the Russia-Ukraine war, rising conflict in the Middle East as well as increasing tensions between the U.S. and China. In response to heightened conflict, such as the Russia-Ukraine war, governments may impose export controls and broad financial and economic sanctions. Our business and operations may be further impacted by the imposition of trade protection measures or other policies adopted by any country that favor domestic companies and technologies over foreign competitors. Additional sanctions or other measures may be imposed by the global community, including but not limited to limitations on our ability to file, prosecute and maintain patents, trademarks and other intellectual property rights. Furthermore, in some countries, such as in Russia, action may be taken that allows companies and individuals to exploit inventions owned by patent holders from the United States and many other countries without consent or compensation and we may not be able to prevent third parties from practicing the Company's inventions in Russia or from selling or importing products in and into Russia.

Weak financial performance, failure to maintain a satisfactory credit rating or disruptions in the financial markets could adversely affect our liquidity, capital position, borrowing costs and access to capital markets.

We currently maintain investment grade credit ratings with Moody's Investors Service and Standard & Poor's Ratings Services. Rating agencies routinely evaluate us, and their ratings of our long-term and short-term debt are based on a number of factors. Any downgrade of our credit ratings by a credit rating agency, whether as a result of our actions or factors which are beyond our control, can increase the cost of borrowing under any indebtedness we may incur, reduce market capacity for our commercial paper or require the posting of additional collateral under our derivative contracts. There can be no assurance that we will be able to maintain our credit ratings, and any additional actual or anticipated changes or downgrades in our credit ratings, including any announcement that our ratings are under review for a downgrade, may have a negative impact on our liquidity, capital position and access to capital markets.

Other risks

Our business depends on our ability to recruit and retain talented, highly skilled employees and a diverse workforce.

Our continued growth requires us to recruit and retain talented employees representing diverse backgrounds, experiences, and skill sets. The market for highly skilled workers and leaders in our industry is extremely competitive and our ability to compete depends on our ability to hire, develop and motivate highly skilled personnel in all areas of our organization. Maintaining our brand and reputation, as well as a diverse, equitable and inclusive work environment enables us to attract top talent. If we are less successful in our recruiting efforts, or if we cannot retain highly skilled workers and key leaders, our ability to develop and deliver successful products and services may be adversely affected. In addition, effective succession planning is important to our long-term success. Any unsuccessful implementation of our succession plans or failure to ensure effective transfer of knowledge and smooth transitions involving key employees could adversely affect our business, financial condition, or results of operations.

Climate change or legal, regulatory or market measures to address climate change may negatively affect our business and results of operations.

Climate change resulting from increased concentrations of carbon dioxide and other greenhouse gases in the atmosphere could present risks to our operations, including an adverse impact on global temperatures, weather patterns and the frequency and severity of extreme weather and natural disasters. Natural disasters and extreme weather conditions, such as a hurricane, tornado, earthquake, wildfire or flooding, may pose physical risks to our facilities and disrupt the operation of our supply chain. The impacts of the changing climate on water resources may result in water scarcity, limiting our ability to access sufficient high-quality water in certain locations, which may increase operational costs.

Concern over climate change may also result in new or additional legal or regulatory requirements designed to reduce greenhouse gas emissions and/or mitigate the effects of climate change on the environment. If such laws or regulations are more stringent than current legal or regulatory obligations, we may experience disruption in, or an increase in the costs associated with sourcing, manufacturing and distribution of our products, which may adversely affect our business, results of operations or financial condition. Further, the impacts of climate change have an influence on customer preferences, and failure to provide climate-friendly products could potentially result in loss of market share.

An information security incident, including a cybersecurity breach, could have a negative impact on the Company's business or reputation.

To meet business objectives, the Company relies on both internal information technology (IT) systems and networks, and those of third parties and their vendors, to process and store sensitive data, including confidential research, business plans, financial information, intellectual property, and personal data that may be subject to legal protection, and ensure the continuity of the Company's supply chain and operations. The extensive information security and cybersecurity threats, which affect companies globally, pose a risk to the security and availability of these systems and networks, including customer products that are connected to or rely on such systems and networks, and the confidentiality, integrity, and availability of the Company's sensitive data. The Company assesses these threats and makes investments to increase internal protection, detection, and response capabilities, as well as ensure the Company's third-party providers have required capabilities and controls, to address this risk. Because of the frequently changing attack techniques, along with the increased volume and sophistication of the attacks, there is the potential for the Company to be adversely impacted. This impact could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action. Also, increasing use of AI could increase these risks. The Company maintains cybersecurity insurance in the event of an information security or cyber incident; however, the coverage may not be sufficient to cover all financial, legal, business or reputational losses.

As a result of increased global tensions, the Company expects there will continue to be, an increased risk of information security or cybersecurity incidents, including cyberattacks perpetrated by adversaries of countries where the Company maintains operations. Given the potential sophistication of these attacks, the Company may not be able to address the threat of information security or cybersecurity incidents proactively or implement adequate preventative measures and we may not be able to detect and address any such disruption or security breach promptly, or at all, which could adversely affect our business, results of operations or financial condition. Moreover, these threats could also impact our third-party partners resulting in compromise of the Company's IT systems, networks and data which could negatively affect the Company.

A breach of privacy laws or unauthorized access, loss or misuse of personal data could have a negative impact on the Company's business or reputation.

The Company is subject to privacy and data protection laws across the globe that impose broad compliance obligations on the collection, use, storage, access, transfer and protection of personal data. Breach of such requirements could result in substantial fines, penalties, private right of actions, claims and damage to our reputation and business. New privacy laws are expected in other territories, together with greater privacy enforcement by governmental authorities globally, particularly on data localization requirements and international data flows. The Company has established privacy compliance programs and controls that our businesses worldwide are required to comply with, but with many technology and data-driven initiatives being prioritized across the Company and involving multiple vendors and third parties, there are potential risks of controls imposed on cross border data flows, unauthorized access, and loss of personal data through internal and external threats that could impact our business operations and research activities.

The Company may be unable to achieve some or all of the anticipated strategic and financial benefits following the separation of Kenvue Inc. (Kenvue), including with respect to the Company's remaining ownership interest.

The Company incurred significant expenses in connection with the Kenvue separation (the Separation). In addition, the Company may not be able to achieve the full strategic and financial benefits that are expected to result from the Separation. The anticipated benefits of the Separation were based on a number of assumptions, some of which may prove incorrect. The Company holds a 9.5% ownership interest in Kenvue. The Company cannot predict the trading price of shares of Kenvue's common stock and the market value of the Kenvue shares are subject to market volatility and other factors outside of the Company's control. The Company intends to divest its ownership interest in Kenvue, but there can be no assurance regarding the ultimate timing of such divestiture. Unanticipated developments could delay, prevent or otherwise adversely affect the divestiture, including but not limited to financial market conditions.

The Separation could result in substantial tax liability.

The Company received a private letter ruling from the IRS as to the tax-free nature of the Separation under the U.S. Internal Revenue Code of 1986, as amended. Notwithstanding the private letter ruling and opinions of tax advisors, if the IRS determines that certain steps of the transaction did not qualify for tax-free treatment for U.S. federal income tax purposes, the resulting tax liability to the Company and its shareholders could be substantial. The Separation may also not qualify for tax-free treatment in other countries around the world, and as a result may trigger substantial tax liability to the Company.

Item 1B. Unresolved staff comments

Not applicable.

Item 1C. Cybersecurity

Risk management and strategy

The Company has documented cybersecurity policies and standards, assesses risks from cybersecurity threats, and monitors information systems for potential cybersecurity issues. To protect the Company's information systems from cybersecurity threats, the Company uses various security tools supporting protection, detection, and response capabilities. The Company maintains a cybersecurity incident response plan to help ensure a timely, consistent response to actual or attempted cybersecurity incidents impacting the Company.

The Company also identifies and assesses third-party risks within the enterprise, and through the Company's use of third-party service providers, across a range of areas including data security and supply chain through a structured third-party risk management program.

The Company maintains a formal information security training program for all employees that includes training on matters such as phishing and email security best practices. Employees are also required to complete mandatory training on data privacy.

To evaluate and enhance its cybersecurity program, the Company periodically utilizes third-party experts to undertake maturity assessments of the Company's information security program.

To date, the Company is not aware of any cybersecurity incident that has had or is reasonably likely to have a material impact on the Company's business or operations; however, because of the frequently changing attack techniques, along with the increased volume and sophistication of the attacks, there is the potential for the Company to be adversely impacted. This impact could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action. Refer to the risk factor captioned An information security incident, including a cybersecurity breach, could have a negative impact to the Company's business or reputation in Part I, Item 1A. Risk factors for additional description of cybersecurity risks and potential related impacts on the Company.

Governance - management's responsibility

The Company takes a risk-based approach to cybersecurity and has implemented cybersecurity controls designed to address cybersecurity threats and risks. The Chief Information Officer (CIO), who is a member of the Company's Executive Committee, and the Chief Information Security Officer (CISO) are responsible for assessing and managing cybersecurity risks, including the prevention, mitigation, detection, and remediation of cybersecurity incidents.

The Company's CISO, in coordination with the CIO, is responsible for leading the Company's cybersecurity program and management of cybersecurity risk. The current CISO has over twenty-five years of experience in information security, and his background includes technical experience, strategy and architecture focused roles, cyber and threat experience, and various leadership roles.

Governance - board oversight

The Company's Board of Directors oversees the overall risk management process, including cybersecurity risks, directly and through its committees. The Regulatory Compliance & Sustainability Committee (RCSC) of the board is primarily responsible for oversight of risk from cybersecurity threats and oversees compliance with applicable laws, regulations and Company policies related to, among others, privacy and cybersecurity.

RCSC meetings include discussions of specific risk areas throughout the year including, among others, those relating to cybersecurity. The CISO provides at least two updates each year to RCSC on cybersecurity matters. These reports include an overview of the cybersecurity threat landscape, key cybersecurity initiatives to improve the Company's risk posture, changes in the legal and regulatory landscape relative to cybersecurity, and overviews of certain cybersecurity incidents that have occurred within the Company and within the industry.

Item 2. Properties

The Company's subsidiaries operate 61 manufacturing facilities occupying approximately 9.8 million square feet of floor space. The manufacturing facilities are used by the industry segments of the Company's business approximately as follows:

Segment	Square Feet (in thousands)
Innovative Medicine	5,026
MedTech	4,782
Worldwide Total	9,808

Within the U.S., five facilities are used by the Innovative Medicine segment and 18 by the MedTech segment. Outside of the U.S., 13 facilities are used by the Innovative Medicine segment and 25 by the MedTech segment.

The locations of the manufacturing facilities by major geographic areas of the world are as follows:

Geographic Area	Number of Facilities	Square Feet (in thousands)
United States	23	2,973
Europe	20	4,900
Western Hemisphere, excluding U.S.	5	692
Africa, Asia and Pacific	13	1,243
Worldwide Total	61	9,808

In addition to the manufacturing facilities discussed above, the Company maintains numerous office and warehouse facilities throughout the world.

The Company's subsidiaries generally seek to own, rather than lease, their manufacturing facilities, although some, principally in non-U.S. locations, are leased. Office and warehouse facilities are often leased. The Company also engages contract manufacturers.

The Company is committed to maintaining all of its properties in good operating condition.

Segment information on additions to property, plant and equipment is contained in Note 17 Segments of business and geographic areas of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 3. Legal proceedings

The information called for by this item is incorporated herein by reference to the information set forth in Note 19 Legal proceedings of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 4. Mine safety disclosures

Not applicable.

Executive officers of the registrant

Listed below are the executive officers of the Company. There are no family relationships between any of the executive officers, and there is no arrangement or understanding between any executive officer and any other person pursuant to which the executive officer was selected. At the annual meeting of the Board of Directors, the executive officers are elected by the Board to hold office for one year and until their respective successors are elected and qualified, or until earlier resignation or removal.

Name	Age	Position
Vanessa Broadhurst	55	Member, Executive Committee; Executive Vice President, Global Corporate Affairs[(a)]
Joaquin Duato	61	Chairman of the Board; Chief Executive Officer[(b)]
Peter M. Fasolo, Ph.D.	61	Member, Executive Committee; Executive Vice President, Chief Human Resources Officer[(c)]
Elizabeth Forminard	53	Member, Executive Committee; Executive Vice President, General Counsel[(d)]
William N. Hait, M.D., Ph. D.	74	Member, Executive Committee; Executive Vice President, Chief External Innovation and Medical Officer[(e)]
John C. Reed, M.D., Ph.D.	65	Member, Executive Committee; Executive Vice President, Innovative Medicine, R&D[(f)]
Tim Schmid	54	Member, Executive Committee; Executive Vice President, Worldwide Chairman, MedTech[(g)]
James Swanson	58	Member, Executive Committee; Executive Vice President, Chief Information Officer[(h)]
Jennifer L. Taubert	60	Member, Executive Committee; Executive Vice President, Worldwide Chairman, Innovative Medicine[(i)]
Kathryn E. Wengel	58	Member, Executive Committee; Executive Vice President, Chief Technical Operations & Risk Officer[(j)]
Joseph J. Wolk	57	Member, Executive Committee; Executive Vice President, Chief Financial Officer[(k)]

(a) Ms. V. Broadhurst was named Executive Vice President, Global Corporate Affairs and appointed to the Executive Committee in 2022. Ms. Broadhurst rejoined the Company in 2017 and was appointed Company Group Chairman, Global Commercial Strategy Organization in 2018. From 2013 to 2017, she held General Manager roles at Amgen in Inflammation & Cardiovascular, and Cardiovascular & Bone. Prior to her roles at Amgen, she served in various leadership roles at the Company from 2005-2013.

(b) Mr. J. Duato became Chairman of the Board of Directors in January 2023 subsequent to his appointments as Chief Executive Officer and Director in January 2022. Mr. Duato was appointed to the Executive Committee in 2016 when he was named Executive Vice President, Worldwide Chairman, Pharmaceuticals and subsequently served as Vice Chairman of the Executive Committee. Mr. Duato first joined the Company in 1989 with Janssen-Farmaceutica S.A. (Spain), a subsidiary of the Company, and held executive positions of increasing responsibility in all business sectors and across multiple geographies and functions.

(c) Dr. P. M. Fasolo was appointed to the Executive Committee in 2011 and was named Executive Vice President, Chief Human Resources Officer in 2016. He first joined the Company in 2004 as Worldwide Vice President, Human Resources in the MedTech segment, and subsequently served as the Company's Chief Talent Officer. He left Johnson & Johnson in 2007 to join Kohlberg Kravis Roberts & Co. as Chief Talent Officer and returned to the Company in 2010 as the Vice President, Global Human Resources.

(d) Ms. E. Forminard was appointed as Executive Vice President, General Counsel and a member of the Executive Committee in October 2022. Ms. Forminard joined the Company in 2006, serving in roles of increasing responsibility including General Counsel Medical Devices & Diagnostics, General Counsel Consumer Group & Supply Chain, Worldwide Vice President Corporate Governance, and in her immediate past role as General Counsel Pharmaceuticals.

(e) Dr. W. Hait was appointed Executive Vice President, Chief External Innovation, Medical Safety and Global Public Health Officer, and a member of the Executive Committee in 2022. He first joined the Company in 2007 and has served in a number of leadership roles including

Global Head, Janssen Research & Development from 2011 to 2018 and Global Head, Johnson & Johnson Global External Innovation from 2018 to 2022.

(f) Dr. J. C. Reed joined the Company in 2023 as Executive Vice President, Innovative Medicine, R&D and a member of the Executive Committee. Prior to joining the Company, Dr. Reed held executive leadership positions at Sanofi (2018-2022) and Roche (2013-2018), serving on their respective executive committees. He also served as CEO of Sanford-Burnham Medical Research Institute (now Sanford Burnham Prebys) where he established multiple therapeutic area-aligned research centers and platform technology centers.

(g) Mr. T. Schmid was named as Executive Vice President, Worldwide Chairman, MedTech and appointed to the Executive Committee in October 2023. He joined the Company in 1993 and has served in leadership positions throughout Johnson & Johnson MedTech, including Chief Strategic Customer Officer and President of Ethicon, and most recently served as Company Group Chairman MedTech Asia Pacific from 2018-2023.

(h) Mr. J. Swanson was appointed Executive Vice President, Chief Information Officer and a member of the Executive Committee in 2022. He rejoined the Company in 2019 as Chief Information Officer of Johnson & Johnson from Bayer Crop Science, where he served as a member of the Executive Leadership Team and as Chief Information Officer and Head of Digital Transformation. From 1996 to 2005, Mr. Swanson held positions of increasing responsibility at the Company, including Project Manager, Director IT, Sr. Director IT and Vice President, Chief Information Officer.

(i) Ms. J. L. Taubert was appointed Executive Vice President, Worldwide Chairman, Innovative Medicine (formerly Pharmaceuticals) and a member of the Executive Committee in 2018. She joined the Company in 2005 as Worldwide Vice President and held several executive positions of increasing responsibility in the Pharmaceuticals sector, including Company Group Chairman, North America, and Company Group Chairman, The Americas from 2012-2018.

(j) Ms. K. E. Wengel was appointed Executive Vice President, Chief Technical Operations & Risk Officer in 2023, subsequent to her appointment to the Executive Committee in 2018 when she was named as Executive Vice President, Chief Global Supply Chain Officer. Ms. Wengel first joined the Company in 1988 as Project Engineer and Engineering Supervisor at Janssen, a subsidiary of the Company. During her tenure with the Company, she has held a variety of strategic leadership and executive positions, including in roles within operations, quality, engineering, new products, information technology, and other technical and business functions.

(k) Mr. J. J. Wolk was appointed Executive Vice President, Chief Financial Officer and a member of the Executive Committee in July 2018. He first joined the Company in 1998 as Finance Manager, Business Development for Ortho-McNeil, a subsidiary of the Company. During his tenure at the Company, he has held a variety of senior leadership roles in several segments and functions across the Company's subsidiaries, including Vice President, Finance and Chief Financial Officer of the Janssen Pharmaceutical Companies, and Vice President, Investor Relations.

Part II

Item 5. Market for registrant's common equity, related stockholder matters and issuer purchases of equity securities

As of February 9, 2024, there were 118,772 record holders of common stock of the Company. Additional information called for by this item is incorporated herein by reference to the following sections of this Report: Note 16 "Common Stock, Stock Option Plans and Stock Compensation Agreements" of the Notes to Consolidated Financial Statements included in Item 8; and Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters – Equity Compensation Plan Information."

Issuer purchases of equity securities

On September 14, 2022, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's Common Stock. The repurchase program was completed during the fiscal first quarter of 2023.

The following table provides information with respect to common stock purchases by the Company during the fiscal fourth quarter of 2023. Common stock purchases on the open market are made as part of a systematic plan to meet the needs of the Company's compensation programs. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal fourth quarter.

Fiscal Period	Total Number of Shares Purchased[1]	Avg. Price Paid Per Share	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
October 2, 2023 through October 29, 2023	—	—	—	—
October 30, 2023 through November 26, 2023	125,000	$147.61	—	—
November 27, 2023 through December 31, 2023	1,265,000	$156.76	—	—
Total	**1,390,000**		**—**	

(1) During the fiscal fourth quarter of 2023, the Company repurchased an aggregate of 1,390,000 shares of Johnson & Johnson Common Stock in open-market transactions, all of which were purchased as part of a systematic plan to meet the needs of the Company's compensation programs.

Item 6. Reserved

Item 7. Management's discussion and analysis of results of operations and financial condition

Organization and business segments

Description of the company and business segments

Johnson & Johnson and its subsidiaries (the Company) have approximately 131,900 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the healthcare field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The Company is organized into two business segments: Innovative Medicine and MedTech. The Innovative Medicine segment is focused on the following therapeutic areas, including Immunology, Infectious diseases, Neuroscience, Oncology, Pulmonary Hypertension, and Cardiovascular and Metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, distributors, hospitals and healthcare professionals for prescription use. The MedTech segment includes a broad portfolio of products used in the Orthopaedic, Surgery, Interventional Solutions and Vision fields. These products are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Innovative Medicine and MedTech business segments.

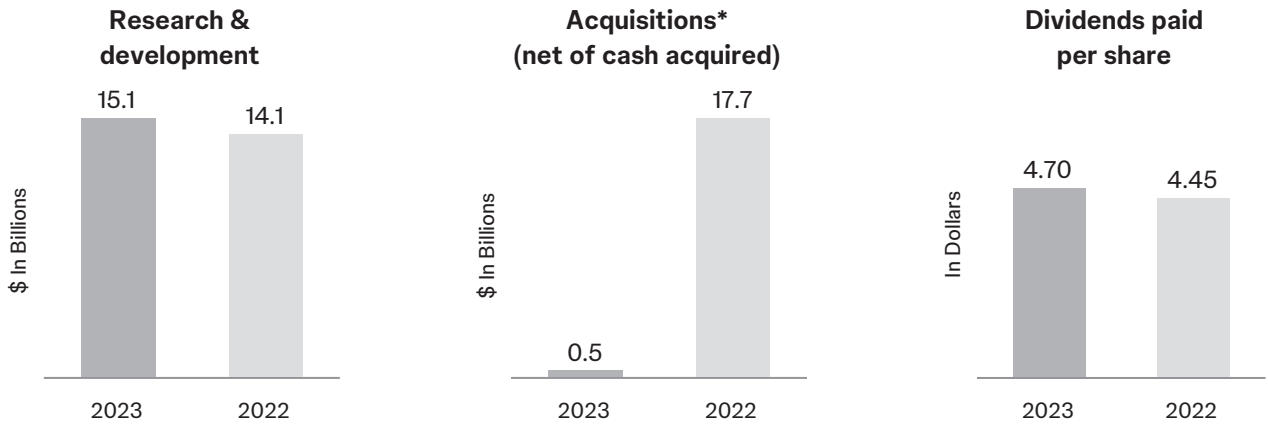
In all of its product lines, the Company competes with other companies both locally and globally, throughout the world. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products, as well as protecting the underlying intellectual property of the Company's product portfolio, is important to the Company's success in all areas of its business. The competitive environment requires substantial investments in continuing research.

Management's objectives

With "Our Credo" as the foundation, the Company's purpose is to blend heart, science and ingenuity to profoundly impact health for humanity. The Company, believes health is everything. The Company's strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through the Company's expertise in Innovative Medicine and MedTech, the Company is uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity.

New products introduced within the past five years accounted for approximately 25% of 2023 sales. In 2023, $15.1 billion was invested in research and development reflecting management's commitment to create life-enhancing innovations and to create value through partnerships that will profoundly impact of health for humanity.

A critical driver of the Company's success is the diversity of its 131,900 employees worldwide. Employees are empowered and inspired to lead with Our Credo and purpose as guides. This allows every employee to use the Company's reach and size to advance the Company's purpose, and to also lead with agility and urgency. Leveraging the extensive resources across the enterprise enables the Company to innovate and execute with excellence. This ensures the Company can remain focused on addressing the unmet needs of society every day and invest for an enduring impact, ultimately delivering value to its patients, consumers and healthcare professionals, employees, communities and shareholders.



*Includes acquisitions of in process research and development assets that were not accounted for as a business combination

Results of operations

Analysis of consolidated sales

For discussion on results of operations and financial condition pertaining to the fiscal years 2022 and 2021 see the Company's Annual Report on Form 10-K for the fiscal year ended January 1, 2023, Item 7. Management's discussion and analysis of results of operations and financial condition. Prior periods disclosed herein were recast to reflect the continuing operations of the Company.

In 2023, worldwide sales increased 6.5% to $85.2 billion as compared to an increase of 1.6% in 2022. These sales changes consisted of the following:

Sales increase/(decrease) due to:	2023	2022
Volume	6.8%	8.3%
Price	0.6	(1.8)
Currency	(0.9)	(4.9)
Total	**6.5%**	**1.6%**

The net impact of acquisitions and divestitures on the worldwide sales growth was a positive impact of 1.5% in 2023 and no impact in 2022.

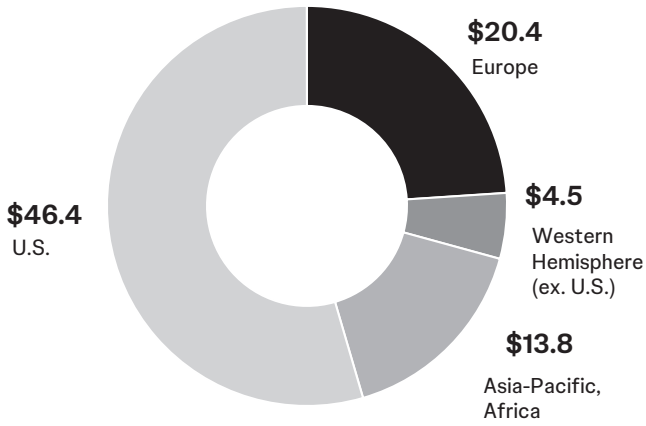
Sales by U.S. companies were $46.4 billion in 2023 and $42.0 billion in 2022. This represents increases of 10.6% in 2023 and 3.3% in 2022. Sales by international companies were $38.7 billion in 2023 and $38.0 billion in 2022. This represents an increase of 1.9% in 2023 and a decrease of 0.2% in 2022.

The five-year compound annual growth rates for worldwide, U.S. and international sales were 4.7%, 5.2% and 4.1%, respectively. The ten-year compound annual growth rates for worldwide, U.S. and international sales were 4.2%, 5.7% and 2.6%, respectively.

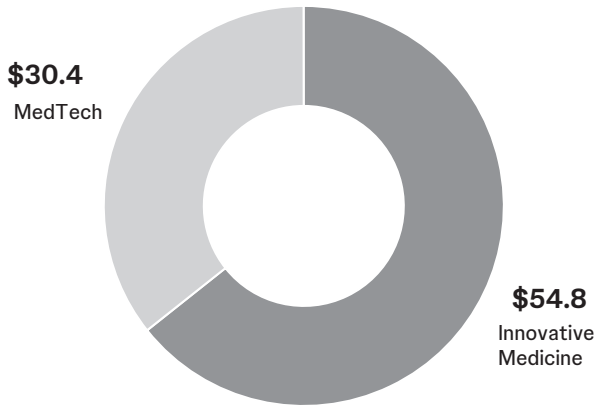
In 2023, sales by companies in Europe experienced a decline of 1.2% as compared to the prior year, which included an operational decline of 2.2% and a positive currency impact of 1.0%. In fiscal 2023, the net impact of the Covid-19 Vaccine and the loss of exclusivity of Zytiga on the European regions change in operational sales was a negative 9.8%. Sales by companies in the Western Hemisphere, excluding the U.S., achieved growth of 10.7% as compared to the prior year, which included operational growth of 15.8%, and a negative currency impact of 5.1%. Sales by companies in the Asia-Pacific, Africa region achieved growth of 3.9% as compared to the prior year, including operational growth of 9.5% and a negative currency impact of 5.6%.

In 2023, the Company utilized three wholesalers distributing products for both segments that represented approximately 18.2%, 15.1% and 14.2% of the total consolidated revenues. In 2022, the Company had three wholesalers distributing products for both segments that represented approximately 18.9%, 15.0% and 13.8% of the total consolidated revenues.

2023 Sales by geographic region (in billions)



2023 Sales by segment (in billions)



Note: values may have been rounded

Analysis of sales by business segments

Innovative Medicine segment[(1)]

Innovative Medicine segment sales in 2023 were $54.8 billion, an increase of 4.2% from 2022, which included operational growth of 4.8% and a negative currency impact of 0.6%. U.S. sales were $31.2 billion, an increase of 9.0%. International sales were $23.6 billion, a decrease of 1.5%, which included an operational decline of 0.2% and a negative currency impact of 1.3%. In 2023, acquisitions and divestitures had a net negative impact of 0.1% on the operational sales growth of the worldwide Innovative Medicine segment.

Major Innovative Medicine therapeutic area sales:

(Dollars in Millions)	2023	2022	Total Change	Operations Change	Currency Change
Total Immunology	**$18,052**	**$16,935**	**6.6%**	**7.1%**	**(0.5)%**
REMICADE	1,839	2,343	(21.5)	(20.7)	(0.8)
SIMPONI/SIMPONI ARIA	2,197	2,184	0.6	2.4	(1.8)
STELARA	10,858	9,723	11.7	11.9	(0.2)
TREMFYA	3,147	2,668	17.9	18.3	(0.4)
Other Immunology	11	17	(33.8)	(33.8)	—
Total Infectious Diseases	**4,418**	**5,449**	**(18.9)**	**(19.8)**	**0.9**
COVID-19 VACCINE	1,117	2,179	(48.8)	(50.1)	1.3
EDURANT/rilpivirine	1,150	1,008	14.1	11.5	2.6
PREZISTA/ PREZCOBIX/REZOLSTA/ SYMTUZA	1,854	1,943	(4.6)	(4.9)	0.3
Other Infectious Diseases	297	318	(6.7)	(3.6)	(3.1)
Total Neuroscience	**7,140**	**6,893**	**3.6**	**5.4**	**(1.8)**
CONCERTA/methylphenidate	783	644	21.6	24.9	(3.3)
INVEGA SUSTENNA/XEPLION/INVEGA TRINZA/TREVICTA	4,115	4,140	(0.6)	0.0	(0.6)
SPRAVATO	689	374	84.1	84.0	0.1
Other Neuroscience[2]	1,553	1,734	(10.4)	(5.9)	(4.5)
Total Oncology	**17,661**	**15,983**	**10.5**	**11.2**	**(0.7)**
CARVYKTI	500	133	*	*	*
DARZALEX	9,744	7,977	22.2	22.9	(0.7)
ERLEADA	2,387	1,881	26.9	27.5	(0.6)
IMBRUVICA	3,264	3,784	(13.7)	(13.2)	(0.5)
ZYTIGA /abiraterone acetate	887	1,770	(49.9)	(48.4)	(1.5)
Other Oncology	879	438	*	*	*
Total Pulmonary Hypertension	**3,815**	**3,417**	**11.6**	**12.9**	**(1.3)**
OPSUMIT	1,973	1,783	10.6	11.6	(1.0)
UPTRAVI	1,582	1,322	19.7	20.4	(0.7)
Other Pulmonary Hypertension	260	313	(16.7)	(12.0)	(4.7)
Total Cardiovascular / Metabolism / Other	**3,671**	**3,887**	**(5.5)**	**(5.5)**	**0.0**
XARELTO	2,365	2,473	(4.4)	(4.4)	—
Other[3]	1,306	1,414	(7.6)	(7.4)	(0.2)
Total Innovative Medicine Sales	**$54,759**	**52,563**	**4.2%**	**4.8%**	**(0.6)%**

* Percentage greater than 100% or not meaningful

(1) Previously referred to as Pharmaceutical

(2) Inclusive of RISPERDAL CONSTA which was previously disclosed separately

(3) Inclusive of INVOKANA which was previously disclosed separately

Immunology products achieved sales of $18.1 billion in 2023, representing an increase of 6.6% as compared to the prior year. Increased sales of STELARA (ustekinumab) were primarily driven by patient mix, market growth, and continued strength in Inflammatory Bowel Disease. Growth of TREMFYA (guselkumab) was due to market growth, continued strength in PsO/PsA (Psoriasis and Psoriatic Arthritis) and patient mix. Additionally, SIMPONI/SIMPONI ARIA growth was driven by growth outside the U.S. Lower sales of REMICADE (infliximab) were due to biosimilar competition.

Biosimilar versions of REMICADE have been introduced in the United States and certain markets outside the United States and additional competitors continue to enter the market. Continued infliximab biosimilar competition will result in a further reduction in sales of REMICADE.

Sales of STELARA in the United States were approximately $7.0 billion in fiscal 2023. Third parties have filed abbreviated Biologics License Applications with the FDA seeking approval to market biosimilar versions of STELARA. The Company has settled certain litigation under the Biosimilar Price Competition and Innovation Act of 2009. As a result of these settlements and other agreements with separate third parties, the Company does not anticipate the launch of a biosimilar version of STELARA until January 1, 2025 in the United States.

Infectious disease products sales were $4.4 billion in 2023, a decline of 18.9% as compared to the prior year primarily driven by a decline in COVID-19 vaccine revenue and loss of exclusivity of PREZISTA.

Neuroscience products sales were $7.1 billion in 2023, representing an increase of 3.6% as compared to the prior year. The growth of SPRAVATO (esketamine) was driven by ongoing launches as well as increased physician confidence and patient demand. Growth was partially offset by declines in RISPERDAL/RISPERDAL CONSTA and the paliperidone long-acting injectables outside the U.S. due to the XEPLION loss of exclusivity in the European Union.

Oncology products achieved sales of $17.7 billion in 2023, representing an increase of 10.5% as compared to the prior year. Sales of DARZALEX (daratumumab) were driven by continued share gains in all regions and market growth. Growth of ERLEADA (apalutamide) was due to continued share gains and market growth in Metastatic Castration Resistant Prostate Cancer. Sales of CARVYKTI (ciltacabtagene autoleucel) were driven by the ongoing launch, share gains and capacity improvement. Additionally, sales from the launch of TECVAYLI (teclistamab-cqyv) and TALVEY (talquetamab-tgvs), included in Other Oncology, contributed to the growth. Growth was partially offset by ZYTIGA (abiraterone acetate) due to loss of exclusivity and IMBRUVICA (ibrutinib) due to global competitive pressures.

Pulmonary Hypertension products sales were $3.8 billion, representing an increase of 11.6% as compared to the prior year. Sales growth was due to favorable patient mix, share gains and market growth from UPTRAVI (selexipag) and OPSUMIT (macitentan) partially offset by declines in Other Pulmonary Hypertension.

Cardiovascular/Metabolism/Other products sales were $3.7 billion, a decline of 5.5% as compared to the prior year. The decline of XARELTO (rivaroxaban) sales was primarily driven by unfavorable patient mix and access changes.

The Company maintains a policy that no end customer will be permitted direct delivery of product to a location other than the billing location. This policy impacts contract pharmacy transactions involving non-grantee 340B covered entities for most of the Company's drugs, subject to multiple exceptions. Both grantee and non-grantee covered entities can maintain certain contract pharmacy arrangements under policy exceptions. The Company has been and will continue to offer 340B discounts to covered entities on all of its covered outpatient drugs, and it believes its policy will improve its ability to identify inappropriate duplicate discounts and diversion prohibited by the 340B statute. The 340B Drug Pricing Program is a U.S. federal government program requiring drug manufacturers to provide significant discounts on covered outpatient drugs to covered entities. This policy had discount implications which positively impacted sales to customers in 2023.

During 2023, the Company advanced its pipeline with several regulatory submissions and approvals for new drugs and additional indications for existing drugs as follows:

Product Name (Chemical Name)	Indication	US Approval	EU Approval	US Filing	EU Filing
AKEEGA (Niraparib and Abiraterone Acetate)	First-And-Only Dual Action Tablet for the Treatment of Patients with BRCA-Positive Metastatic Castration-Resistant Prostate Cancer (MAGNITUDE)	•	•		
BALVERSA (erdafitinib)	Treatment of Patients with Locally Advanced or Metastatic Urothelial Carcinoma and Selected Fibroblast Growth Factor Receptor Gene Alterations (THOR)			•	•
CARVYKTI (ciltacabtagene autoleucel)	Treatment for Relapsed and Refactor multiple myeloma with 1-3 PL (CARTITUDE-4)			•	•
EDURANT (rilpivirine)	Treatment for pediatric patients (2-12 years old) with HIV			•	•
ERLEADA (apalutamide)	Tablet reduction	•	•		
OPSUMIT (macitentan)	Treatment for pediatric pulmonary arterial hypertension				•
OPSYNVI (mecitentan/ tadalafil STCT)	Treatment for pulmonary arterial hypertension			•	•
RYBREVANT (amivantamab)	In Combination with Chemotherapy for the First-Line Treatment of Adult Patients with Advanced Non-Small Cell Lung Cancer with Activating EGFR Exon 20 Insertion Mutations (PAPILLON)			•	•
RYBREVANT / lazertinib	Treatment for Non-Small Cell Lung Cancer 2L (MARIPOSA)			•	•
RYBREVANT / lazertinib	Treatment for Non-Small Cell Lung Cancer 2L (MARIPOSA-2)			•	•
TECVAYLI (teclistamab)	Treatment of Patients with Relapsed Refractory Multiple Myeloma Biweekly Dosing		•		
TALVEY (talquetamab)	Treatment of Patients with Relapsed and Refractory Multiple Myeloma	•	•		

MedTech segment

The MedTech segment sales in 2023 were $30.4 billion, an increase of 10.8% from 2022, which included operational growth of 12.4% and a negative currency impact of 1.6%. U.S. sales were $15.3 billion, an increase of 14.2% as compared to the prior year. International sales were $15.1 billion, an increase of 7.7% as compared to the prior year, which included operational growth of 10.6% and a negative currency impact of 2.9%. In 2023, the net impact of acquisitions and divestitures on the MedTech segment worldwide operational sales growth was a positive 4.6% primarily related to the Abiomed acquisition.

Major MedTech franchise sales:

(Dollars in Millions)	2023	2022	Total Change	Operations Change	Currency Change
Surgery	**$10,037**	**9,690**	**3.6 %**	**5.5%**	**(1.9)%**
Advanced	4,671	4,569	2.2	4.2	(2.0)
General	5,366	5,121	4.8	6.8	(2.0)
Orthopaedics	**8,942**	**8,587**	**4.1**	**4.6**	**(0.5)**
Hips	1,560	1,514	3.0	3.5	(0.5)
Knees	1,456	1,359	7.1	7.5	(0.4)
Trauma	2,979	2,871	3.8	4.0	(0.2)
Spine, Sports & Other	2,947	2,843	3.7	4.5	(0.8)
Interventional Solutions	**6,350**	**4,300**	**47.7**	**49.8**	**(2.1)**
Electrophysiology	4,688	3,937	19.1	21.1	(2.0)
Abiomed	1,306	31	*	*	*
Other Interventional Solutions	356	332	7.1	9.9	(2.8)
Vision	**5,072**	**4,849**	**4.6**	**6.6**	**(2.0)**
Contact Lenses/Other	3,702	3,543	4.5	6.9	(2.4)
Surgical	1,370	1,306	4.9	5.8	(0.9)
Total MedTech Sales	**$30,400**	**27,427**	**10.8%**	**12.4%**	**(1.6)%**

* Percentage greater than 100% or not meaningful

The Surgery franchise sales were $10.0 billion in 2023, representing an increase of 3.6% from 2022. The growth in Advanced Surgery was primarily driven by Biosurgery global procedure growth and strength of the portfolio as well as uptake of new products in Endocutters and Energy. The growth was partially offset by competitive pressures and volume-based procurement impacts in Endocutters and Energy. The growth in General Surgery was primarily driven by increased procedures coupled with technology penetration and benefits from the differentiated Wound Closure portfolio.

The Orthopaedics franchise sales were $8.9 billion in 2023, representing an increase of 4.1% from 2022. The growth in hips reflects global procedure growth and continued strength of the portfolio partially offset by volume-based procurement impacts and Russia sanctions. The growth in knees was primarily driven by procedures, benefits from recent product additions to the ATTUNE portfolio and pull through related to the VELYS Robotic assisted solution. This was partially offset by stocking dynamics, primarily outside the U.S. The growth in Trauma was driven by global procedures and the adoption of recently launched products. This was partially offset by volume-based procurement impacts. The growth in Spine, Sports & Other was primarily driven by Digital Solutions, Shoulders, Sports and Craniomaxillofacial products partially offset by Russia sanctions and supply constraints, primarily outside the U.S.

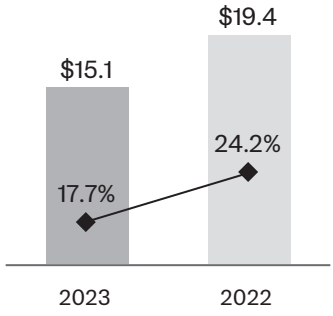
The Interventional Solutions franchise achieved sales of $6.4 billion in 2023, representing an increase of 47.7% from 2022, which includes sales from Abiomed acquired on December 22, 2022. Electrophysiology grew by double digits due to global procedure growth, new product performance and commercial execution. This was partially offset by the impacts of volume-based procurement in China. Abiomed sales reflect the strength of all commercialized regions and continued adoption of Impella 5.5 and Impella RP.

The Vision franchise achieved sales of $5.1 billion in 2023, representing an increase of 4.6% from 2022. The Contact Lenses/Other growth was primarily driven by the continued strong performance in the ACUVUE OASYS 1-Day family including recent launches and commercial execution. This was partially offset by impacts of U.S. stocking dynamics, Russia sanctions, impacts from strategic portfolio decisions and supply challenges. The Surgical operational growth was primarily driven by cataract procedure growth, continued strength of recent innovations and reduction of prior year stocking outside the U.S. This was partially offset by softer Refractive and premium IOL markets and Russia sanctions.

Analysis of consolidated earnings before provision for taxes on income

Consolidated earnings before provision for taxes on income was $15.1 billion and $19.4 billion for the years 2023 and 2022, respectively. As a percent to sales, consolidated earnings before provision for taxes on income was 17.7% and 24.2%, in 2023 and 2022, respectively.

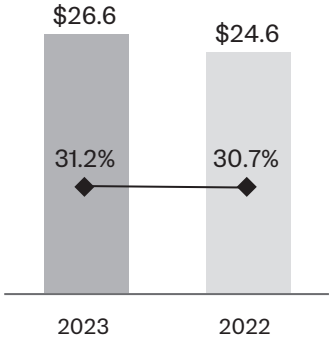
Earnings before provision for taxes



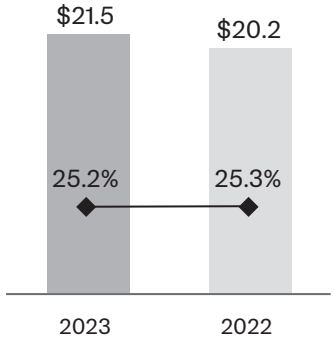
(Dollars in billions. Percentages in chart are as a percent to total sales)

Cost of products sold and selling, marketing and administrative expenses:

Cost of products sold



Selling, marketing & administrative



(Dollars in billions. Percentages in chart are as a percent to total sales)

Cost of products sold:

Cost of products sold increased as a percent to sales driven by:

- Commodity inflation, unfavorable product mix, restructuring related excess inventory costs and Abiomed amortization in the MedTech business

partially offset by

- Favorable patient mix and lower one-time COVID-19 vaccine manufacturing related exit costs in 2023 in the Innovative Medicine business

The intangible asset amortization expense included in cost of products sold was $4.5 billion and $3.9 billion for the fiscal years 2023 and 2022, respectively.

Selling, Marketing and Administrative expense:

Selling, Marketing and Administrative Expenses decreased slightly as a percent to sales driven by:

- Leveraging in Selling and Marketing expenses both the Innovative Medicine and MedTech businesses

partially offset by

- An increase in administrative costs

Research and Development Expense:

Research and development expense by segment of business was as follows:

	2023		2022	
(Dollars in Millions)	**Amount**	**% of Sales***	**Amount**	**% of Sales***
Innovative Medicine	$11,963	21.8%	$11,642	22.1%
MedTech	3,122	10.3	2,493	9.1
Total research and development expense	**$15,085**	**17.7%**	**$14,135**	**17.7%**
Percent increase/(decrease) over the prior year	6.7 %		(1.0%)	

*As a percent to segment sales

Research and development activities represent a significant part of the Company's business. These expenditures relate to the processes of discovering, testing and developing new products, upfront payments and developmental milestones, improving existing products, as well as ensuring product efficacy and regulatory compliance prior to launch. The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products.

Research and Development was flat as a percent to sales primarily driven by:

- Higher milestone payments in the Innovative Medicine business
- Acquired in-process research & development asset from the Laminar acquisition in the MedTech business in the fiscal year 2023

offset by

- Portfolio prioritization in the Innovative Medicine business

In-Process Research and Development Impairments (IPR&D): In the fiscal year 2023, the Company recorded a charge of approximately $0.3 billion which included $0.2 billion related to market dynamics associated with a non-strategic asset (M710) acquired as part of the acquisition of Momenta Pharmaceuticals in 2020, In the fiscal year 2022, the Company recorded an intangible asset impairment charge of approximately $0.8 billion related to an in-process research and development asset, bermekimab (JnJ-77474462), an investigational drug for the treatment of Atopic Dermatitis (AD) and Hidradenitis Suppurativa (HS). Additional information regarding efficacy of the AD indication and HS indication became available which led the Company to the decision to terminate the development of bermekimab for both AD and HS. The Company acquired all rights to bermekimab from XBiotech, Inc. in the fiscal year 2020.

Other (Income) Expense, Net: Other (income) expense, net is the account where the Company records gains and losses related to the sale and write-down of certain investments in equity securities held by Johnson & Johnson Innovation - JJDC, Inc. (JJDC), changes in the fair value of securities, investment (income)/loss related to employee benefit programs, gains and losses on divestitures, certain transactional currency gains and losses, acquisition and divestiture related costs, litigation accruals and settlements, as well as royalty income.

Other (income) expense, net for the fiscal year 2023 was unfavorable by $5.8 billion as compared to the prior year primarily due to the following:

(Dollars in Billions)(Income)/Expense	2023	2022	Change
Litigation related[1]	$6.9	0.9	6.0
Changes in the fair value of securities[2]	0.6	0.7	(0.1)
COVID-19 vaccine manufacturing exit related costs	0.4	0.7	(0.3)
Acquisition, Integration and Divestiture related[3]	0.3	0.2	0.1
Employee benefit plan related	(1.4)	(1.2)	(0.2)
Other	(0.2)	(0.5)	0.3
Total Other (Income) Expense, Net	**$6.6**	**0.8**	**5.8**

(1) 2023 was primarily related to the approximately $7.0 billion charge for talc (See Note 19 to the Consolidated Financial Statements for more details) and favorable intellectual property related litigation settlements of approximately $0.3 billion. 2022 was primarily related to pelvic mesh.

(2) The fiscal 2023 includes $0.4 billion related to the unfavorable change in the fair value of the remaining stake in Kenvue and $0.4 billion related to the partial impairment of Idorsia convertible debt and the change in the fair value of the Idorsia equity securities held.

(3) 2023 primarily related to the impairment of Ponvory and one-time integration costs related to the acquisition of Abiomed. 2022 was primarily costs related to the acquisition of Abiomed.

Interest (Income) Expense: Interest income in the fiscal year 2023 was $1.3 billion as compared to interest income of $0.5 billion in the fiscal year 2022 primarily due to higher rates of interest earned on cash balances. Interest expense in the fiscal year 2023 was $0.8 billion as compared to interest expense of $0.3 billion in the fiscal year 2022 primarily due to higher interest rates on debt balances. Cash, cash equivalents and marketable securities totaled $22.9 billion at the end of 2023, and averaged $22.6 billion as compared to the cash, cash equivalents and marketable securities total of $22.3 billion and $26.9 billion average balance in 2022. The total debt balance at the end of 2023 was $29.3 billion with an average debt balance of $34.5 billion as compared to $39.6 billion at the end of 2022 and an average debt balance of $36.7 billion. The lower average cash, cash equivalents and marketable securities was primarily due to the acquisition of Abiomed in late December of 2022. The lower average debt balance was primarily due to the repayment of commercial paper.

Income before tax by segment

Income (loss) before tax by segment of business were as follows:

	Income Before Tax		Segment Sales		Percent of Segment Sales	
(Dollars in Millions)	2023	2022	2023	2022	2023	2022
Innovative Medicine	$18,246	15,647	54,759	52,563	33.3%	29.8
MedTech	4,669	4,447	30,400	27,427	15.4	16.2
Segment earnings before tax[1]	22,915	20,094	85,159	79,990	26.9	25.1
Less: Expenses not allocated to segments[2]	7,853	735				
Worldwide income before tax	$15,062	19,359	85,159	79,990	17.7%	24.2

(1) See Note 17 to the Consolidated Financial Statements for more details.

(2) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense. Fiscal 2023 includes an approximately $7.0 billion charge related to talc matters and the approximately $0.4 billion unfavorable change in the fair value of the retained stake in Kenvue.

Innovative Medicine segment:

In 2023, the Innovative Medicine segment income before tax as a percent to sales was 33.3% versus 29.8% in 2022. The increase in the income before tax as a percent of sales was primarily driven by the following:

- Lower one-time COVID-19 Vaccine related exit costs of $0.7 billion in 2023 versus $1.5 billion in 2022
- Lower In-process research & development impairments of $0.2 billion in 2023 versus $0.8 billion in 2022
- Unfavorable changes in the fair value of securities in 2023 of $0.4 billion as compared to $0.7 billion in 2022
- Lower litigation related expense of $0.2 billion
- Leveraging in selling and marketing expenses
- R&D Portfolio prioritization

partially offset by

- Restructuring charges of $0.5 billion in 2023 versus $0.1 billion in 2022
- Impairment of Ponvory in 2023
- Higher milestone payments in 2023

MedTech segment:

In 2023, the MedTech segment income before tax as a percent to sales was 15.4% versus 16.2% in 2022. The decrease in the income before tax as a percent to sales was primarily driven by the following:

- Higher amortization expense of $0.5 billion in 2023 related to Abiomed
- Expense of $0.4 billion for an acquired in process research and development asset from the Laminar acquisition in 2023
- Commodity inflation in 2023

partially offset by

- Income from litigation settlements of $0.1 billion in 2023 versus expense of $0.6 billion in 2022
- Lower integration/acquisition costs related to Abiomed of $0.2 billion in 2023 versus $0.3 billion in 2022
- Leveraging in selling and marketing expenses in 2023

Restructuring: In the fiscal year 2023, the Company completed a prioritization of its research and development (R&D) investment within the Innovative Medicine segment to focus on the most promising medicines with the greatest benefit to patients. This resulted in the exit of certain programs within therapeutic areas. The R&D program exits are primarily in infectious diseases and vaccines including the discontinuation of its respiratory syncytial virus (RSV) adult vaccine program, hepatitis and HIV development. The pre-tax restructuring charge of approximately $0.5 billion in the fiscal year 2023, of which $449 million was recorded in Restructuring and $30 million was recorded in Cost of products sold on the Consolidated Statement of Earnings, included the termination of partnered and non-partnered program costs and asset impairments.

In the fiscal year 2023, the Company initiated a restructuring program of its Orthopaedics franchise within the MedTech segment to streamline operations by exiting certain markets, product lines and distribution network arrangements. The pre-tax restructuring expense of $0.3 billion in the fiscal year 2023, of which $40 million was recorded in Restructuring and $279 million was recorded in Cost of products sold on the Consolidated Statement of Earnings, primarily included inventory and instrument charges related to market and product exits.

In 2022, the Company recorded a pre-tax charge of $0.4 billion related to a restructuring program of its Global Supply Chain. The Global Supply Chain program was announced in the second quarter of 2018 and was completed in the fiscal fourth quarter of 2022.

See Note 20 to the Consolidated Financial Statements for additional details related to the restructuring programs.

Provision for Taxes on Income: The worldwide effective income tax rate from continuing operations was 11.5% in 2023 and 15.4% in 2022.

On December 15, 2022, the European Union (EU) Member States formally adopted the EU's Pillar Two Directive, which generally provides for a minimum effective tax rate of 15%, as established by the Organization for Economic Co-operation and Development (OECD) Pillar Two Framework that was supported by over 130 countries worldwide. As of December 31, 2023, several EU and non-EU countries have enacted Pillar 2 legislation with an initial effective date of January 1, 2024, with other aspects of the law effective in 2025 or later. The Company is estimating that as result of this legislation the 2024 effective tax rate will increase by approximately 1.5% or 150 basis points compared to fiscal 2023. Further legislation, guidance and regulations that may be issued in fiscal 2024, as well as other business events, may impact this estimate.

For discussion related to the fiscal 2023 provision for taxes refer to Note 8 to the Consolidated Financial Statements.

Liquidity and capital resources

Liquidity & cash flows

Cash and cash equivalents were $21.9 billion at the end of 2023 as compared to $14.1 billion at the end of 2022.

The primary sources and uses of cash that contributed to the $7.8 billion increase were:

(Dollars in billions)	
$14.1	Q4 2022 Cash and cash equivalents balance
22.8	cash generated from operating activities
0.9	net cash from investing activities
(15.8)	net cash used by financing activities
(0.1)	effect of exchange rate and rounding
$21.9	Q4 2023 Cash and cash equivalents balance

In addition, the Company had $1.1 billion in marketable securities at the end of fiscal year 2023 and $9.4 billion at the end of fiscal year 2022. See Note 1 to the Consolidated Financial Statements for additional details on cash, cash equivalents and marketable securities.

Cash flow from operations of $22.8 billion was the result of:

(Dollars In billions)	
$35.2	Net Earnings
(14.9)	gain on the Kenvue separation, net gain on sale of assets/businesses and the deferred tax provision partially offset by non-cash expenses and other adjustments primarily for depreciation and amortization, stock-based compensation, asset write-downs and charge for purchase of in process research and development assets
5.6	an increase in current and non-current liabilities
(3.5)	an increase in other current and non-current assets
2.3	an increase in accounts payable and accrued liabilities
(1.9)	an increase in accounts receivable and inventories
$22.8	Cash flow from operations

Cash flow from investing activities of $0.9 billion was primarily due to:

(Dollars in billions)	
$(4.5)	additions to property, plant and equipment
0.4	proceeds from the disposal of assets/businesses, net
(0.5)	purchases of in-process research and development assets
8.5	net sales of investments
(3.0)	credit support agreements activity, net
$0.9	Net cash from investing activities

Cash flow used for financing activities of $15.8 billion was primarily due to:

(Dollars in billions)	
$(11.8)	dividends to shareholders
(5.1)	repurchase of common stock
(10.8)	net repayment from short and long term debt
1.1	proceeds from stock options exercised/employee withholding tax on stock awards, net
(0.2)	Credit support agreements activity, net
8.0	Proceeds of short and long-term debt, net of issuance cost, related to the debt that transferred to Kenvue at separation
4.2	proceeds from Kenvue initial public offering
(1.1)	Cash transferred to Kenvue at separation
(0.1)	other and rounding
$(15.8)	Net cash used for financing activities

As of December 31, 2023, the Company's notes payable and long-term debt was in excess of cash, cash equivalents and marketable securities. As of December 31, 2023, the net debt position was $6.4 billion as compared to the prior year of $17.4 billion. The debt balance at the end of 2023 was $29.3 billion as compared to $39.6 billion in 2022. Considering recent market conditions, the Company has re-evaluated its operating cash flows and liquidity profile and does not foresee any significant incremental risk. The Company anticipates that operating cash flows, the ability to raise funds from external sources, borrowing capacity from existing committed credit facilities and access to the commercial paper markets will continue to provide sufficient resources to fund operating needs, including the Company's remaining balance to be paid on the agreement to settle opioid litigation for approximately $2.1 billion and the establishment of the approximately $9 billion reserve for talc matters (See Note 19 to the Consolidated Financial Statements for additional details). In addition, the Company monitors the global capital markets on an ongoing basis and from time to time may raise capital when market conditions are favorable.

On May 8, 2023, Kenvue, completed an initial public offering (the IPO) resulting in the issuance of 198,734,444 shares of its common stock, par value $0.01 per share (the Kenvue Common Stock), at an initial public offering of $22.00 per share for net proceeds of $4.2 billion. The excess of the net proceeds from the IPO over the net book value of the Johnson & Johnson divested interest was $2.5 billion and was recorded to additional paid-in capital. As of the closing of the IPO, Johnson & Johnson owned approximately 89.6% of the total outstanding shares of Kenvue Common Stock and at July 2, 2023, the non-controlling interest of $1.3 billion associated with Kenvue was reflected in equity attributable to non-controlling interests in the consolidated balance sheet.

On August 23, 2023, Johnson & Johnson completed the disposition of an additional 80.1% ownership of Kenvue Common Stock through an exchange offer, which resulted in Johnson & Johnson acquiring 190,955,436 shares of the Company’s common stock in exchange for 1,533,830,450 shares of Kenvue Common Stock. The $31.4 billion of Johnson & Johnson common stock received in the exchange offer is recorded in Treasury stock. Following the exchange offer, the Company owns 9.5% of the total outstanding shares of Kenvue Common Stock that was recorded in other assets within continuing operations at the fair market value of $4.3 billion as of August 23, 2023 and $3.9 billion as of December 31, 2023.

Johnson & Johnson divested net assets of $11.6 billion as of August 23, 2023, and the accumulated other comprehensive loss attributable to the Consumer Health business at that date was $4.3 billion. Additionally, at the date of the exchange offer,

Johnson & Johnson decreased the non-controlling interest by $1.2 billion to record the deconsolidation of Kenvue. This resulted in a gain on the exchange offer of $21.0 billion that was recorded in Net earnings from discontinued operations, net of taxes in the consolidated statements of earnings for the fiscal third quarter of 2023. This one-time gain includes a gain of $2.8 billion on the Kenvue Common Stock retained by Johnson & Johnson. The gain on the exchange offer qualifies as a tax-free transaction for U.S. federal income tax purposes.

On September 14, 2022, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's Common Stock. In the fiscal year 2022, approximately $2.5 billion was repurchased under the program. In the fiscal year 2023, $2.5 billion has been repurchased and the repurchase program was completed.

The following table summarizes the Company's material contractual obligations and their aggregate maturities as of December 31, 2023: To satisfy these obligations, the Company intends to use cash from operations.

(Dollars in Millions)	Tax Legislation (TCJA)	Debt Obligations	Interest on Debt Obligations	Total
2024	$2,029	1,469	843	4,341
2025	2,536	1,700	789	5,025
2026	—	1,997	744	2,741
2027	—	2,320	736	3,056
2028	—	2,325	691	3,016
After 2028	—	17,539	8,706	26,245
Total	**$4,565**	**27,350**	**12,509**	**44,424**

For tax matters, see Note 8 to the Consolidated Financial Statements.

Financing and market risk

The Company uses financial instruments to manage the impact of foreign exchange rate changes on cash flows. Accordingly, the Company enters into forward foreign exchange contracts to protect the value of certain foreign currency assets and liabilities and to hedge future foreign currency transactions primarily related to product costs. Gains or losses on these contracts are offset by the gains or losses on the underlying transactions. A 10% appreciation of the U.S. Dollar from the December 31, 2023 market rates would increase the unrealized value of the Company's forward contracts by $0.1 billion. Conversely, a 10% depreciation of the U.S. Dollar from the December 31, 2023 market rates would decrease the unrealized value of the Company's forward contracts by $0.1 billion. In either scenario, the gain or loss on the forward contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated earnings and cash flows.

The Company hedges the exposure to fluctuations in currency exchange rates, and the effect on certain assets and liabilities in foreign currency, by entering into currency swap contracts. A 1% change in the spread between U.S. and foreign interest rates on the Company's interest rate sensitive financial instruments would either increase or decrease the unrealized value of the Company's swap contracts by approximately $1.6 billion. In either scenario, at maturity, the gain or loss on the swap contract would be offset by the gain or loss on the underlying transaction, and therefore, would have no impact on future anticipated cash flows.

The Company does not enter into financial instruments for trading or speculative purposes. Further, the Company has a policy of only entering into contracts with parties that have at least an investment grade credit rating. The counterparties to these contracts are major financial institutions and there is no significant concentration of exposure with any one counterparty. Management believes the risk of loss is remote. The Company entered into credit support agreements (CSA) with certain derivative counterparties establishing collateral thresholds based on respective credit ratings and netting agreements. See Note 6 to the Consolidated Financial Statements for additional details on credit support agreements.

The Company invests in both fixed rate and floating rate interest earning securities which carry a degree of interest rate risk. The fair market value of fixed rate securities may be adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than predicted if interest rates fall. A 1% (100 basis points) change in spread on the Company's interest rate sensitive investments would either increase or decrease the unrealized value of cash equivalents and current marketable securities by less than $0.8 billion.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2023, the Company secured a new 364-day Credit Facility of $10 billion, which expires on September 5, 2024. The Company early terminated the additional 364-day revolving Credit Facility of $10 billion, which had an expiration of November 21, 2023. Interest charged on borrowings under the credit line agreement is based on either Secured Overnight Financing Rate (SOFR) Reference Rate or other applicable market rate as allowed plus applicable margins. Commitment fees under the agreement are not material.

Total borrowings at the end of 2023 and 2022 were $29.3 billion and $39.6 billion, respectively. The decrease in the debt balance was due to the repayment of commercial paper. In 2023, net debt (cash and current marketable securities, net of debt) was $6.4 billion compared to net debt of $17.4 billion in 2022. Total debt represented 30.0% of total capital (shareholders' equity and total debt) in 2023 and 34.0% of total capital in 2022. Shareholders' equity per share at the end of 2023 was $28.57 compared to $29.39 at year-end 2022.

A summary of borrowings can be found in Note 7 to the Consolidated Financial Statements.

Dividends

The Company increased its dividend in 2023 for the 61st consecutive year. Cash dividends paid were $4.70 per share in 2023 and $4.45 per share in 2022.

On January 2, 2024, the Board of Directors declared a regular cash dividend of $1.19 per share, payable on March 5, 2024 to shareholders of record as of February 20, 2024.

Other information

Critical accounting policies and estimates

Management's discussion and analysis of results of operations and financial condition are based on the Company's consolidated financial statements that have been prepared in accordance with accounting principles generally accepted in the U.S. (GAAP). The preparation of these financial statements requires that management make estimates and assumptions that affect the amounts reported for revenues, expenses, assets, liabilities and other related disclosures. Actual results may or may not differ from these estimates. The Company believes that the understanding of certain key accounting policies and estimates are essential in achieving more insight into the Company's operating results and financial condition. These key accounting policies include revenue recognition, income taxes, legal and self-insurance contingencies, valuation of long-lived assets, assumptions used to determine the amounts recorded for pensions and other employee benefit plans and accounting for stock based awards.

Revenue Recognition: The Company recognizes revenue from product sales when obligations under the terms of a contract with the customer are satisfied; generally, this occurs with the transfer of control of the goods to customers. The Company's global payment terms are typically between 30 to 90 days. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns, discounts to customers and governmental clawback provisions are accounted for as variable consideration and recorded as a reduction in sales.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including consideration of competitor pricing. Rebates are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns are estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales return accruals.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The sales returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Innovative Medicine segments are almost exclusively not resalable. Sales returns for certain franchises in the MedTech segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been less than 1.0% of annual net trade sales during the fiscal years 2023, 2022 and 2021.

Promotional programs, such as product listing allowances are recorded in the same period as related sales and include volume-based sales incentive programs. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue. The Company also earns profit-share payments through collaborative arrangements of certain products, which are included in sales to customers. Profit-share payments were less than 2.0% of the total revenues in fiscal year 2023 and less than 3.0% of the total revenues in fiscal year 2022 and 2021 are included in sales to customers.

In addition, the Company enters into collaboration arrangements that contain multiple revenue generating activities. Amounts due from collaborative partners for these arrangements are recognized as each activity is performed or delivered, based on the relative selling price. Upfront fees received as part of these arrangements are deferred and recognized over the performance period. See Note 1 to the Consolidated Financial Statements for additional disclosures on collaborations.

Reasonably likely changes to assumptions used to calculate the accruals for rebates, returns and promotions are not anticipated to have a material effect on the financial statements. The Company currently discloses the impact of changes to assumptions in the quarterly or annual filing in which there is a material financial statement impact.

Below are tables that show the progression of accrued rebates, returns, promotions, reserve for doubtful accounts and reserve for cash discounts by segment of business for the fiscal years ended December 31, 2023 and January 1, 2023.

Innovative Medicine segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/ Credits[2]	Balance at End of Period
2023				
Accrued rebates [1]	$12,289	47,523	(45,151)	14,661
Accrued returns	649	332	(347)	634
Accrued promotions	1	12	(7)	6
Subtotal	**$12,939**	**47,867**	**(45,505)**	**15,301**
Reserve for doubtful accounts	44	0	(11)	33
Reserve for cash discounts	110	1,386	(1,385)	111
Total	**$13,093**	**49,253**	**(46,901)**	**15,445**
2022				
Accrued rebates [1]	$10,331	43,026	(41,068)	12,289
Accrued returns	520	444	(315)	649
Accrued promotions	3	5	(7)	1
Subtotal	**$10,854**	**43,475**	**(41,390)**	**12,939**
Reserve for doubtful accounts	50	0	(6)	44
Reserve for cash discounts	94	1,281	(1,265)	110
Total	**$10,998**	**44,756**	**(42,661)**	**13,093**

(1) Includes reserve for customer rebates of $165 million at December 31, 2023 and $203 million at January 1, 2023, recorded as a contra asset.

(2) Includes prior period adjustments

MedTech segment

(Dollars in Millions)	Balance at Beginning of Period	Accruals	Payments/ Credits	Balance at End of Period
2023				
Accrued rebates[1]	$1,470	6,241	(6,256)	1,455
Accrued returns	134	555	(564)	125
Accrued promotions	43	74	(92)	25
Subtotal	**$1,647**	**6,870**	**(6,912)**	**1,605**
Reserve for doubtful accounts	125	33	(25)	133
Reserve for cash discounts	9	96	(100)	5
Total	**$1,781**	**6,999**	**(7,037)**	**1,743**
2022				
Accrued rebates[1]	$1,446	6,131	(6,107)	1,470
Accrued returns	134	531	(531)	134
Accrued promotions	54	102	(113)	43
Subtotal	**$1,634**	**6,764**	**(6,751)**	**1,647**
Reserve for doubtful accounts	148	6	(29)	125
Reserve for cash discounts	10	99	(100)	9
Total	**$1,792**	**6,869**	**(6,880)**	**1,781**

(1) Includes reserve for customer rebates of $740 million at December 31, 2023 and $802 million at January 1, 2023, recorded as a contra asset.

Income Taxes: Income taxes are recorded based on amounts refundable or payable for the current year and include the results of any difference between U.S. GAAP accounting and tax reporting, recorded as deferred tax assets or liabilities. The Company estimates deferred tax assets and liabilities based on enacted tax regulations and rates. Future changes in tax laws and rates may affect recorded deferred tax assets and liabilities.

The Company has unrecognized tax benefits for uncertain tax positions. The Company follows U.S. GAAP, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Management believes that changes in these estimates would not have a material effect on the Company's results of operations, cash flows or financial position.

The Company has recorded deferred tax liabilities on all undistributed earnings prior to December 31, 2017 from its international subsidiaries. The Company has not provided deferred taxes on the undistributed earnings subsequent to January 1, 2018 from certain international subsidiaries where the earnings are considered to be indefinitely reinvested. The Company intends to continue to reinvest these earnings in those international operations. If the Company decides at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company estimates that the tax effect of this repatriation would be approximately $0.5 billion under currently enacted tax laws and regulations and at current currency exchange rates. This amount does not include the possible benefit of U.S. foreign tax credits, which may substantially offset this cost.

See Note 1 and Note 8 to the Consolidated Financial Statements for further information regarding income taxes.

Legal and Self Insurance Contingencies: The Company records accruals for various contingencies, including legal proceedings and product liability claims as these arise in the normal course of business. The accruals are based on management's judgment as to the probability of losses and, where applicable, actuarially determined estimates. The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated.

The Company follows the provisions of U.S. GAAP when recording litigation related contingencies. A liability is recorded when a loss is probable and can be reasonably estimated.

See Notes 1 and 19 to the Consolidated Financial Statements for further information regarding product liability and legal proceedings.

Long-Lived and Intangible Assets: The Company assesses changes, both qualitatively and quantitatively, in economic conditions and makes assumptions regarding estimated future cash flows in evaluating the value of the Company's property, plant and equipment, goodwill and intangible assets. As these assumptions and estimates may change over time, it may or may not be necessary for the Company to record impairment charges.

Employee Benefit Plans: The Company sponsors various retirement and pension plans, including defined benefit, defined contribution and termination indemnity plans, which cover most employees worldwide. These plans are based on assumptions for the discount rate, expected return on plan assets, mortality rates, expected salary increases, healthcare cost trend rates and attrition rates. See Note 10 to the Consolidated Financial Statements for further details on these rates.

Stock Based Compensation: The Company recognizes compensation expense associated with the issuance of equity instruments to employees for their services. Based on the type of equity instrument, the fair value is estimated on the date of grant using either the Black-Scholes option valuation model or a combination of both the Black-Scholes option valuation model and Monte Carlo valuation model, and is expensed in the financial statements over the service period. The input assumptions used in determining fair value are the expected life, expected volatility, risk-free rate and expected dividend yield. For performance share units, the fair market value is calculated for the two component goals at the date of grant: adjusted operational earnings per share and relative total shareholder return. The fair values for the earnings per share goal of each performance share unit was estimated on the date of grant using the fair market value of the shares at the time of the award, discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. See Note 16 to the Consolidated Financial Statements for additional information.

New accounting pronouncements

Refer to Note 1 to the Consolidated Financial Statements for recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of December 31, 2023.

Economic and market factors

The Company is aware that its products are used in an environment where, for more than a decade, policymakers, consumers and businesses have expressed concerns about the rising cost of healthcare. In response to these concerns, the Company has a long-standing policy of pricing products responsibly. For the period 2013 - 2023, in the U.S., the weighted average compound annual growth rate of the Company's net price increases for healthcare products (prescription and over-the-counter drugs, hospital and professional products) was below the U.S. Consumer Price Index (CPI).

The Company operates in certain countries where the economic conditions continue to present significant challenges. The Company continues to monitor these situations and take appropriate actions. Inflation rates continue to have an effect on worldwide economies and, consequently, on the way companies operate. The Company has accounted for operations in Argentina, Venezuela and Turkey (beginning in the fiscal second quarter of 2022) as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. This did not have a material impact to the Company's results in the period. In the face of increasing costs, the Company strives to maintain its profit margins through cost reduction programs, productivity improvements and periodic price increases.

In December 2023, the Argentine government devalued the peso by approximately 50%. During 2023, the Company recorded a charge of approximately $130 million related to operations in Argentina due to the application of highly inflationary accounting. As of December 31, 2023, the Company's Argentine subsidiaries represented less than 1.0% of the Company's consolidated assets, liabilities, revenues and profits from continuing operations; therefore, the effect of a change in the exchange rate is not expected to have a material adverse effect on the Company's 2024 full-year results.

In July 2023, Janssen Pharmaceuticals, Inc. (Janssen) filed litigation against the U.S. Department of Health and Human Services as well as the Centers for Medicare and Medicaid Services challenging the constitutionality of the Inflation Reduction Act's (IRA) Medicare Drug Price Negotiation Program. The litigation requests a declaration that the IRA violates Janssen's rights under the First Amendment and the Fifth Amendment to the Constitution and therefore that Janssen is not subject to the IRA's mandatory pricing scheme.

Russia-Ukraine War

Although the long-term implications of Russia's invasion of Ukraine are difficult to predict at this time, the financial impact of the conflict in the fiscal year 2023, including accounts receivable or inventory reserves, was not material. As of and for each of the fiscal years ending December 31, 2023 and January 1, 2023, the business of the Company's Russian subsidiaries represented less than 1% of the Company's consolidated assets and represented 1% of revenues. The Company does not maintain Ukraine subsidiaries subsequent to the Kenvue separation.

In early March of 2022, the Company took steps to suspend all advertising, enrollment in clinical trials, and any additional investment in Russia. The Company continues to supply products relied upon by patients for healthcare purposes.

Conflict in the Middle East

Although the long-term implications of Israel's conflict are difficult to predict at this time, the financial impact of the conflict in the fiscal year 2023, including accounts receivable or inventory reserves, was not material. As of and for the fiscal year ending December 31, 2023, the business of the Company's Israel subsidiaries represented 1% of the Company's consolidated assets and represented less than 1% of revenues.

The Company is exposed to fluctuations in currency exchange rates. A 1% change in the value of the U.S. Dollar as compared to all foreign currencies in which the Company had sales, income or expense in 2023 would have increased or decreased the translation of foreign sales by approximately $0.4 billion and net income by approximately $0.2 billion.

Governments around the world consider various proposals to make changes to tax laws, which may include increasing or decreasing existing statutory tax rates. In connection with various government initiatives, companies are required to disclose more information to tax authorities on operations around the world, which may lead to greater audit scrutiny of profits earned in other countries. A change in statutory tax rate in any country would result in the revaluation of the Company's deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is enacted. This change would result in an expense or benefit recorded to the Company's Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries where it operates. Changes to the statutory tax rate may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted.

The Company faces various worldwide healthcare changes that may continue to result in pricing pressures that include healthcare cost containment and government legislation relating to sales, promotions, pricing and reimbursement of healthcare products.

Changes in the behavior and spending patterns of purchasers of healthcare products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing healthcare insurance coverage may continue to impact the Company's businesses.

The Company also operates in an environment increasingly hostile to intellectual property rights. Firms have filed Abbreviated New Drug Applications or Biosimilar Biological Product Applications with the U.S. FDA or otherwise challenged the coverage and/or validity of the Company's patents, seeking to market generic or biosimilar forms of many of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the event the Company is not successful in defending the patent claims challenged in the resulting lawsuits, generic or biosimilar versions of the products at issue will be introduced to the market, resulting in the potential for substantial market share and revenue losses for those products, and which may result in a non-cash impairment charge in any associated intangible asset. There is also a risk that one or more competitors could launch a generic or biosimilar version of the product at issue following regulatory approval even though one or more valid patents are in place.

Legal proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability, intellectual property, commercial, employment, indemnification and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of business.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of December 31, 2023, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25, Contingencies. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; ability to achieve comprehensive multi-party settlements; complexity of related cross-claims and counterclaims; and/or there are numerous parties involved. To the extent adverse awards, judgments or verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution of, or increase in accruals for, one or more of these matters in any reporting period may have a material adverse effect on the Company's results of operations and cash flows for that period.

See Note 19 to the Consolidated Financial Statements included in Item 8 of this report for further information regarding legal proceedings.

Common stock

The Company's Common Stock is listed on the New York Stock Exchange under the symbol JNJ. As of February 9, 2024, there were 118,772 record holders of Common Stock of the Company.

Item 7A. Quantitative and qualitative disclosures about market risk

The information called for by this item is incorporated herein by reference to Item 7. Management's discussion and analysis of results of operations and financial condition - Liquidity and capital resources - Financing and market risk of this Report; and Note 1 Summary of significant accounting policies - Financial instruments of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Item 8. Financial statements and supplementary data

Index to audited Consolidated Financial Statements

Johnson & Johnson and subsidiaries consolidated balance sheets

At December 31, 2023 and January 1, 2023
(Dollars in Millions Except Share and Per Share Amounts) (Note 1)

	2023	2022
Assets		
Current assets		
Cash and cash equivalents (Notes 1 and 2)	$21,859	12,889
Marketable securities (Notes 1 and 2)	1,068	9,392
Accounts receivable trade, less allowances $166 (2022, $169)	14,873	14,039
Inventories (Notes 1 and 3)	11,181	10,268
Prepaid expenses and other receivables	4,514	2,876
Current assets of discontinued operations (Note 21)	—	5,830
Total current assets	**53,495**	**55,294**
Property, plant and equipment, net (Notes 1 and 4)	19,898	17,982
Intangible assets, net (Notes 1 and 5)	34,175	38,489
Goodwill (Notes 1 and 5)	36,558	36,047
Deferred taxes on income (Note 8)	9,279	8,947
Other assets	14,153	9,212
Noncurrent assets of discontinued operations (Note 21)	—	21,407
Total assets	**$167,558**	**187,378**
Liabilities and Shareholders' Equity		
Current liabilities		
Loans and notes payable (Note 7)	$3,451	12,756
Accounts payable	9,632	9,889
Accrued liabilities	10,212	10,719
Accrued rebates, returns and promotions	16,001	13,579
Accrued compensation and employee related obligations	3,993	3,049
Accrued taxes on income (Note 8)	2,993	2,220
Current liabilities of discontinued operations (Note 21)	—	3,590
Total current liabilities	**46,282**	**55,802**
Long-term debt (Note 7)	25,881	26,886
Deferred taxes on income (Note 8)	3,193	3,991
Employee related obligations (Notes 9 and 10)	7,149	6,542
Long-term taxes payable (Note 1)	2,881	4,306
Other liabilities	13,398	10,146
Noncurrent liabilities of discontinued operations (Note 21)	—	2,901
Total liabilities	**98,784**	**110,574**
Commitments and Contingencies (Note 19)		
Shareholders' equity		
Preferred stock — without par value (authorized and unissued 2,000,000 shares)	—	—
Common stock — par value $1.00 per share (Note 12) (authorized 4,320,000,000 shares; issued 3,119,843,000 shares)	3,120	3,120
Accumulated other comprehensive income (loss) (Note 13)	(12,527)	(12,967)
Retained earnings and Additional-paid-in-capital	153,843	128,345
Less: common stock held in treasury, at cost (Note 12) (712,765,000 shares and 506,246,000 shares)	75,662	41,694
Total shareholders' equity	**68,774**	**76,804**
Total liabilities and shareholders' equity	**$167,558**	**187,378**

See Notes to Consolidated Financial Statements

Johnson & Johnson and subsidiaries consolidated statements of earnings

(Dollars and Shares in Millions Except Per Share Amounts) (Note 1)

	2023	2022	2021
Sales to customers	$85,159	79,990	78,740
Cost of products sold	26,553	24,596	23,402
Gross profit	58,606	55,394	55,338
Selling, marketing and administrative expenses	21,512	20,246	20,118
Research and development expense	15,085	14,135	14,277
In-process research and development impairments	313	783	900
Interest income	(1,261)	(490)	(53)
Interest expense, net of portion capitalized (Note 4)	772	276	183
Other (income) expense, net	6,634	810	526
Restructuring (Note 20)	489	275	209
Earnings before provision for taxes on income	15,062	19,359	19,178
Provision for taxes on income (Note 8)	1,736	2,989	1,377
Net earnings from continuing operations	13,326	16,370	17,801
Net earnings from discontinued operations, net of tax (Note 21)	21,827	1,571	3,077
Net earnings	**$35,153**	**17,941**	**20,878**
Net earnings per share (Notes 1 and 15)			
Continuing operations - basic	$5.26	6.23	6.76
Discontinued operations - basic	$8.62	0.60	1.17
Total net earnings per share - basic	**$13.88**	**6.83**	**7.93**
Continuing operations - diluted	$5.20	6.14	6.66
Discontinued operations - diluted	$8.52	0.59	1.15
Total net earnings per share - diluted	**$13.72**	**6.73**	**7.81**
Average shares outstanding (Notes 1 and 15)			
Basic	**2,533.5**	**2,625.2**	**2,632.1**
Diluted	**2,560.4**	**2,663.9**	**2,674.0**

See Notes to Consolidated Financial Statements

Johnson & Johnson and subsidiaries consolidated statements of comprehensive income

(Dollars in Millions) (Note 1)

	2023	2022	2021
Net earnings	$35,153	17,941	20,878
Other comprehensive income (loss), net of tax			
Foreign currency translation	(3,221)	(1,796)	(1,079)
Securities:			
Unrealized holding gain (loss) arising during period	26	(24)	(4)
Reclassifications to earnings	—	—	—
Net change	26	(24)	(4)
Employee benefit plans:			
Prior service credit (cost), net of amortization	(149)	(160)	(169)
Gain (loss), net of amortization	(1,183)	1,854	4,318
Consumer settlement/ curtailment	23	—	—
Effect of exchange rates	(90)	111	106
Net change	(1,399)	1,805	4,255
Derivatives & hedges:			
Unrealized gain (loss) arising during period	422	454	(199)
Reclassifications to earnings	(569)	(348)	(789)
Net change	(147)	106	(988)
Other comprehensive income (loss)	(4,741)	91	2,184
Comprehensive income	**$30,412**	**18,032**	**23,062**

The tax effects in other comprehensive income for the fiscal years 2023, 2022 and 2021 respectively: Foreign Currency Translation; $797 million, $460 million and $346 million; Employee Benefit Plans: $289 million, $461 million and $1,198 million, Derivatives & Hedges: $39 million, $30 million and $263 million.

See Notes to Consolidated Financial Statements

Amounts presented have not been recast to exclude discontinued operations

Johnson & Johnson and subsidiaries consolidated statements of equity

(Dollars in Millions) (Note 1)

	Total	Retained Earnings and Additional paid-in capital	Accumulated Other Comprehensive Income (Loss)	Common Stock Issued Amount	Treasury Stock Amount
Balance, January 3, 2021	**$63,278**	**113,890**	**(15,242)**	**3,120**	**(38,490)**
Net earnings	20,878	20,878			
Cash dividends paid ($4.19 per share)	(11,032)	(11,032)			
Employee compensation and stock option plans	2,171	(676)			2,847
Repurchase of common stock	(3,456)				(3,456)
Other comprehensive income (loss), net of tax	2,184		2,184		
Balance, January 2, 2022	**74,023**	**123,060**	**(13,058)**	**3,120**	**(39,099)**
Net earnings	17,941	17,941			
Cash dividends paid ($4.45 per share)	(11,682)	(11,682)			
Employee compensation and stock option plans	2,466	(974)			3,440
Repurchase of common stock	(6,035)				(6,035)
Other comprehensive income (loss), net of tax	91		91		
Balance, January 1, 2023	**76,804**	**128,345**	**(12,967)**	**3,120**	**(41,694)**
Net earnings	35,153	35,153			
Cash dividends paid ($4.70 per share)	(11,770)	(11,770)			
Employee compensation and stock option plans	2,193	(336)			2,529
Repurchase of common stock	(5,054)				(5,054)
Other	(25)				(25)
Kenvue Separation /IPO (Note 21)	(23,786)	2,451	5,181		(31,418)
Other comprehensive income (loss), net of tax	(4,741)		(4,741)		
Balance, December 31, 2023	**$68,774**	**153,843**	**(12,527)**	**3,120**	**(75,662)**

See Notes to Consolidated Financial Statements

Johnson & Johnson and subsidiaries consolidated statements of cash flows

(Dollars in Millions) (Note 1)

	2023	2022	2021
Cash flows from operating activities			
Net earnings	$35,153	17,941	20,878
Adjustments to reconcile net earnings to cash flows from operating activities:			
Depreciation and amortization of property and intangibles	7,486	6,970	7,390
Stock based compensation	1,162	1,138	1,135
Asset write-downs	1,295	1,216	989
Charge for purchase of in-process research and development assets	483	—	—
Gain on Kenvue separation	(20,984)	—	—
Net gain on sale of assets/businesses	(117)	(380)	(617)
Deferred tax provision	(4,194)	(1,663)	(2,079)
Credit losses and accounts receivable allowances	—	(17)	(48)
Changes in assets and liabilities, net of effects from acquisitions and divestitures:			
Increase in accounts receivable	(624)	(1,290)	(2,402)
Increase in inventories	(1,323)	(2,527)	(1,248)
Increase in accounts payable and accrued liabilities	2,346	1,098	2,437
(Increase)/Decrease in other current and non-current assets	(3,480)	687	(1,964)
Increase/(Decrease) in other current and non-current liabilities	5,588	(1,979)	(1,061)
Net cash flows from operating activities	**22,791**	**21,194**	**23,410**
Cash flows from investing activities			
Additions to property, plant and equipment	(4,543)	(4,009)	(3,652)
Proceeds from the disposal of assets/businesses, net	358	543	711
Acquisitions, net of cash acquired (Note 18)	—	(17,652)	(60)
Purchases of in-process research and development assets (Note 18)	(470)	—	—
Purchases of investments	(10,906)	(32,384)	(30,394)
Sales of investments	19,390	41,609	25,006
Credit support agreements activity, net	(2,963)	(249)	214
Other (including capitalized licenses and milestones)	12	(229)	(508)
Net cash from/(used) by investing activities	**878**	**(12,371)**	**(8,683)**
Cash flows from financing activities			
Dividends to shareholders	(11,770)	(11,682)	(11,032)
Repurchase of common stock	(5,054)	(6,035)	(3,456)
Proceeds from short-term debt	13,743	16,134	1,997
Repayment of short-term debt	(22,973)	(6,550)	(1,190)
Proceeds from long-term debt, net of issuance costs	—	2	5
Repayment of long-term debt	(1,551)	(2,134)	(1,802)
Proceeds from the exercise of stock options/employee withholding tax on stock awards, net	1,094	1,329	1,036
Credit support agreements activity, net	(219)	(28)	281

	2023	2022	2021
Proceeds of short and long-term debt, net of issuance cost, related to the debt that transferred to Kenvue at separation	8,047	—	—
Proceeds from Kenvue initial public offering	4,241	—	—
Cash transferred to Kenvue at separation	(1,114)	—	—
Other	(269)	93	114
Net cash used by financing activities	**(15,825)**	**(8,871)**	**(14,047)**
Effect of exchange rate changes on cash and cash equivalents	(112)	(312)	(178)
Increase/(Decrease) in cash and cash equivalents	7,732	(360)	502
Cash and cash equivalents from continuing operations, beginning of period	12,889	13,309	12,697
Cash and cash equivalents from discontinued operations, beginning of period	1,238	1,178	1,288
Cash and cash equivalents, beginning of year (Note 1)	14,127	14,487	13,985
Cash and cash equivalents from continuing operations, end of period	21,859	12,889	13,309
Cash and cash equivalents from discontinued operations, end of period	—	1,238	1,178
Cash and cash equivalents, end of year (Note 1)	**$21,859**	**14,127**	**14,487**
Supplemental cash flow data			
Cash paid during the year for:			
Interest	$1,836	982	990
Interest, net of amount capitalized	1,766	933	941
Income taxes, inclusive of discontinued operations	8,574	5,223	4,768
Supplemental schedule of non-cash investing and financing activities			
Treasury stock issued for employee compensation and stock option plans, net of cash proceeds/ employee withholding tax on stock awards	$1,435	2,114	1,811
Acquisitions			
Fair value of assets acquired	$—	18,710	61
Fair value of liabilities assumed	—	(1,058)	(1)
Net cash paid for acquisitions (Note 18)	$—	17,652	60

See Notes to Consolidated Financial Statements

Amounts presented have not been recast to exclude discontinued operations.

Notes to Consolidated Financial Statements

1. Summary of significant accounting policies

Principles of consolidation

The consolidated financial statements include the accounts of Johnson & Johnson and its subsidiaries (the Company). Intercompany accounts and transactions are eliminated. Columns and rows within tables may not add due to rounding. Percentages have been calculated using actual, non-rounded figures.

Description of the company and business segments

The Company has approximately 131,900 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the healthcare field. The Company conducts business in virtually all countries of the world and its primary focus is on products related to human health and well-being.

Kenvue IPO/separation and discontinued operations

On May 8, 2023, Kenvue, completed an initial public offering (the IPO) resulting in the issuance of 198,734,444 shares of its common stock, par value $0.01 per share (the "Kenvue Common Stock"), at an initial public offering of $22.00 per share for net proceeds of $4.2 billion. The excess of the net proceeds from the IPO over the net book value of the Johnson & Johnson divested interest was $2.5 billion and was recorded to additional paid-in capital. As of the closing of the IPO, Johnson & Johnson owned approximately 89.6% of the total outstanding shares of Kenvue Common Stock and at July 2, 2023, the non-controlling interest of $1.3 billion associated with Kenvue was reflected in equity attributable to non-controlling interests in the consolidated balance sheet in the fiscal second quarter of 2023.

On August 23, 2023, Johnson & Johnson completed the disposition of an additional 80.1% ownership of the shares of Kenvue through an exchange offer. Following the exchange offer, the Company owns 9.5% of the shares of Kenvue which are accounted for as an equity investment carried at fair value within continuing operations. The historical results of the Consumer Health business (which previously represented the Consumer Health business segment) are reflected as discontinued operations in the Company's Consolidated Financial Statements through the date of the exchange offer (see Note 21 for additional details). Unless otherwise indicated, the information in the notes to the Consolidated Financial Statements refer only to Johnson & Johnson's continuing operations.

Business segments

Following the completion of the exchange offer, the Company is organized into two business segments: Innovative Medicine and MedTech. The Innovative Medicine segment is focused on the following therapeutic areas, including Immunology, Infectious diseases, Neuroscience, Oncology, Pulmonary Hypertension, and Cardiovascular and Metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, distributors, hospitals and healthcare professionals for prescription use. The MedTech segment includes a broad portfolio of products used in the Orthopaedic, Surgery, Interventional Solutions and Vision fields. These products are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

New accounting standards

Recently adopted accounting standards

ASU 2022-04: Liabilities-Supplier Finance Programs (Topic 405-50) – Disclosure of Supplier Finance Program Obligations

The Company adopted the standard as of the beginning of fiscal year 2023, which requires that a buyer in a supplier finance program disclose additional information about the program for financial statement users.

The Company has agreements for supplier finance programs with third-party financial institutions. These programs provide participating suppliers the ability to finance payment obligations from the Company with the third-party financial institutions. The Company is not a party to the arrangements between the suppliers and the third-party financial institutions. The Company's obligations to its suppliers, including amounts due, and scheduled payment dates (which have general payment terms of 90 days), are not affected by a participating supplier's decision to participate in the program.

As of both December 31, 2023, and January 1, 2023, $0.7 billion were valid obligations under the program. The obligations are presented as Accounts payable on the Consolidated Balance Sheets.

Recently issued accounting standards

Not adopted as of December 31, 2023

ASU 2023-07: Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures
This update requires expanded annual and interim disclosures for significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss. This update will be effective for fiscal years beginning after December 15, 2023, and is to be applied retrospectively to all periods presented in the financial statements. Early adoption is permitted. As this accounting standard only impacts disclosures, it will not have a material impact on the Company's Consolidated Financial Statements.

ASU 2023-09: Income Taxes (Topic 740) - Improvements to Income Tax Disclosures
This update standardizes categories for the effective tax rate reconciliation, requires disaggregation of income taxes and additional income tax-related disclosures. This update is required to be effective for the Company for fiscal periods beginning after December 15, 2024. As this accounting standard only impacts disclosures, it will not have a material impact on the Company's Consolidated Financial Statements.

Cash equivalents

The Company classifies all highly liquid investments with stated maturities of three months or less from date of purchase as cash equivalents and all highly liquid investments with stated maturities of greater than three months from the date of purchase as current marketable securities. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating. The Company invests its cash primarily in government securities and obligations, corporate debt securities, money market funds and reverse repurchase agreements (RRAs).

RRAs are collateralized by deposits in the form of Government Securities and Obligations for an amount not less than 102% of their value. The Company does not record an asset or liability as the Company is not permitted to sell or repledge the associated collateral. The Company has a policy that the collateral has at least an A (or equivalent) credit rating. The Company utilizes a third party custodian to manage the exchange of funds and ensure that collateral received is maintained at 102% of the value of the RRAs on a daily basis. RRAs with stated maturities of greater than three months from the date of purchase are classified as marketable securities.

Investments

Investments classified as held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings. Investments classified as available-for-sale debt securities are carried at estimated fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income. Available-for-sale securities available for current operations are classified as current assets; otherwise, they are classified as long term. Management determines the appropriate classification of its investment in debt and equity securities at the time of purchase and re-evaluates such determination at each balance sheet date. The Company reviews its investments for impairment and adjusts these investments to fair value through earnings, as required.

Property, plant and equipment and depreciation

Property, plant and equipment are stated at cost. The Company utilizes the straight-line method of depreciation over the estimated useful lives of the assets:

Building and building equipment	30 years
Land and leasehold improvements	10 - 20 years
Machinery and equipment	2 - 13 years

The Company capitalizes certain computer software and development costs, included in machinery and equipment, when incurred in connection with developing or obtaining computer software for internal use. Capitalized software costs are amortized over the estimated useful lives of the software, which generally range from 3 to 8 years.

The Company reviews long-lived assets to assess recoverability using undiscounted cash flows. When certain events or changes in operating or economic conditions occur, an impairment assessment may be performed on the recoverability of the

carrying value of these assets. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows.

Revenue recognition

The Company recognizes revenue from product sales when obligations under the terms of a contract with the customer are satisfied; generally, this occurs with the transfer of control of the goods to customers. The Company's global payment terms are typically between 30 to 90 days. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns, discounts to customers and governmental clawback provisions are accounted for as variable consideration and recorded as a reduction in sales. The liability is recognized within Accrued rebates, returns, and promotions on the consolidated balance sheet.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including consideration of competitor pricing. Rebates are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. A significant portion of the liability related to rebates is from the sale of the Company's pharmaceutical products within the U.S., primarily the Managed Care, Medicare and Medicaid programs, which amounted to $11.5 billion and $9.6 billion as of December 31, 2023 and January 1, 2023, respectively. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns are estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales return accruals.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The sales returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Innovative Medicine segments are almost exclusively not resalable. Sales returns for certain franchises in the MedTech segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been less than 1.0% of annual net trade sales during each of the fiscal years 2023, 2022 and 2021.

Promotional programs, such as product listing allowances are recorded in the same period as related sales and include volume-based sales incentive programs. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue. The Company also earns profit-share payments through collaborative arrangements of certain products, which are included in sales to customers. Profit-share payments were less than 2.0% of the total revenues in fiscal year 2023 and less than 3.0% of the total revenues in the fiscal years 2022 and 2021 and are included in sales to customers.

See Note 17 to the Consolidated Financial Statements for further disaggregation of revenue.

Shipping and handling

Shipping and handling costs incurred were $0.9 billion, $0.8 billion and $0.8 billion in fiscal years 2023, 2022 and 2021, respectively, and are included in selling, marketing and administrative expense. The amount of revenue received for shipping and handling is less than 1.0% of sales to customers for all periods presented.

Inventories

Inventories are stated at the lower of cost or net realizable value determined by the first-in, first-out method.

Intangible assets and goodwill

The authoritative literature on U.S. GAAP requires that goodwill and intangible assets with indefinite lives be assessed annually for impairment. The Company completed its annual impairment test for 2023 in the fiscal fourth quarter. Future impairment

tests will be performed annually in the fiscal fourth quarter, or sooner if warranted. Purchased in-process research and development is accounted for as an indefinite lived intangible asset until the underlying project is completed, at which point the intangible asset will be accounted for as a definite lived intangible asset. If warranted the purchased in-process research and development could be written off or partially impaired depending on the underlying program.

Intangible assets that have finite useful lives continue to be amortized over their useful lives, and are reviewed for impairment when warranted by economic conditions. See Note 5 for further details on Intangible Assets and Goodwill.

Financial instruments

As required by U.S. GAAP, all derivative instruments are recorded on the balance sheet at fair value. Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value, with Level 1 having the highest priority and Level 3 having the lowest. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The Company documents all relationships between hedged items and derivatives. The overall risk management strategy includes reasons for undertaking hedge transactions and entering into derivatives. The objectives of this strategy are: (1) minimize foreign currency exposure's impact on the Company's financial performance; (2) protect the Company's cash flow from adverse movements in foreign exchange rates; (3) ensure the appropriateness of financial instruments; and (4) manage the enterprise risk associated with financial institutions. See Note 6 for additional information on Financial Instruments.

Leases

The Company determines whether an arrangement is a lease at contract inception by establishing if the contract conveys the right to control the use of identified property, plant, or equipment for a period of time in exchange for consideration. Right of Use (ROU) Assets and Lease Liabilities for operating leases are included in Other assets, Accrued liabilities, and Other liabilities on the consolidated balance sheet. The ROU Assets represent the right to use an underlying asset for the lease term and lease liabilities represent an obligation to make lease payments arising from the lease. Commitments under finance leases are not significant, and are included in Property, plant and equipment, Loans and notes payable, and Long-term debt on the consolidated balance sheet.

ROU Assets and Lease Liabilities are recognized at the lease commencement date based on the present value of all minimum lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments, when the implicit rate is not readily determinable. Lease terms may include options to extend or terminate the lease. These options are included in the lease term when it is reasonably certain that the Company will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term. The Company has elected the following policy elections on adoption: use of portfolio approach on leases of assets under master service agreements, exclusion of short term leases on the balance sheet, and not separating lease and non-lease components.

The Company primarily has operating lease for space, vehicles, manufacturing equipment and data processing equipment. The ROU asset pertaining to leases from continuing operation was $1.0 billion in both fiscal years 2023 and 2022. The lease liability from continuing operations was $1.1 billion in both fiscal years 2023 and 2022. The operating lease costs from continuing operations were $0.2 billion in fiscal years 2023, 2022 and 2021. Cash paid for amounts included in the measurement of lease liabilities from continuing operations were $0.2 billion in fiscal years 2023, 2022 and 2021.

Product liability

Accruals for product liability claims are recorded, on an undiscounted basis, when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated based on existing information and actuarially determined estimates where applicable. The accruals are adjusted periodically as additional information becomes available. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated.

Research and development

Research and development expenses are expensed as incurred in accordance with ASC 730, Research and Development. Upfront and milestone payments made to third parties in connection with research and development collaborations are expensed as incurred up to the point of regulatory approval. Payments made to third parties subsequent to regulatory approval are capitalized and amortized over the remaining useful life of the related product. Amounts capitalized for such payments are included in other intangibles, net of accumulated amortization.

The Company enters into collaborative arrangements, typically with other pharmaceutical or biotechnology companies, to develop and commercialize drug candidates or intellectual property. These arrangements typically involve two (or more) parties who are active participants in the collaboration and are exposed to significant risks and rewards dependent on the commercial success of the activities. These collaborations usually involve various activities by one or more parties, including research and development, marketing and selling and distribution. Often, these collaborations require upfront, milestone and royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development. Amounts due from collaborative partners related to development activities are generally reflected as a reduction of research and development expense because the performance of contract development services is not central to the Company's operations. In general, the income statement presentation for these collaborations is as follows:

Nature/Type of Collaboration	Statement of Earnings Presentation
Third-party sale of product & profit share payments received	Sales to customers
Royalties/milestones paid to collaborative partner (post-regulatory approval)*	Cost of products sold
Royalties received from collaborative partner	Other income (expense), net
Upfront payments & milestones paid to collaborative partner (pre-regulatory approval)	Research and development expense
Research and development payments to collaborative partner	Research and development expense
Research and development payments received from collaborative partner or government entity	Reduction of Research and development expense

* Milestones are capitalized as intangible assets and amortized to cost of products sold over the useful life.

For all years presented, there was no individual project that represented greater than 5% of the total annual consolidated research and development expense.

The Company has a number of products and compounds developed in collaboration with strategic partners including XARELTO, co-developed with Bayer HealthCare AG and IMBRUVICA, developed in collaboration and co-marketed with Pharmacyclics LLC, an AbbVie company.

Separately, the Company has a number of licensing arrangements for products and compounds including DARZALEX, licensed from Genmab A/S.

Advertising

Costs associated with advertising are expensed in the year incurred and are included in selling, marketing and administrative expenses. Advertising expenses worldwide, which comprised television, radio, print media and Internet advertising, were $0.5 billion, $0.7 billion and $1.2 billion in fiscal years 2023, 2022 and 2021, respectively.

Income taxes

Income taxes are recorded based on amounts refundable or payable for the current year and include the results of any difference between U.S. GAAP accounting and tax reporting, recorded as deferred tax assets or liabilities. The Company

estimates deferred tax assets and liabilities based on enacted tax regulations and rates. Future changes in tax laws and rates may affect recorded deferred tax assets and liabilities in the future.

The Company has unrecognized tax benefits for uncertain tax positions. The Company follows U.S. GAAP which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Management believes that changes in these estimates would not have a material effect on the Company's results of operations, cash flows or financial position.

In 2017, the United States enacted into law new U.S. tax legislation, the U.S. Tax Cuts and Jobs Act (TCJA). This law included provisions for a comprehensive overhaul of the corporate income tax code, including a reduction of the statutory corporate tax rate from 35% to 21%, effective on January 1, 2018. The TCJA included a provision for a tax on all previously undistributed earnings of U.S. companies located in foreign jurisdictions. Undistributed earnings in the form of cash and cash equivalents were taxed at a rate of 15.5% and all other earnings were taxed at a rate of 8.0%. This tax is payable over 8 years and will not accrue interest. These payments began in 2018 and will continue through 2025. The remaining balance at the end of the 2023 was approximately $4.5 billion, of which $2.5 billion is classified as noncurrent and reflected as “Long-term taxes payable” on the Company’s balance sheet.

The TCJA also includes provisions for a tax on global intangible low-taxed income (GILTI). GILTI is described as the excess of a U.S. shareholder’s total net foreign income over a deemed return on tangible assets, as provided by the TCJA. In January 2018, the FASB issued guidance that allows companies to elect as an accounting policy whether to record the tax effects of GILTI in the period the tax liability is generated (i.e., “period cost”) or provide for deferred tax assets and liabilities related to basis differences that exist and are expected to effect the amount of GILTI inclusion in future years upon reversal (i.e., “deferred method”). The Company has elected to account for GILTI under the deferred method. The deferred tax amounts recorded are based on the evaluation of temporary differences that are expected to reverse as GILTI is incurred in future periods.

The Company has recorded deferred tax liabilities on all undistributed earnings prior to December 31, 2017 from its international subsidiaries. The Company has not provided deferred taxes on the undistributed earnings subsequent to January 1, 2018 from certain international subsidiaries where the earnings are considered to be indefinitely reinvested. The Company intends to continue to reinvest these earnings in those international operations. If the Company decides at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company estimates that the tax effect of this repatriation would be approximately $0.5 billion under currently enacted tax laws and regulations and at current currency exchange rates. This amount does not include the possible benefit of U.S. foreign tax credits, which may substantially offset this cost.

See Note 8 to the Consolidated Financial Statements for further information regarding income taxes.

Net earnings per share

Basic earnings per share is computed by dividing net earnings available to common shareholders by the weighted average number of common shares outstanding for the period. Diluted earnings per share reflects the potential dilution that could occur if securities were exercised or converted into common stock using the treasury stock method.

Use of estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the amounts reported. Estimates are used when accounting for sales discounts, rebates, allowances and incentives, product liabilities, income taxes, withholding taxes, depreciation, amortization, employee benefits, contingencies and intangible asset and liability valuations. Actual results may or may not differ from those estimates.

The Company follows the provisions of U.S. GAAP when recording litigation related contingencies. A liability is recorded when a loss is probable and can be reasonably estimated. The best estimate of a loss within a range is accrued; however, if no estimate in the range is better than any other, the minimum amount is accrued.

Annual closing date

The Company follows the concept of a fiscal year, which ends on the Sunday nearest to the end of the month of December. Normally each fiscal year consists of 52 weeks, but every five or six years the fiscal year consists of 53 weeks, and therefore includes additional shipping days, as was the case in fiscal year 2020, and will be the case again in fiscal year 2026.

2. Cash, cash equivalents and current marketable securities

At the end of the fiscal year 2023 and 2022, cash, cash equivalents and current marketable securities comprised:

	2023				
(Dollars in Millions)	Carrying Amount	Unrecognized Loss	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	$3,340	—	3,340	3,340	—
Non-U.S. Sovereign Securities[1]	522	—	522	174	348
U.S. Reverse repurchase agreements	4,377	—	4,377	4,377	—
Corporate debt securities[1]	338	—	338	189	149
Money market funds	4,814	—	4,814	4,814	—
Time deposits[1]	662	—	662	662	—
Subtotal	**$14,053**	**—**	**14,053**	**13,556**	**497**
U.S. Gov't Securities	$8,562	—	8,562	8,259	303
U.S. Gov't Agencies	71	(1)	70	—	70
Other Sovereign Securities	5	—	5	1	4
Corporate and other debt securities	237	—	237	43	194
Subtotal available for sale[2]	**$8,875**	**(1)**	**8,874**	**8,303**	**571**
Total cash, cash equivalents and current marketable securities				**$21,859**	**1,068**

	2022				
(Dollars in Millions)	Carrying Amount	Unrecognized Loss	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	$3,691	—	3,691	3,691	—
U.S. Reverse repurchase agreements	1,419	—	1,419	1,419	—
Corporate debt securities[1]	873	(1)	872	—	873
Money market funds	5,368	—	5,368	5,368	—
Time deposits[1]	443	—	443	443	—
Subtotal	**11,794**	**(1)**	**11,793**	**10,921**	**873**
U.S. Gov't Securities	$9,959	(28)	9,931	1,922	8,009
U.S. Gov't Agencies	210	(5)	205	—	205
Corporate and other debt securities	352	(1)	351	46	305
Subtotal available for sale[2]	**$10,521**	**(34)**	**10,487**	**1,968**	**8,519**
Total cash, cash equivalents and current marketable securities				**$12,889**	**9,392**

(1) Held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings.

(2) Available for sale debt securities are reported at fair value with unrealized gains and losses reported net of taxes in other comprehensive income.

Fair value of government securities and obligations and corporate debt securities were estimated using quoted broker prices and significant other observable inputs.

The contractual maturities of the available for sale debt securities at December 31, 2023 are as follows:

(Dollars in Millions)	Cost Basis	Fair Value
Due within one year	$8,865	8,864
Due after one year through five years	10	10
Due after five years through ten years	—	—
Total debt securities	**$8,875**	**8,874**

The Company invests its excess cash in both deposits with major banks throughout the world and other high-quality money market instruments. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating.

3. Inventories

At the end of fiscal years 2023 and 2022, inventories comprised:

(Dollars in Millions)	2023	2022
Raw materials and supplies	$2,355	1,719
Goods in process	1,952	1,577
Finished goods	6,874	6,972
Total inventories	**$11,181**	**10,268**

4. Property, plant and equipment

At the end of fiscal years 2023 and 2022, property, plant and equipment at cost and accumulated depreciation were:

(Dollars in Millions)	2023	2022
Land and land improvements	$795	784
Buildings and building equipment	12,375	11,470
Machinery and equipment	28,979	26,603
Construction in progress	5,627	4,677
Total property, plant and equipment, gross	**$47,776**	**43,534**
Less accumulated depreciation	27,878	25,552
Total property, plant and equipment, net	**$19,898**	**17,982**

The Company capitalizes interest expense as part of the cost of construction of facilities and equipment. Interest expense capitalized in fiscal years 2023, 2022 and 2021 was $70 million, $49 million and $49 million, respectively.

Depreciation expense, including the amortization of capitalized interest in fiscal years 2023, 2022 and 2021 was $2.6 billion, $2.4 billion and $2.4 billion, respectively.

Upon retirement or other disposal of property, plant and equipment, the costs and related amounts of accumulated depreciation or amortization are eliminated from the asset and accumulated depreciation accounts, respectively. The difference, if any, between the net asset value and the proceeds are recorded in earnings.

5. Intangible assets and goodwill

At the end of fiscal years 2023 and 2022, the gross and net amounts of intangible assets were:

(Dollars in Millions)	2023	2022
Intangible assets with definite lives:		
Patents and trademarks — gross	$40,417	39,388
Less accumulated amortization	(24,808)	(20,616)
Patents and trademarks — net	**$15,609**	**18,772**
Customer relationships and other intangibles — gross	$20,322	19,764
Less accumulated amortization	(12,685)	(11,363)
Customer relationships and other intangibles — net[1]	**$7,637**	**8,401**
Intangible assets with indefinite lives:		
Trademarks	$1,714	1,630
Purchased in-process research and development	9,215	9,686
Total intangible assets with indefinite lives	**$10,929**	**11,316**
Total intangible assets — net	**$34,175**	**38,489**

[1] The majority is comprised of customer relationships

Goodwill as of December 31, 2023 and January 1, 2023, as allocated by segment of business, was as follows:

(Dollars in Millions)	Innovative Medicine	MedTech	Total
Goodwill at January 2, 2022	$10,580	14,856	25,436
Goodwill, related to acquisitions	—	11,056	11,056
Goodwill, related to divestitures	—	—	—
Currency translation/other	(396)	(49)	(445)
Goodwill at January 1, 2023	10,184	25,863	36,047
Goodwill, related to acquisitions	—	—	—
Goodwill, related to divestitures	—	—	—
Currency translation/other	223	288 *	511
Goodwill at December 31, 2023	$10,407	26,151	36,558

*Includes purchase price allocation adjustments for Abiomed

The weighted average amortization period for patents and trademarks is approximately 11 years. The weighted average amortization period for customer relationships and other intangible assets is approximately 19 years. The amortization expense of amortizable assets included in Cost of products sold was $4.5 billion, $3.9 billion and $4.2 billion before tax, for the fiscal years ended December 31, 2023, January 1, 2023 and January 2, 2022, respectively. Intangible asset write-downs are included in Other (income) expense, net.

The estimated amortization expense related to intangible assets for approved products, before tax, for the five succeeding years is approximately:

(Dollars in Millions)				
2024	2025	2026	2027	2028
$4,300	3,500	2,900	2,300	1,600

See Note 18 to the Consolidated Financial Statements for additional details related to acquisitions and divestitures.

6. Fair value measurements

The Company uses forward foreign exchange contracts to manage its exposure to the variability of cash flows, primarily related to the foreign exchange rate changes of future intercompany products and third-party purchases of materials denominated in a foreign currency. The Company uses cross currency interest rate swaps to manage currency risk primarily related to borrowings. Both types of derivatives are designated as cash flow hedges.

Additionally, the Company primarily uses interest rate swaps as an instrument to manage interest rate risk related to fixed rate borrowings. These derivatives are designated as fair value hedges. The Company uses cross currency interest rate swaps and forward foreign exchange contracts designated as net investment hedges. Additionally, the Company uses forward foreign exchange contracts to offset its exposure to certain foreign currency assets and liabilities. These forward foreign exchange contracts are not designated as hedges and therefore, changes in the fair values of these derivatives are recognized in earnings, thereby offsetting the current earnings effect of the related foreign currency assets and liabilities.

The Company does not enter into derivative financial instruments for trading or speculative purposes, or that contain credit risk related contingent features. The Company maintains credit support agreements (CSA) with certain derivative counterparties establishing collateral thresholds based on respective credit ratings and netting agreements. As of December 31, 2023 and January 1, 2023, the total amount of cash collateral paid by the Company under the CSA amounted to $4.0 billion and $0.8 billion net respectively, related to net investment and cash flow hedges. On an ongoing basis, the Company monitors counter-party credit ratings. The Company considers credit non-performance risk to be low, because the Company primarily enters into agreements with commercial institutions that have at least an investment grade credit rating. Refer to the table on significant financial assets and liabilities measured at fair value contained in this footnote for receivables and payables with these commercial institutions. As of December 31, 2023, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of $42.9 billion, $39.7 billion and $10.0 billion, respectively. As of January 1, 2023, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of $41.5 billion, $36.2 billion and $10.0 billion, respectively.

All derivative instruments are recorded on the balance sheet at fair value. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The designation as a cash flow hedge is made at the entrance date of the derivative contract. At inception, all derivatives are expected to be highly effective. Foreign exchange contracts designated as cash flow hedges are accounted for under the forward method and all gains/losses associated with these contracts will be recognized in the income statement when the hedged item impacts earnings. Changes in the fair value of these derivatives are recorded in accumulated other comprehensive income until the underlying transaction affects earnings, and are then reclassified to earnings in the same account as the hedged transaction.

Gains and losses associated with interest rate swaps and changes in fair value of hedged debt attributable to changes in interest rates are recorded to interest expense in the period in which they occur. Gains and losses on net investment hedges are accounted through the currency translation account within accumulated other comprehensive income. The portion excluded from effectiveness testing is recorded through interest (income) expense using the spot method. On an ongoing basis, the Company assesses whether each derivative continues to be highly effective in offsetting changes of hedged items. If and when a derivative is no longer expected to be highly effective, hedge accounting is discontinued.

The Company designated its Euro denominated notes issued in May 2016 with due dates ranging from 2022 to 2035 as a net investment hedge of the Company's investments in certain of its international subsidiaries that use the Euro as their functional currency in order to reduce the volatility caused by changes in exchange rates.

As of December 31, 2023, the balance of deferred net loss on derivatives included in accumulated other comprehensive income was $377 million after-tax. For additional information, see the Consolidated Statements of Comprehensive Income and Note 13. The Company expects that substantially all of the amounts related to forward foreign exchange contracts will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months, excluding interest rate contracts and net investment hedges. The amount ultimately realized in earnings may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity of the derivative.

The following table is a summary of the activity related to derivatives and hedges for the fiscal years ended December 31, 2023 and January 1, 2023, net of tax:

	December 31, 2023					January 1, 2023				
(Dollars in Millions)	Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense	Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense
The effects of fair value, net investment and cash flow hedging:										
Gain (Loss) on fair value hedging relationship:										
Interest rate swaps contracts:										
Hedged items	$—	—	—	(930)	—	—	—	—	(1,098)	—
Derivatives designated as hedging instruments	—	—	—	930	—	—	—	—	1,098	—
Gain (Loss) on net investment hedging relationship:										
Cross currency interest rate swaps contracts:										
Amount of gain or (loss) recognized in income on derivative amount excluded from effectiveness testing	$—	—	—	130	—	—	—	—	140	—
Amount of gain or (loss) recognized in AOCI	—	—	—	130	—	—	—	—	140	—
Gain (Loss) on cash flow hedging relationship:										
Forward foreign exchange contracts:										
Amount of gain or (loss) reclassified from AOCI into income	7	186	(37)	—	8	(72)	(271)	149	—	(23)
Amount of gain or (loss) recognized in AOCI	10	447	(18)	—	9	5	319	61	—	(113)
Cross currency interest rate swaps contracts:										
Amount of gain or (loss) reclassified from AOCI into income	—	—	—	275	—	—	—	—	425	—
Amount of gain or (loss) recognized in AOCI	$—	—	—	(156)	—	—	—	—	42	—

As of December 31, 2023 and January 1, 2023, the following amounts were recorded on the consolidated balance sheet related to cumulative basis adjustment for fair value hedges

Line item in the Consolidated Balance Sheet in which the hedged item is included	Carrying Amount of the Hedged Liability		Cumulative Amount of Fair Value Hedging Adjustment Included in the Carrying Amount of the Hedged Liability	
(Dollars in Millions)	December 31, 2023	January 1, 2023	December 31, 2023	January 1, 2023
Long-term Debt	$8,862	$8,665	$(1,216)	$(1,435)

The following table is the effect of derivatives not designated as hedging instrument for the fiscal years ended December 31, 2023 and January 1, 2023:

(Dollars in Millions)	Location of Gain /(Loss) Recognized in Income on Derivative	Gain/(Loss) Recognized In Income on Derivative	
Derivatives Not Designated as Hedging Instruments		December 31, 2023	January 1, 2023
Foreign Exchange Contracts	Other (income) expense	$(60)	94

The following table is the effect of net investment hedges for the fiscal years ended December 31, 2023 and January 1, 2023:

	Gain/(Loss) Recognized In Accumulated OCI		Location of Gain or (Loss) Reclassified from Accumulated Other Comprehensive Income Into Income	Gain/(Loss) Reclassified From Accumulated OCI Into Income	
(Dollars in Millions)	December 31, 2023	January 1, 2023		December 31, 2023	January 1, 2023
Debt	$(131)	197	Interest (income) expense	—	—
Cross Currency interest rate swaps	$642	766	Interest (income) expense	—	—

The Company holds equity investments with readily determinable fair values and equity investments without readily determinable fair values. The Company measures equity investments that do not have readily determinable fair values at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer.

The following table is a summary of the activity related to equity investments for the fiscal years ended December 31, 2023 and January 1, 2023:

	January 1, 2023			December 31, 2023	
(Dollars in Millions)	Carrying Value	Changes in Fair Value Reflected in Net Income[1]	Sales/ Purchases/ Other[2]	Carrying Value	Non Current Other Assets
Equity Investments with readily determinable value *	$576	(368)	4,265	4,473	4,473
Equity Investments without readily determinable value	$613	1	82	696	696

(Dollars in Millions)	January 2, 2022 Carrying Value	Changes in Fair Value Reflected in Net Income[1]	Sales/ Purchases/ Other[2]	January 1, 2023 Carrying Value	Non Current Other Assets
Equity Investments with readily determinable value	$1,884	(538)	(770)	576	576
Equity Investments without readily determinable value	$413	93	107	613	613

(1) Recorded in Other Income/Expense

(2) Other includes impact of currency

* Includes the 9.5% remaining stake in Kenvue and the $0.4 billion unfavorable change in fair value of the investment between separation date and the end of the fiscal year.

For the fiscal years ended December 31, 2023 and January 1, 2023 for equity investments without readily determinable market values, $1 million and $51 million, respectively, of the changes in fair value reflected in net income were the result of impairments. There were offsetting impacts of $27 million and $142 million, respectively, of changes in the fair value reflected in net income due to changes in observable prices and gains on the disposal of investments.

Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. In accordance with ASC 820, a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described below with Level 1 having the highest priority and Level 3 having the lowest.

The fair value of a derivative financial instrument (i.e., forward foreign exchange contracts, interest rate contracts) is the aggregation by currency of all future cash flows discounted to its present value at the prevailing market interest rates and subsequently converted to the U.S. Dollar at the current spot foreign exchange rate. The Company does not believe that fair values of these derivative instruments materially differ from the amounts that could be realized upon settlement or maturity, or that the changes in fair value will have a material effect on the Company's results of operations, cash flows or financial position. The Company also holds equity investments which are classified as Level 1 and debt securities which are classified as Level 2. The Company holds acquisition related contingent liabilities based upon certain regulatory and commercial events, which are classified as Level 3, whose values are determined using discounted cash flow methodologies or similar techniques for which the determination of fair value requires significant judgment or estimations.

The following three levels of inputs are used to measure fair value:

Level 1 — Quoted prices in active markets for identical assets and liabilities.

Level 2 — Significant other observable inputs.

Level 3 — Significant unobservable inputs.

The Company's significant financial assets and liabilities measured at fair value as of the fiscal year ended December 31, 2023 and January 1, 2023 were as follows:

	2023				2022
(Dollars in Millions)	Level 1	Level 2	Level 3	Total	Total[1]
Derivatives designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	$—	539	—	539	629
Interest rate contracts [2]	—	988	—	988	1,534
Total	**$—**	**1,527**	**—**	**1,527**	**2,163**
Liabilities:					
Forward foreign exchange contracts	—	624	—	624	511
Interest rate contracts [2]	—	5,338	—	5,338	2,778
Total	**$—**	**5,962**	**—**	**5,962**	**3,289**
Derivatives not designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	$—	64	—	64	38
Liabilities:					
Forward foreign exchange contracts	—	75	—	75	68
Available For Sale Other Investments:					
Equity investments[3]	4,473	—	—	4,473	576
Debt securities[4]	—	8,874	—	8,874	10,487
Other Liabilities					
Contingent Consideration[5]	$		1,092	1,092	1,120

Gross to Net Derivative Reconciliation	2023	2022
(Dollars in Millions)		
Total Gross Assets	$1,591	2,201
Credit Support Agreements (CSA)	(1,575)	(2,176)
Total Net Asset	16	25
Total Gross Liabilities	6,037	3,357
Credit Support Agreements (CSA)	(5,604)	(3,023)
Total Net Liabilities	$433	334

Summarized information about changes in liabilities for contingent consideration is as follows:

(Dollars in Millions)	2023	2022	2021
Beginning Balance	$1,120	533	633
Changes in estimated fair value	29	(194)	(52)
Additions [6]	—	792	—
Payments/Other	(57)	(11)	(48)
Ending Balance [5]	$1,092	1,120	533

(1) 2022 assets and liabilities are all classified as Level 2 with the exception of equity investments of $576 million, which are classified as Level 1 and contingent consideration of $1,120 million, classified as Level 3.

(2) Includes cross currency interest rate swaps and interest rate swaps.

(3) Classified as non-current other assets.

(4) Classified as cash equivalents and current marketable securities.

(5) Includes $1,092 million, $1,116 million and $520 million, classified as non-current other liabilities as of December 31, 2023, January 1, 2023 and January 2, 2022, respectively. Includes $4 million and $13 million classified as current liabilities as of January 1, 2023 and January 2, 2022, respectively.

(6) In fiscal year 2022, the Company recorded $704 million of contingent consideration related to Abiomed.

See Notes 2 and 7 for financial assets and liabilities held at carrying amount on the Consolidated Balance Sheet.

7. Borrowings

The components of long-term debt are as follows:

(Dollars in Millions)	2023	Effective Rate %	2022	Effective Rate %
6.73% Debentures due 2023	$—	—%	$250	6.73%
3.375% Notes due 2023	—	—	801	3.17
2.05% Notes due 2023	—	—	500	2.09
0.650% Notes due 2024 (750MM Euro 1.1090)[2]/(750MM Euro 1.0651)[3]	831 [2]	0.68	792 [3]	0.68
5.50% Notes due 2024 (500MM 1.2756 GBP)[2]/(500MM GBP 1.2037)[3]	637 [2]	6.75	600 [3]	6.75
2.625% Notes due 2025	750	2.63	749	2.63
0.55% Notes due 2025	950	0.57	918	0.57
2.46% Notes due 2026	1,997	2.47	1,996	2.47
2.95% Notes due 2027	900	2.96	877	2.96
0.95% Notes due 2027	1,419	0.96	1,394	0.96
1.150% Notes due 2028 (750MM Euro 1.1090)[2]/(750MM Euro 1.0651)[3]	828 [2]	1.21	794 [3]	1.21
2.90% Notes due 2028	1,497	2.91	1,496	2.91
6.95% Notes due 2029	298	7.14	298	7.14
1.30% Notes due 2030	1,630	1.30	1,607	1.30
4.95% Debentures due 2033	499	4.95	498	4.95
4.375% Notes due 2033	854	4.24	854	4.24
1.650% Notes due 2035 (1.5B Euro 1.1090)[2]/(1.5B Euro 1.0651)[3]	1,652 [2]	1.68	1,591 [3]	1.68
3.587% Notes due 2036	864	3.59	842	3.59
5.95% Notes due 2037	994	5.99	993	5.99
3.625% Notes due 2037	1,357	3.64	1,336	3.64
5.85% Debentures due 2038	697	5.85	697	5.85
3.400% Notes due 2038	993	3.42	992	3.42
4.50% Debentures due 2040	541	4.63	540	4.63
2.10% Notes due 2040	849	2.14	828	2.14
4.85% Notes due 2041	297	4.89	297	4.89
4.50% Notes due 2043	496	4.52	496	4.52
3.73% Notes due 2046	1,977	3.74	1,976	3.74
3.75% Notes due 2047	832	3.76	812	3.76
3.500% Notes due 2048	743	3.52	743	3.52
2.250% Notes due 2050	826	2.29	808	2.29
2.450% Notes due 2060	1,073	2.49	1,055	2.49
Other	69	—	7	—
Subtotal	**27,350** [4]	**2.98%** [1]	**28,437** [4]	**3.04%** [1]
Less current portion	1,469		1,551	
Total long-term debt	**$25,881**		**$26,886**	

[1] Weighted average effective rate.

(2) Translation rate at December 31, 2023.

(3) Translation rate at January 1, 2023.

(4) The excess of the carrying value over the fair value of debt was $1.0 billion and $1.6 billion at the end of fiscal year 2023 and fiscal year 2022, respectively.

Fair value of the long-term debt was estimated using market prices, which were corroborated by quoted broker prices and significant other observable inputs.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2023, the Company secured a new 364-day Credit Facility of $10 billion, which expires on September 5, 2024. The Company early terminated the additional 364-day revolving Credit Facility of $10 billion, which had an expiration of November 21, 2023. Interest charged on borrowings under the credit line agreement is based on either the Term SOFR Reference Rate or other applicable market rates as allowed under the terms of the agreement, plus applicable margins. Commitment fees under the agreements are not material.

Throughout fiscal years 2023 and 2022, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $3.5 billion and $12.8 billion at the end of fiscal years 2023 and 2022, respectively. The current portion of the long term debt was $1.5 billion and $1.6 billion in 2023 and 2022, respectively, and the remainder is commercial paper and local borrowing by international subsidiaries.

The current debt balance as of December 31, 2023 includes $2.0 billion of commercial paper which has a weighted average interest rate of 5.37% and a weighted average maturity of approximately two months. The current debt balance as of January 1, 2023 includes $11.2 billion of commercial paper which has a weighted average interest rate of 4.23% and a weighted average maturity of approximately two months.

Aggregate maturities of long-term debt obligations commencing in 2024 are:

(Dollars in Millions)					
2024	2025	2026	2027	2028	After 2028
$1,469	1,700	1,997	2,320	2,325	17,539

8. Income taxes

The provision for taxes on income consists of:

(Dollars in Millions)	2023	2022	2021
Currently payable:			
U.S. taxes	$2,705	2,274	1,338
International taxes	3,090	2,295	2,069
Total currently payable	5,795	4,569	3,407
Deferred:			
U.S. taxes	(3,440)	(1,990)	565
International taxes	(619)	410	(2,595)
Total deferred	(4,059)	(1,580)	(2,030)
Provision for taxes on income	**$1,736**	**2,989**	**1,377**

A comparison of income tax expense at the U.S. statutory rate of 21% in fiscal years 2023, 2022 and 2021, to the Company's effective tax rate is as follows:

(Dollars in Millions)	2023	2022	2021
U.S.	$(2,033)	4,606	4,275
International	17,095	14,753	14,903
Earnings before taxes on income:	$15,062	19,359	19,178
Tax rates:			
U.S. statutory rate	21.0%	21.0	21.0
International operations[1]	(8.1)	(5.0)	(19.1)
U.S. Tax Settlements	(3.0)	—	—
U.S. taxes on international income[2]	(0.3)	(1.1)	8.9
Tax benefits from loss on capital assets	—	—	(1.6)
Tax benefits on share-based compensation	(0.8)	(1.4)	(1.2)
All other	2.7	1.9	(0.8)
Effective Rate	11.5%	15.4	7.2

(1) International operations reflect the impacts of operations in jurisdictions with statutory tax rates different than the U.S., particularly Ireland, Switzerland, Belgium and Puerto Rico, which is a favorable impact on the effective tax rate as compared with the U.S. statutory rate.

(2) Includes the impact of the GILTI tax, the Foreign-Derived Intangible Income deduction and other foreign income that is taxable under the U.S. tax code. The 2023 and 2022 amount includes the impact of certain provisions of the 2017 TCJA that became effective in fiscal 2022. The 2023 amount includes the impact of certain foreign subsidiaries deferred tax remeasurements for legislative elections and the 2021 amounts include the reorganization of international subsidiaries further described below.

The fiscal year 2023 effective tax rate decreased 3.9% as compared to the fiscal year 2022 effective tax rate as the Company recorded certain non-recurring favorable tax items in fiscal year 2023 when compared to the prior fiscal year.

In the fiscal fourth quarter of 2023, the Company settled the U.S. Internal Revenue Service audit for tax years 2013 through 2016 which resulted in a favorable impact to the rate of 3.0%. This settlement was partially offset by the Company recording a $0.4 billion decrease in expected U.S. foreign tax credits, an unfavorable effective rate impact of 2.6%, which has been reflected as a current tax expense in U.S. taxes on international income on the Company's effective tax rate reconciliation.

In the fiscal year 2023, the Company had certain non-recurring impacts as a result of legislative tax elections made in certain international subsidiaries which resulted in a change in the Company's tax basis in certain assets resulting in deferred tax re-measurements. The net impact of these non-recurring items is a net benefit of 3.4% to the Company's annual effective tax rate, comprised of the following items:

- approximately $0.3 billion of tax benefit on local deferred tax assets to record the remeasurement of the increased tax basis, this benefit has been reflected as International operations on the Company's effective tax rate reconciliation. This benefit was offset by approximately $0.1 billion of U.S. deferred tax expense on the GILTI deferred tax liability resulting from the remeasurement of these deferred tax assets. This has been reflected in the "U.S. tax on international income" on the Company's effective tax rate reconciliation.
- approximately $0.3 billion of U.S. deferred tax benefit on the GILTI deferred tax as a result of an international subsidiary making an election to change the treatment of a local deferred tax asset to a refundable tax credit. This has been reflected in the U.S. taxes on international income on the Company's effective tax rate reconciliation.

The Company's 2023 and 2022 tax rates benefited from certain provisions of the Tax Cuts and Jobs Act of 2017 that became effective in fiscal 2022. The Company also had lower income in higher tax jurisdictions vs. fiscal year 2022, primarily in the U.S. where the Company recorded an approximately $7.0 billion charge related to talc matters in the United States at an effective tax rate of 21.1% (for further information see Note 19 to the Consolidated Financial Statements).

The fiscal year 2022 effective tax rate increased 8.2% as compared to the fiscal year 2021 effective tax rate as the Company recorded certain non-recurring favorable tax items in fiscal year 2021 which resulted in an unfavorable impact to the Company's fiscal 2022 effective tax rate when compared to the prior fiscal year. These items are described below. The Company's 2022 tax rate also benefited from the impairment of bermekimab for AD IPR&D and changes in the fair value of securities in the Company's investment portfolio, both recorded at the U.S. statutory rate.

In the fiscal year 2021, the Company reorganized the ownership structure of certain wholly-owned international subsidiaries. As part of this reorganization, the Company increased the tax basis of certain assets to fair value in accordance with applicable local regulations. The net impact of this restructuring was approximately $0.6 billion net benefit or 3.2% benefit to the Company's annual effective tax rate, comprised of the following items:

- approximately $2.3 billion of local deferred tax assets to record the remeasurement of the tax basis of these assets to fair value, this benefit has been reflected as International operations on the Company's effective tax rate reconciliation.
- approximately $1.7 billion of U.S. deferred tax expense relating to the GILTI deferred tax liability resulting from the remeasurement of these deferred tax assets. This expense has been reflected as U.S. taxes on international income on the Company's effective tax rate reconciliation.

Also, in the fiscal fourth quarter of 2021, the Company recognized a loss on certain U.S. affiliates related to the previously impaired book value of certain intangibles, which reduced the 2021 effective tax rate by approximately 1.6% which is reflected as a Tax benefits from loss on capital assets on the effective tax rate reconciliation. Additionally other fiscal 2021 impacts to the rate were primarily driven by litigation and acquisition related items as follows:

- the Company accrued additional legal expenses, of approximately $1.6 billion for talc at an effective tax rate of 23.5% and $0.8 billion for Risperdal Gynecomastia settlements at an effective tax rate of 16.4% (See Note 19 to the Consolidated Financial Statements for more details).
- the Company recorded a partial IPR&D charge of $0.9 billion for the Ottava intangible asset (acquired with the Auris Health acquisition in 2019) at an effective rate of 22.4%.

Temporary differences and carryforwards at the end of fiscal years 2023 and 2022 were as follows:

	2023 Deferred Tax		2022 Deferred Tax	
(Dollars in Millions)	**Asset**	**Liability**	**Asset**	**Liability**
Employee related obligations	$586		685	
Stock based compensation	686		632	
Depreciation of property, plant and equipment		(902)		(845)
Goodwill and intangibles		(1,252)		(1,737)
R&D capitalized for tax	3,595		2,611	
Reserves & liabilities	3,816		2,733	
Income reported for tax purposes[1]	359		2,026	
Net realizable operating loss carryforwards[2]	996		1,319	
Undistributed foreign earnings	1,801	(1,695)	1,517	(1,604)
Global intangible low-taxed income		(2,731)		(3,628)
Miscellaneous international	831		861	(66)
Miscellaneous U.S.		(4)	452	
Total deferred income taxes	**$12,670**	**(6,584)**	**12,836**	**(7,880)**

(1) In fiscal 2023, the Company changed the presentation of income taxes accrued on intercompany profits on inventory still owned by the Company as part of "Prepaid expenses and other" on the Consolidated Balance Sheet.

(2) Net of valuation allowances of $1.1 billion and $0.8 billion in 2023 and 2022. The change in the valuation allowance from 2022 to 2023 was driven by approximately $0.1 billion from acquisition related activity and the remainder was due to normal operations during the fiscal year.

The Company has wholly-owned international subsidiaries that have cumulative net losses. The Company believes that it is more likely than not that these subsidiaries will generate future taxable income sufficient to utilize these deferred tax assets. However, in certain jurisdictions, valuation allowances have been recorded against deferred tax assets for loss carryforwards that are not more likely than not to be realized.

The following table summarizes the activity related to unrecognized tax benefits for continuing operations:

(Dollars in Millions)	2023	2022	2021
Beginning of year	$3,716	3,210	3,260
Increases related to current year tax positions	239	523	242
Increases related to prior period tax positions	244	143	23
Decreases related to prior period tax positions	(781)	(148)	(128)
Settlements	(880)	(1)	(187)
Lapse of statute of limitations	(53)	(11)	—
End of year	**$2,485**	**3,716**	**3,210**

As of December 31, 2023 the Company had approximately $2.5 billion of unrecognized tax benefits. The Company conducts business and files tax returns in numerous countries and currently has tax audits in progress with a number of tax authorities. With respect to the United States the Internal Revenue Service has completed its audit for all tax years through 2016.

In other major jurisdictions where the Company conducts business, the years that remain open to tax audits go back to the year 2008. The Company believes it is possible that some tax audits may be completed over the next twelve months by taxing authorities in some jurisdictions, including in the United States. However, the Company is not able to provide a reasonably reliable estimate of the timing of any other future tax payments or change in uncertain tax positions, if any.

The Company classifies liabilities for unrecognized tax benefits and related interest and penalties as long-term liabilities. Interest expense and penalties related to unrecognized tax benefits are classified as income tax expense. The Company recognized after tax interest expense of $99 million, $136 million and $42 million in fiscal years 2023, 2022 and 2021, respectively. The total amount of accrued interest was $264 million and $637 million in fiscal years 2023 and 2022, respectively.

9. Employee related obligations

At the end of fiscal 2023 and fiscal 2022, employee related obligations recorded on the Consolidated Balance Sheets were:

(Dollars in Millions)	2023	2022
Pension benefits	$3,129	2,475
Postretirement benefits	1,963	1,728
Postemployment benefits	2,527	2,832
Deferred compensation	68	100
Total employee obligations	7,687	7,135
Less current benefits payable	538	593
Employee related obligations — non-current	**$7,149**	**6,542**

Prepaid employee related obligations of $4,992 million and $4,581 million for 2023 and 2022, respectively, are included in Other assets on the Consolidated Balance Sheets.

10. Pensions and other benefit plans

The Company sponsors various retirement and pension plans, including defined benefit, defined contribution and termination indemnity plans, which cover most employees worldwide. The Company also provides post-retirement benefits, primarily healthcare, to all eligible U.S. retired employees and their dependents.

Many international employees are covered by government-sponsored programs and the cost to the Company is not significant.

In the U.S, non-union pension benefits for employees hired before January 1, 2015 are primarily based on the employee's compensation during the last five years before retirement and the number of years of service (the Final Average Pay formula). U.S. pension benefits for employees hired after 2014, are calculated using a different formula based on employee compensation over total years of service (the Retirement Value formula).

In January 2021, the Company announced that, effective on January 1, 2026, all eligible U.S. non-union employees, regardless of hire date, will earn benefits under the Retirement Value formula. This amendment does not affect the benefits accrued under the Final Average Pay formula for service before January 1, 2026.

International subsidiaries have plans under which funds are deposited with trustees, annuities are purchased under group contracts, or reserves are provided.

The Company does not fund retiree healthcare benefits in advance and has the right to modify these plans in the future.

In 2023 and 2022 the Company used December 31, 2023 and December 31, 2022, respectively, as the measurement date for all U.S. and international retirement and other benefit plans.

Net periodic benefit costs for the Company's defined benefit retirement plans and other benefit plans for 2023, 2022 and 2021 include the following components:

	Retirement Plans			Other Benefit Plans		
(Dollars in Millions)	**2023**	**2022**	**2021**	**2023**	**2022**	**2021**
Service cost	$893	1,319	1,412	264	320	309
Interest cost	1,437	908	768	214	104	80
Expected return on plan assets	(2,716)	(2,756)	(2,644)	(7)	(8)	(7)
Amortization of prior service cost	(184)	(184)	(181)	(2)	(5)	(31)
Recognized actuarial losses (gains)	(199)	650	1,251	23	122	151
Curtailments and settlements	93	1	1	(5)	—	—
Net periodic benefit cost (credit)	**$(676)**	**(62)**	**607**	**487**	**533**	**502**

The service cost component of net periodic benefit cost is presented in the same line items on the Consolidated Statement of Earnings where other employee compensation costs are reported, including Cost of products sold, Research and development expense, Selling, marketing and administrative expenses, and Net earnings from discontinued operations, net of taxes if related to the separation of Kenvue. All other components of net periodic benefit cost are presented as part of Other (income) expense, net on the Consolidated Statement of Earnings, with the exception of certain amounts for curtailments and settlements, which are reported in Net earnings from discontinued operations, net of taxes if related to the separation of Kenvue (as noted above).

Unrecognized gains and losses for the U.S. pension plans are amortized over the average remaining future service for each plan. For plans with no active employees, they are amortized over the average life expectancy. The amortization of gains and losses for the other U.S. benefit plans is determined by using a 10% corridor of the greater of the market value of assets or the accumulated postretirement benefit obligation. Total unamortized gains and losses in excess of the corridor are amortized over the average remaining future service.

Prior service costs/benefits for the U.S. pension plans are amortized over the average remaining future service of plan participants at the time of the plan amendment. Prior service cost/benefit for the other U.S. benefit plans is amortized over the average remaining service to full eligibility age of plan participants at the time of the plan amendment.

The following table represents the weighted-average actuarial assumptions:

	Retirement Plans			Other Benefit Plans		
Worldwide Benefit Plans	**2023**	**2022**	**2021**	**2023**	**2022**	**2021**
Net Periodic Benefit Cost						
Service cost discount rate	4.85%	2.46	2.14	5.40	2.59	2.09
Interest cost discount rate	5.25%	2.80	2.34	5.43	2.64	2.33
Rate of increase in compensation levels	3.71%	4.02	4.01	4.22	4.21	4.25
Expected long-term rate of return on plan assets	7.21%	7.25	7.71			
Benefit Obligation						
Discount rate	4.58%	5.01	2.49	5.11	5.42	2.68
Rate of increase in compensation levels	3.69%	4.00	4.01	4.22	4.21	4.21

The Company's discount rates are determined by considering current yield curves representing high quality, long-term fixed income instruments. The resulting discount rates are consistent with the duration of plan liabilities. The Company's methodology in determining service and interest cost uses duration specific spot rates along that yield curve to the plans' liability cash flows.

The expected rates of return on plan asset assumptions represent the Company's assessment of long-term returns on diversified investment portfolios globally. The assessment is determined using projections from external financial sources, long-term historical averages, actual returns by asset class and the various asset class allocations by market.

The following table displays the assumed healthcare cost trend rates, for all individuals:

Healthcare Plans	**2023**	**2022**
Healthcare cost trend rate assumed for next year	13.90% *	5.96%
Rate to which the cost trend rate is assumed to decline (ultimate trend)	4.00%	3.99%
Year the rate reaches the ultimate trend rate	2048	2047

*excludes ongoing negotiations regarding healthcare cost with service providers

The following table sets forth information related to the benefit obligation and the fair value of plan assets at fiscal year-end 2023 and 2022 for the Company's defined benefit retirement plans and other post-retirement plans:

	Retirement Plans		Other Benefit Plans	
(Dollars in Millions)	**2023**	**2022**	**2023**	**2022**
Change in Benefit Obligation				
Projected benefit obligation — beginning of year	$29,390	41,272	4,192	4,874
Service cost	893	1,319	264	320
Interest cost	1,437	908	214	104
Plan participant contributions	73	67	—	—
Amendments	(6)	7	—	—
Actuarial (gains) losses[1]	2,068	(12,159)	469	(704)
Divestitures & acquisitions[2]	(352)	—	1	—
Curtailments, settlements & restructuring	(238)	(7)	(332)	—
Benefits paid from plan[3]	(2,122)	(1,220)	(702)	(393)
Effect of exchange rates	601	(797)	2	(9)
Projected benefit obligation — end of year	**$31,744**	**29,390**	**4,108**	**4,192**

Change in Plan Assets				
Plan assets at fair value — beginning of year	$31,496	41,909	78	102
Actual return (loss) on plan assets	3,951	(8,663)	16	(17)
Company contributions	268	261	694	386
Plan participant contributions	73	67	—	—
Settlements	(176)	(5)	—	—
Divestitures & acquisitions[2]	(509)	—	—	—
Benefits paid from plan assets[3]	(2,122)	(1,220)	(702)	(393)
Effect of exchange rates	626	(853)	—	—
Plan assets at fair value — end of year	**$33,607**	**31,496**	**86**	**78**
Funded status — end of year	**$1,863**	**2,106**	**(4,022)**	**(4,114)**
Amounts Recognized in the Company's Balance Sheet consist of the following:				
Non-current assets	$4,992	4,581	—	—
Current liabilities	(119)	(127)	(416)	(461)
Non-current liabilities	(3,010)	(2,348)	(3,606)	(3,653)
Total recognized in the consolidated balance sheet — end of year	**$1,863**	**2,106**	**(4,022)**	**(4,114)**
Amounts Recognized in Accumulated Other Comprehensive Income consist of the following:				
Net actuarial loss	$4,962	3,948	354	239
Prior service cost (credit)	(1,236)	(1,417)	(6)	(7)
Unrecognized net transition obligation	—	—	—	
Total before tax effects	**$3,726**	**2,531**	**348**	**232**
Accumulated Benefit Obligations — end of year	**$30,139**	**27,797**		

(1) The actuarial (gains)/losses for retirement plans in 2023 and 2022 were primarily driven by changes in the discount rates.

(2) Primarily driven by the Kenvue separation.

(3) Includes approximately $800 million transferred to a group annuity contract issued by a third-party insurer for the U.S. Salaried Pension Plan.

	Retirement Plans		Other Benefit Plans	
(Dollars in Millions)	**2023**	**2022**	**2023**	**2022**
Amounts Recognized in Net Periodic Benefit Cost and Other Comprehensive Income				
Net periodic benefit cost (credit)	$(676)	(62)	487	533
Net actuarial (gain) loss	711	(793)	136	(751)
Amortization of net actuarial loss	199	(655)	(22)	(121)
Prior service cost (credit)	(2)	7	—	—
Amortization of prior service (cost) credit	185	183	2	5
Effect of exchange rates	103	(140)	—	(1)
Total loss/(income) recognized in other comprehensive income, before tax	**$1,195**	**(1,398)**	**116**	**(868)**
Total recognized in net periodic benefit cost and other comprehensive income	**$519**	**(1,460)**	**603**	**(335)**

The Company plans to continue to fund its U.S. Qualified Plans to comply with the Pension Protection Act of 2006. International Plans are funded in accordance with local regulations. Additional discretionary contributions are made when deemed appropriate to meet the long-term obligations of the plans. For certain plans, funding is not a common practice, as funding provides no economic benefit. Consequently, the Company has several pension plans that are not funded.

In 2023, the Company contributed $135 million and $133 million to its U.S. and international pension plans, respectively.

The following table displays the funded status of the Company's U.S. Qualified & Non-Qualified pension plans and international funded and unfunded pension plans at December 31, 2023 and December 31, 2022, respectively:

	U.S. Plans				International Plans			
	Qualified Plans		Non-Qualified Plans		Funded Plans		Unfunded Plans	
(Dollars in Millions)	2023	2022	2023	2022	2023	2022	2023	2022
Plan Assets	$22,298	20,937	—	—	11,309	10,559	—	—
Projected Benefit Obligation	19,152	18,394	2,037	1,937	10,431	8,982	124	77
Accumulated Benefit Obligation	18,557	17,696	1,982	1,872	9,498	8,166	102	63
Over (Under) Funded Status								
Projected Benefit Obligation	$3,146	2,543	(2,037)	(1,937)	878	1,577	(124)	(77)
Accumulated Benefit Obligation	3,741	3,241	(1,982)	(1,872)	1,811	2,393	(102)	(63)

Plans with accumulated benefit obligations in excess of plan assets have an accumulated benefit obligation, projected benefit obligation and plan assets of $5.8 billion, $6.1 billion and $3.1 billion, respectively, at the end of 2023, and $2.7 billion, $2.7 billion and $0.3 billion, respectively, at the end of 2022.

The following table displays the projected future benefit payments from the Company's retirement and other benefit plans:

(Dollars in Millions)	2024	2025	2026	2027	2028	2029-2033
Projected future benefit payments						
Retirement plans	$1,481	1,473	1,549	1,647	1,745	10,133
Other benefit plans	$427	438	396	411	428	2,360

The following table displays the projected future minimum contributions to the unfunded retirement plans. These amounts do not include any discretionary contributions that the Company may elect to make in the future.

(Dollars in Millions)	2024	2025	2026	2027	2028	2029-2033
Projected future contributions	$122	126	133	139	145	787

Each pension plan is overseen by a local committee or board that is responsible for the overall administration and investment of the pension plans. In determining investment policies, strategies and goals, each committee or board considers factors including, local pension rules and regulations; local tax regulations; availability of investment vehicles (separate accounts, commingled accounts, insurance funds, etc.); funded status of the plans; ratio of actives to retirees; duration of liabilities; and other relevant factors including: diversification, liquidity of local markets and liquidity of base currency. A majority of the Company's pension funds are open to new entrants and are expected to be on-going plans. Permitted investments are primarily liquid and/or listed, with little reliance on illiquid and non-traditional investments such as hedge funds.

The Company's retirement plan asset allocation at the end of 2023 and 2022 and target allocations for 2024 are as follows:

	Percent of Plan Assets		Target Allocation
	2023	2022	2024
Worldwide Retirement Plans			
Equity securities	58%	62%	58%
Debt securities	42	38	42
Total plan assets	**100%**	**100%**	**100%**

Determination of fair value of plan assets

The Plan has an established and well-documented process for determining fair values. Fair value is based upon quoted market prices, where available. If listed prices or quotes are not available, fair value is based upon models that primarily use, as inputs, market-based or independently sourced market parameters, including yield curves, interest rates, volatilities, equity or debt prices, foreign exchange rates and credit curves.

While the Plan believes its valuation methods are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

Valuation hierarchy

The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described in the table below with Level 1 having the highest priority and Level 3 having the lowest.

The Net Asset Value (NAV) is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Following is a description of the valuation methodologies used for the investments measured at fair value.

- *Short-term investment funds* — Cash and quoted short-term instruments are valued at the closing price or the amount held on deposit by the custodian bank. Other investments are through investment vehicles valued using the NAV provided by the administrator of the fund. The NAV is a quoted price in a market that is not active and classified as Level 2.
- *Government and agency securities* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified within Level 1 of the valuation hierarchy. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows. When quoted market prices for a security are not available in an active market, they are classified as Level 2.
- *Debt instruments* — A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified as Level 1. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows and are classified as Level 2. Level 3 debt instruments are priced based on unobservable inputs.
- *Equity securities* — Equity securities are valued at the closing price reported on the major market on which the individual securities are traded. Substantially all equity securities are classified within Level 1 of the valuation hierarchy.
- *Commingled funds* — These investment vehicles are valued using the NAV provided by the fund administrator. Assets in the Level 2 category have a quoted market price.
- *Other assets* — Other assets are represented primarily by limited partnerships. These investment vehicles are valued using the NAV provided by the fund administrator. Other assets that are exchange listed and actively traded are classified as Level 1, while inactively traded assets are classified as Level 2.

The following table sets forth the Retirement Plans' investments measured at fair value as of December 31, 2023 and December 31, 2022:

	Quoted Prices in Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs[1] (Level 3)		Investments Measured at Net Asset Value		Total Assets	
(Dollars in Millions)	**2023**	**2022**	**2023**	**2022**	**2023**	**2022**	**2023**	**2022**	**2023**	**2022**
Short-term investment funds	$12	26	829	13	—	—	—	—	841	39
Government and agency securities	—	—	5,985	5,863	—	—	—	—	5,985	5,863
Debt instruments	—	—	3,899	3,681	—	—	—	—	3,899	3,681
Equity securities	7,764	8,846	—	2	—	—	—	—	7,764	8,848
Commingled funds	—	—	4,967	4,362	43	56	6,672	6,096	11,682	10,514
Other assets	—	—	49	33	92	12	3,295	2,506	3,436	2,551
Investments at fair value	**$7,776**	**8,872**	**15,729**	**13,954**	**135**	**68**	**9,967**	**8,602**	**33,607**	**31,496**

[1] The activity for the Level 3 assets is not significant for all years presented.

The Company's Other Benefit Plans are unfunded except for U.S. commingled funds (Level 2) of $86 million and $78 million at December 31, 2023 and December 31, 2022, respectively.

The fair value of Johnson & Johnson Common Stock directly held in plan assets was $14 million (0.0% of total plan assets) at December 31, 2023 and $21 million (0.1% of total plan assets) at December 31, 2022.

11. Savings plan

The Company has voluntary 401(k) savings plans designed to enhance the existing retirement programs covering eligible employees. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which the employee is eligible. Total Company matching contributions to the plans were $263 million, $257 million and $239 million in fiscal years 2023, 2022 and 2021, respectively.

12. Capital and treasury stock

Changes in treasury stock were:

	Treasury Stock	
(Amounts in Millions Except Treasury Stock Shares in Thousands)	Shares	Amount
Balance at January 3, 2021	487,331	$38,490
Employee compensation and stock option plans	(17,399)	(2,847)
Repurchase of common stock	20,946	3,456
Balance at January 2, 2022	490,878	39,099
Employee compensation and stock option plans	(20,007)	(3,440)
Repurchase of common stock	35,375	6,035
Balance at January 1, 2023	506,246	41,694
Employee compensation and stock option plans	(15,521)	(2,529)
Repurchase of common stock	31,085	5,079
Kenvue share exchange (Note 21)	190,955	31,418
Balance at December 31, 2023	712,765	$75,662

Aggregate shares of common stock issued were approximately 3,119,843,000 shares at the end of fiscal years 2023, 2022 and 2021.

Cash dividends paid were $4.70 per share in fiscal year 2023, compared with dividends of $4.45 per share in fiscal year 2022, and $4.19 per share in fiscal year 2021.

On January 2, 2024, the Board of Directors declared a regular cash dividend of $1.19 per share, payable on March 5, 2024 to shareholders of record as of February 20, 2024.

On September 14, 2022, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's shares of common stock. The repurchase program was completed during the fiscal first quarter of 2023.

13. Accumulated other comprehensive income (loss)

Components of other comprehensive income (loss) consist of the following:

(Dollars in Millions)	Foreign Currency Translation	Gain/ (Loss) On Securities	Employee Benefit Plans	Gain/ (Loss) On Derivatives & Hedges	Total Accumulated Other Comprehensive Income (Loss)
January 3, 2021	$(8,938)	1	(6,957)	652	(15,242)
Net 2021 changes	(1,079)	(4)	4,255	(988)	2,184
January 2, 2022	(10,017)	(3)	(2,702)	(336)	(13,058)
Net 2022 changes	(1,796)	(24)	1,805	106	91
January 1, 2023	(11,813)	(27)	(897)	(230)	(12,967)
Net 2023 changes	(3,221)	26	(1,399)	(147)	(4,741)
Kenvue Separation/IPO	4,885		296 *		5,181
December 31, 2023	$(10,149)	(1)	(2,000)	(377)	(12,527)

Amounts in accumulated other comprehensive income are presented net of the related tax impact. Foreign currency translation is not adjusted for income taxes where it relates to permanent investments in international subsidiaries. For additional details on comprehensive income see the Consolidated Statements of Comprehensive Income.

Details on reclassifications out of Accumulated Other Comprehensive Income:

Gain/(Loss) On Securities - reclassifications released to Other (income) expense, net.

Employee Benefit Plans - reclassifications are included in net periodic benefit cost. See Note 10 for additional details.

Gain/(Loss) On Derivatives & Hedges - reclassifications to earnings are recorded in the same account as the hedged transaction. See Note 6 for additional details.

* Includes impact of curtailments and settlements in connection with separation from Kenvue.

14. International currency translation

For translation of its subsidiaries operating in non-U.S. Dollar currencies, the Company has determined that the local currencies of its international subsidiaries are the functional currencies except those in highly inflationary economies, which are defined as those which have had compound cumulative rates of inflation of 100% or more during the past three years, or where a substantial portion of its cash flows are not in the local currency. For the majority of the Company's subsidiaries the local currency is the functional currency.

In consolidating international subsidiaries, balance sheet currency effects are recorded as a component of accumulated other comprehensive income. The other current and non-current assets line within the Statement of Cash flows includes the impact of foreign currency translation. This equity account includes the results of translating certain balance sheet assets and liabilities at current exchange rates and some accounts at historical rates, except for those located in highly inflationary economies (Argentina and Venezuela). Beginning in the fiscal second quarter of 2022, the Company also accounted for operations in Turkey as highly inflationary. The translation of balance sheet accounts for highly inflationary economies are reflected in the operating results.

A rollforward of the changes during fiscal years 2023, 2022 and 2021 for foreign currency translation adjustments is included in Note 13.

Net currency transaction gains and losses included in Other (income) expense were losses of $366 million, $286 million and $216 million in fiscal years 2023, 2022 and 2021, respectively.

15. Earnings per share

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal years ended December 31, 2023, January 1, 2023 and January 2, 2022:

(In Millions Except Per Share Amounts)	2023	2022	2021
Basic net earnings per share from continuing operations	$5.26	6.23	6.76
Basic net earnings per share from discontinued operations	8.62	0.60	1.17
Total net earnings per share - basic	13.88	6.83	7.93
Average shares outstanding — basic	2,533.5	2,625.2	2,632.1
Potential shares exercisable under stock option plans	94.1	140.1	138.0
Less: shares repurchased under treasury stock method	(67.2)	(101.4)	(96.1)
Adjusted average shares outstanding — diluted	2,560.4	2,663.9	2,674.0
Diluted net earnings per share from continuing operations	5.20	6.14	6.66
Diluted net earnings per share from discontinuing operations	8.52	0.59	1.15
Total net earnings per share - diluted	$13.72	6.73	7.81

The diluted net earnings per share calculation for fiscal year 2023 excluded 43 million shares related to stock options, as the exercise price of these options was greater than the average market value of the Company's stock.

The diluted net earnings per share calculation for the fiscal years 2022 and 2021 included all shares related to stock options, as the exercise price of these options was less than the average market value of the Company's stock.

16. Common stock, stock option plans and stock compensation agreements

At December 31, 2023, the Company had one stock-based compensation plan. The shares outstanding are for contracts under the Company's 2012 Long-Term Incentive Plan and the 2022 Long-Term Incentive Plan. The 2012 Long-Term Incentive Plan expired on April 26, 2022. All awards (stock options, restricted shares units and performance share units) granted subsequent to that date were under the 2022 Long-Term Incentive Plan. Under the 2022 Long-Term Incentive Plan, the Company may issue up to 150 million shares of common stock, of which up to 110 million shares of common stock may be issued subject to stock options or stock appreciation rights and up to 40 million shares of common stock may be issued subject to full value awards. Awards will generally be counted on a 1-for-1 basis against the share reserve, provided that if more than 40 million full value awards are granted, each full value award in excess of 40 million will be counted on a 5-for-1 basis against the share reserve. Shares available for future grants under the 2022 Long-Term Incentive Plan were 130 million at the end of fiscal year 2023.

The compensation cost that has been charged against income for these plans was $1,087 million, $1,028 million and $1,038 million for fiscal years 2023, 2022 and 2021, respectively. The total income tax benefit recognized in the income statement for share-based compensation costs was $221 million, $177 million and $199 million for fiscal years 2023, 2022 and 2021, respectively. The Company also recognized additional income tax benefits of $126 million, $267 million and $213 million for fiscal years 2023, 2022 and 2021, respectively, for which options were exercised or restricted shares were vested. The total unrecognized compensation cost was $907 million, $866 million and $775 million for fiscal years 2023, 2022 and 2021, respectively. The weighted average period for this cost to be recognized was 1.80 years, 1.80 years and 1.78 years for fiscal years 2023, 2022, and 2021, respectively. Share-based compensation costs capitalized as part of inventory were insignificant in all periods.

The Company settles employee benefit equity issuances with treasury shares. Treasury shares are replenished through market purchases throughout the year for the number of shares used to settle employee benefit equity issuances.

Stock options

Stock options expire 10 years from the date of grant and vest over service periods that range from 6 months to 4 years. Options granted under the 2012 Long-Term Incentive Plan were granted at the average of the high and low prices of the Company's Common Stock on the New York Stock Exchange on the date of grant. Options granted under the 2022 Long-Term incentive Plan were granted at the closing price of the Company's Common Stock on the New York Stock Exchange on the date of grant.

The fair value of each option award was estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the following table. For 2023, 2022, and 2021 grants, expected volatility represents a blended rate of 10-year weekly historical overall volatility rate, and a 5-week average implied volatility rate based on at-the-money traded Johnson & Johnson options with a life of 2 years. For all grants, historical data is used to determine the expected life of the option. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant.

The average fair value of options granted was $27.85, $23.23 and $20.86, in fiscal years 2023, 2022 and 2021, respectively. The fair value was estimated based on the weighted average assumptions of:

	2023	2022	2021
Risk-free rate	3.74%	1.98%	0.83%
Expected volatility	17.69%	18.00%	18.59%
Expected life (in years)	7.0	7.0	7.0
Expected dividend yield	2.90%	2.70%	2.50%

A summary of option activity under the Plan as of December 31, 2023, is presented below:

(Shares in Thousands)	Outstanding Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (Dollars in Millions)
Shares at January 1, 2023	118,672	$134.95	$4,949
Options granted	16,320	162.75	
Options exercised	(12,386)	109.48	
Options canceled/forfeited*	(10,368)	155.62	
Shares at December 31, 2023	**112,238**	**$139.88**	**$2,239**

The total intrinsic value of options exercised was $729 million, $1,228 million and $919 million in fiscal years 2023, 2022 and 2021, respectively.

*includes 7,689 shares of options cancelled as a result of the conversion of Johnson & Johnson stock options held by Kenvue employees into Kenvue stock options

The following table summarizes stock options outstanding and exercisable at December 31, 2023:

(Shares in Thousands)	Outstanding			Exercisable	
Exercise Price Range	Options	Average Life[1]	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
$90.44 - $101.87	20,774	1.4	$99.21	20,774	$99.21
$115.67 - $129.51	19,368	3.6	122.49	19,368	122.49
$131.94 - $151.41	27,391	5.6	142.84	26,676	142.61
$162.70 - $162.75	13,928	9.1	162.75	6	162.75
$164.62 - $165.89	30,777	7.6	165.29	174	165.12
	112,238	**5.5**	**$139.88**	**66,998**	**$123.39**

[1] Average contractual life remaining in years.

Stock options outstanding at January 1, 2023 and January 2, 2022 were 118,672 and an average life of 5.8 years and 117,361 and an average life of 5.8 years, respectively. Stock options exercisable at January 1, 2023 and January 2, 2022 were 63,661 at an average price of $113.06 and 62,742 at an average price of $104.42, respectively.

Restricted share units and performance share units

The Company grants restricted share units which vest over service periods that range from 6 months to 3 years. The Company also grants performance share units, which are paid in shares of Johnson & Johnson Common Stock after the end of a three-year performance period. Performance shares were granted with two equally-weighted goals that directly align with or help drive long-term total shareholder return: adjusted operational earnings per share and relative total shareholder return. The number of shares actually earned at the end of the three-year period will vary, based only on actual performance, from 0% to 200% of the target number of performance share units granted.

A summary of the restricted share units and performance share units activity under the Plans as of December 31, 2023 is presented below:

(Shares in Thousands)	Outstanding Restricted Share Units	Outstanding Performance Share Units
Shares at January 1, 2023	13,616	2,357
Granted	5,910	828
Issued	(4,329)	(785)
Canceled/forfeited/adjusted*	(2,259)	(363)
Shares at December 31, 2023	12,938	2,037

*includes 1,421 shares of restricted share units and 264 shares of performance share units cancelled as a result of the conversion of Johnson & Johnson restricted share units and performance share units held by Kenvue employees into Kenvue restricted share units

The average fair value of the restricted share units granted was $152.63, $153.67 and $152.62 in fiscal years 2023, 2022 and 2021, respectively, using the fair market value at the date of grant. The fair value of restricted share units was discounted for dividends, which are not paid on the restricted share units during the vesting period. The fair value of restricted share units issued was $605 million, $591 million and $611 million in 2023, 2022 and 2021, respectively.

The weighted average fair value of the performance share units granted was $145.17, $170.46 and $179.35 in fiscal years 2023, 2022 and 2021, calculated using the weighted average fair market value for each of the component goals at the date of grant.

The fair values for the earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. The fair value of performance share units issued was $140 million, $94 million and $83 million in fiscal years 2023, 2022 and 2021, respectively.

17. Segments of business and geographic areas

Following the separation of the Consumer Health business in the fiscal third quarter of 2023, the Company is now organized into two business segments: Innovative Medicine (formerly referred to as Pharmaceutical) and MedTech. The segment results have been recast for all periods to reflect the continuing operations of the Company.

	Sales to Customers			% Change	
(Dollars in Millions)	2023	2022	2021	'23 vs. '22	'22 vs. '21
INNOVATIVE MEDICINE[1]					
Immunology					
U.S.	$11,539	11,036	10,843	4.6 %	1.8
International	6,513	5,899	5,907	10.4	(0.1)
Worldwide	18,052	16,935	16,750	6.6	1.1
REMICADE					
U.S.	1,143	1,417	2,019	(19.3)	(29.8)
U.S. Exports	147	204	236	(28.0)	(13.6)
International	549	722	935	(23.9)	(22.8)
Worldwide	1,839	2,343	3,190	(21.5)	(26.6)
SIMPONI / SIMPONI ARIA					
U.S.	1,124	1,166	1,127	(3.6)	3.5
International	1,073	1,017	1,148	5.4	(11.4)
Worldwide	2,197	2,184	2,276	0.6	(4.0)
STELARA					
U.S.	6,966	6,388	5,938	9.0	7.6
International	3,892	3,335	3,196	16.7	4.4
Worldwide	10,858	9,723	9,134	11.7	6.5
TREMFYA					
U.S.	2,147	1,844	1,503	16.5	22.7
International	999	824	624	21.2	32.0
Worldwide	3,147	2,668	2,127	17.9	25.4
OTHER IMMUNOLOGY					
U.S.	11	17	21	(33.8)	(18.4)
International	0	0	3	—	*
Worldwide	11	17	24	(33.8)	(28.2)
Infectious Diseases					
U.S.	1,500	1,680	2,249	(10.7)	(25.3)
International	2,918	3,769	3,576	(22.6)	5.4
Worldwide	4,418	5,449	5,825	(18.9)	(6.5)
COVID-19 VACCINE					
U.S.	0	120	634	*	(81.1)
International	1,117	2,059	1,751	(45.8)	17.6
Worldwide	1,117	2,179	2,385	(48.8)	(8.6)

(Dollars in Millions)	Sales to Customers 2023	2022	2021	% Change '23 vs. '22	'22 vs. '21
EDURANT / rilpivirine					
U.S.	35	36	41	(3.7)	(10.8)
International	1,115	972	953	14.8	2.0
Worldwide	1,150	1,008	994	14.1	1.5
PREZISTA / PREZCOBIX / REZOLSTA / SYMTUZA					
U.S.	1,446	1,494	1,508	(3.2)	(1.0)
International	408	449	575	(9.2)	(21.9)
Worldwide	1,854	1,943	2,083	(4.6)	(6.7)
OTHER INFECTIOUS DISEASES					
U.S.	19	30	66	(34.5)	(55.5)
International	278	289	297	(3.8)	(2.6)
Worldwide	297	318	363	(6.7)	(12.3)
Neuroscience					
U.S.	4,065	3,570	3,347	13.9	6.7
International	3,076	3,323	3,641	(7.5)	(8.7)
Worldwide	7,140	6,893	6,988	3.6	(1.4)
CONCERTA / methylphenidate					
U.S.	230	151	172	52.5	(12.5)
International	554	493	495	12.2	(0.4)
Worldwide	783	644	667	21.6	(3.5)
INVEGA SUSTENNA / XEPLION / INVEGA TRINZA / TREVICTA					
U.S.	2,897	2,714	2,550	6.7	6.5
International	1,218	1,426	1,472	(14.6)	(3.1)
Worldwide	4,115	4,140	4,022	(0.6)	3.0
SPRAVATO					
U.S.	589	328	198	79.7	65.7
International	100	46	26	*	76.9
Worldwide	689	374	224	84.1	67.0
OTHER NEUROSCIENCE[2]					
U.S.	349	376	427	(7.3)	(11.9)
International	1,204	1,358	1,647	(11.3)	(17.5)
Worldwide	1,553	1,734	2,074	(10.4)	(16.4)
Oncology					
U.S.	8,462	6,930	5,958	22.1	16.3
International	9,199	9,052	8,590	1.6	5.4
Worldwide	17,661	15,983	14,548	10.5	9.9

(Dollars in Millions)	Sales to Customers 2023	2022	2021	% Change '23 vs. '22	'22 vs. '21
CARVYKTI					
U.S.	469	133	—	*	*
International	30	—	—	*	*
Worldwide	500	133	—	*	*
DARZALEX					
U.S.	5,277	4,210	3,169	25.4	32.8
International	4,467	3,767	2,854	18.6	32.0
Worldwide	9,744	7,977	6,023	22.2	32.4
ERLEADA					
U.S.	1,065	968	813	10.0	19.2
International	1,322	913	478	44.8	*
Worldwide	2,387	1,881	1,291	26.9	45.7
IMBRUVICA					
U.S.	1,051	1,390	1,747	(24.4)	(20.4)
International	2,214	2,394	2,622	(7.5)	(8.7)
Worldwide	3,264	3,784	4,369	(13.7)	(13.4)
ZYTIGA /abiraterone acetate					
U.S.	50	74	119	(32.1)	(37.8)
International	837	1,696	2,178	(50.7)	(22.1)
Worldwide	887	1,770	2,297	(49.9)	(22.9)
OTHER ONCOLOGY					
U.S.	549	156	110	*	41.8
International	330	283	458	16.9	(38.2)
Worldwide	879	438	568	*	(22.9)
Pulmonary Hypertension					
U.S.	2,697	2,346	2,365	15.0	(0.8)
International	1,117	1,071	1,085	4.3	(1.3)
Worldwide	3,815	3,417	3,450	11.6	(1.0)
OPSUMIT					
U.S.	1,292	1,132	1,147	14.1	(1.3)
International	681	651	672	4.6	(3.2)
Worldwide	1,973	1,783	1,819	10.6	(2.0)
UPTRAVI					
U.S.	1,326	1,104	1,056	20.1	4.5
International	255	218	181	17.3	20.4
Worldwide	1,582	1,322	1,237	19.7	6.9
OTHER PULMONARY HYPERTENSION					
U.S.	79	110	163	(28.6)	(32.3)
International	182	202	232	(10.3)	(12.8)
Worldwide	260	313	395	(16.7)	(20.8)

(Dollars in Millions)	Sales to Customers 2023	2022	2021	% Change '23 vs. '22	'22 vs. '21
Cardiovascular / Metabolism / Other					
U.S.	2,906	3,042	3,192	(4.5)	(4.7)
International	765	845	927	(9.4)	(8.9)
Worldwide	3,671	3,887	4,119	(5.5)	(5.6)
XARELTO					
U.S.	2,365	2,473	2,438	(4.4)	1.4
International	—	—	—	—	—
Worldwide	2,365	2,473	2,438	(4.4)	1.4
OTHER[3]					
U.S.	541	569	754	(5.0)	(24.5)
International	765	845	927	(9.4)	(8.8)
Worldwide	1,306	1,414	1,682	(7.6)	(15.9)
TOTAL INNOVATIVE MEDICINE					
U.S.	31,169	28,604	27,954	9.0	2.3
International	23,590	23,959	23,726	(1.5)	1.0
Worldwide	54,759	52,563	51,680	4.2	1.7
MEDTECH					
Interventional Solutions					
U.S.	3,633	2,169	1,836	67.5	18.2
International	2,717	2,131	2,135	27.5	(0.2)
Worldwide	6,350	4,300	3,971	47.7	8.3
ELECTROPHYSIOLOGY					
U.S.	2,458	2,036	1,730	20.7	17.7
International	2,230	1,901	1,893	17.3	0.4
Worldwide	4,688	3,937	3,623	19.1	8.7
ABIOMED[4]					
U.S.	1,066	31	—	*	*
International	240	—	—	*	*
Worldwide	1,306	31	—	*	*
OTHER INTERVENTIONAL SOLUTIONS					
U.S.	109	102	106	6.7	(3.8)
International	247	230	242	7.3	(5.0)
Worldwide	356	332	348	7.1	(4.6)
Orthopaedics					
U.S.	5,525	5,321	5,126	3.8	3.8
International	3,417	3,267	3,462	4.6	(5.6)
Worldwide	8,942	8,587	8,588	4.1	0.0
HIPS					
U.S.	996	943	878	5.6	7.3
International	564	571	602	(1.2)	(5.1)
Worldwide	1,560	1,514	1,480	3.0	2.3

(Dollars in Millions)	Sales to Customers 2023	2022	2021	% Change '23 vs. '22	'22 vs. '21
KNEES					
U.S.	896	851	787	5.3	8.2
International	559	508	538	10.2	(5.7)
Worldwide	1,456	1,359	1,325	7.1	2.6
TRAUMA					
U.S.	1,949	1,882	1,819	3.6	3.5
International	1,030	989	1,066	4.1	(7.2)
Worldwide	2,979	2,871	2,885	3.8	(0.5)
SPINE, SPORTS & OTHER					
U.S.	1,684	1,645	1,642	2.4	0.2
International	1,263	1,198	1,256	5.4	(4.6)
Worldwide	2,947	2,843	2,898	3.7	(1.9)
Surgery					
U.S.	4,031	3,897	3,867	3.4	0.8
International	6,006	5,793	5,945	3.7	(2.6)
Worldwide	10,037	9,690	9,812	3.6	(1.2)
ADVANCED					
U.S.	1,833	1,784	1,761	2.8	1.3
International	2,837	2,785	2,861	1.9	(2.6)
Worldwide	4,671	4,569	4,622	2.2	(1.1)
GENERAL					
U.S.	2,198	2,113	2,105	4.0	0.4
International	3,168	3,008	3,085	5.3	(2.5)
Worldwide	5,366	5,121	5,190	4.8	(1.3)
Vision					
U.S.	2,086	1,990	1,857	4.8	7.2
International	2,986	2,859	2,831	4.5	1.0
Worldwide	5,072	4,849	4,688	4.6	3.4
CONTACT LENSES / OTHER					
U.S.	1,626	1,522	1,398	6.8	8.9
International	2,076	2,022	2,043	2.7	(1.0)
Worldwide	3,702	3,543	3,440	4.5	3.0
SURGICAL					
U.S.	460	468	459	(1.8)	2.0
International	910	837	788	8.6	6.2
Worldwide	1,370	1,306	1,248	4.9	4.6
TOTAL MEDTECH					
U.S.	15,275	13,377	12,686	14.2	5.4
International	15,125	14,050	14,374	7.7	(2.3)
Worldwide	30,400	27,427	27,060	10.8	1.4

(Dollars in Millions)	Sales to Customers 2023	2022	2021	% Change '23 vs. '22	'22 vs. '21
WORLDWIDE					
U.S.	46,444	41,981	40,640	10.6	3.3
International	38,715	38,009	38,100	1.9	(0.2)
Worldwide	$85,159	79,990	78,740	6.5%	1.6

*Percentage greater than 100% or not meaningful

(1) Previously referred to as Pharmaceutical

(2) Inclusive of RISPERDAL CONSTA which was previously disclosed separately

(3) Inclusive of INVOKANA which was previously disclosed separately

(4) Acquired on December 22, 2022

(Dollars in Millions)	Income Before Tax 2023 (3)	2022 (4)	2021 (5)	Identifiable Assets 2023	2022
Innovative Medicine	$18,246	15,647	17,750	$58,324	58,436
MedTech	4,669	4,447	4,208	74,710	70,956
Total	**22,915**	**20,094**	**21,958**	**133,034**	**129,392**
Less: Expense not allocated to segments (1)	7,853	735	2,780		
Discontinued operations				—	27,237
General corporate (2)				34,524	30,749
Worldwide total	**$15,062**	**19,359**	**19,178**	**$167,558**	**187,378**

(Dollars in Millions)	Additions to Property, Plant & Equipment 2023	2022	2021	Depreciation and Amortization 2023	2022	2021
Innovative Medicine	$1,653	1,374	1,198	$3,847	3,687	4,029
MedTech	2,372	2,120	1,933	2,943	2,302	2,286
Segments total	4,025	3,494	3,131	6,790	5,989	6,315
Discontinued operations	162	303	314	383	641	739
General corporate	356	212	207	313	340	336
Worldwide total	**$4,543**	**4,009**	**3,652**	**$7,486**	**6,970**	**7,390**

(Dollars in Millions)	Sales to Customers 2023	2022	2021	Long-Lived Assets (6) 2023	2022
United States	$46,444	41,981	40,640	$54,832	58,750
Europe	20,410	20,664	20,595	31,616	29,878
Western Hemisphere excluding U.S.	4,549	4,108	3,927	1,491	1,289
Asia-Pacific, Africa	13,756	13,237	13,578	1,500	1,520
Segments total	85,159	79,990	78,740	89,439	91,437
Discontinued operations				—	27,237
General corporate				1,192	1,081
Other non long-lived assets				76,927	67,623
Worldwide total	**$85,159**	**79,990**	**78,740**	**$167,558**	**187,378**

See Note 1 for a description of the segments in which the Company operates.

Export sales are not significant. In fiscal year 2023, the Company utilized three wholesalers distributing products for both segments that represented approximately 18.2%, 15.1% and 14.2% of the total consolidated revenues. In fiscal year 2022, the Company had three wholesalers distributing products for both segments that represented approximately 18.9%, 15.0% and 13.8% of the total consolidated revenues. In fiscal year 2021, the Company had three wholesalers distributing products for all three segments that represented approximately 16.6%, 12.6%, and 12.6% of the total consolidated revenues.

(1) Amounts not allocated to segments include interest (income)/expense and general corporate (income)/expense. Fiscal 2023 includes an approximately $7 billion charge related to talc matters (See Note 19, Legal proceedings, for additional details) and $0.4 billion related to the unfavorable change in the fair value of the retained stake in Kenvue.

(2) General corporate includes cash, cash equivalents and marketable securities.

(3) Innovative Medicine includes:

- One-time COVID-19 Vaccine manufacturing exit related costs of $0.7 billion
- A restructuring related charge of $0.5 billion
- Unfavorable changes in the fair value of securities of $0.4 billion
- Favorable litigation related items of $0.1 billion
- Loss on divestiture $0.2 billion.
- An intangible asset impairment charge of approximately $0.2 billion related to market dynamics associated with a non-strategic asset (M710) acquired as part of the acquisition of Momenta Pharmaceuticals in 2020.

MedTech includes:

- Acquired in process research and development asset of $0.4 billion related to the Laminar acquisition in 2023
- A restructuring related charge of $0.3 billion
- Acquisition and integration related costs of $0.2 billion primarily related to the acquisition of Abiomed
- A Medical Device Regulation charge of $0.3 billion
- Income from litigation settlements of $0.1 billion

(4) Innovative Medicine includes:

- One-time COVID-19 Vaccine manufacturing exit related costs of $1.5 billion
- An intangible asset impairment charge of approximately $0.8 billion related to an in-process research and development asset, bermekimab (JnJ-77474462), an investigational drug for the treatment of Atopic Dermatitis (AD) and Hidradenitis Suppurativa (HS) acquired with the acquisition of XBiotech, Inc. in the fiscal year 2020. Additional information regarding efficacy of the AD and HS indications became available which led the Company to the decision to terminate the development of bermekimab for AD and HS
- Litigation expense of $0.1 billion
- Unfavorable changes in the fair value of securities of $0.7 billion
- A restructuring related charge of $0.1 billion

MedTech includes:

- Litigation expense of $0.6 billion primarily for pelvic mesh related costs
- A restructuring related charge of $0.3 billion
- Acquisition and integration related costs of $0.3 billion primarily related to the acquisition of Abiomed
- A Medical Device Regulation charge of $0.3 billion

(5) Innovative Medicine includes:

- Litigation expense of $0.6 billion, primarily related to Risperdal Gynecomastia
- Divestiture gains of $0.6 billion
- Gains of $0.5 billion related to the change in the fair value of securities
- A restructuring related charge of $0.1 billion

MedTech includes:

- An in-process research and development expense of $0.9 billion related to Ottava
- A restructuring related charge of $0.3 billion
- A Medical Device Regulation charge of $0.2 billion

- Litigation expense of $0.1 billion

(6) Long-lived assets include property, plant and equipment, net for fiscal years 2023, and 2022 of $19,898 and $17,982, respectively, and intangible assets and goodwill, net for fiscal years 2023 and 2022 of $70,733 and $74,536, respectively.

18. Acquisitions and divestitures

In the fiscal first quarter of 2024, the Company announced it has entered into a definitive agreement to acquire Ambrx Biopharma, Inc., or Ambrx (Nasdaq: AMAM), a clinical-stage biopharmaceutical company with a proprietary synthetic biology technology platform to design and develop next-generation antibody drug conjugates (ADCs), in an all-cash merger transaction for a total equity value of approximately $2.0 billion, or $1.9 billion net of estimated cash acquired. The Company will acquire all of the outstanding shares of Ambrx's common stock for $28.00 per share through a merger of Ambrx with a subsidiary of the Company. The closing of the transaction is expected to occur in the first half of 2024, subject to receipt of Ambrx shareholder approval, as well as clearance under the Hart-Scott-Rodino Antitrust Improvements Act and other customary closing conditions. The Company expects that the transaction will be accounted for as a business combination and the results of operations will be included in the Innovative Medicine segment as of the acquisition date.

During the fiscal year 2023, the Company did not make any acquisitions that qualified as a business combination.

During the fiscal year 2023, there were asset acquisitions of in-process research and development of approximately $0.5 billion in cash, primarily consisting of the acquisition of Laminar Inc. for $0.4 billion which was closed on November 30, 2023. Laminar Inc. is a privately-held medical device company focused on eliminating the left atrial appendage (LAA) in patients with non-valvular atrial fibrillation (AFib).

During the fiscal year 2022, certain businesses were acquired for $17.7 billion in cash and $1.1 billion of liabilities assumed. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $17.3 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

The fiscal year 2022 acquisitions primarily included Abiomed, Inc. (Abiomed). The remaining acquisitions were not material.

On December 22, 2022, the Company completed the acquisition of Abiomed, a leading, first-to-market provider of cardiovascular medical technology with a first-in-kind portfolio for the treatment of coronary artery disease and heart failure which also has an extensive innovation pipeline of life-saving technologies. The transaction broadens the Company's position as a growing cardiovascular innovator, advancing the standard of care in heart failure and recovery, one of healthcare's largest areas of unmet need. The transaction was accounted for as a business combination and the results of operations were included in the MedTech segment as of the date of the acquisition. The acquisition was completed through a tender offer for all outstanding shares. The consideration paid in the acquisition consisted of an upfront payment of $380.00 per share in cash, amounting to $17.1 billion, net of cash acquired, as well as a non-tradeable contingent value right ("CVR") entitling the holder to receive up to $35.00 per share in cash (which with respect to the CVRs total approximately $1.6 billion in the aggregate) if certain commercial and clinical milestones are achieved. The corresponding enterprise value (without taking into account the CVRs) of approximately $16.5 billion includes cash, cash equivalents and marketable securities acquired.

The milestones of the CVR consist of:

a. $17.50 per share, payable if net sales for Abiomed products exceeds $3.7 billion during Johnson & Johnson's fiscal second quarter of 2027 through fiscal first quarter of 2028, or if this threshold is not met during this period and is subsequently met during any rolling four quarter period up to the end of Johnson & Johnson's fiscal first quarter of 2029, $8.75 per share;

b. $7.50 per share payable upon FDA premarket application approval of the use of Impella® products in ST-elevated myocardial infarction (STEMI) patients without cardiogenic shock by January 1, 2028; and

c. $10.00 per share payable upon the first publication of a Class I recommendation for the use of Impella® products in high risk PCI or STEMI with or without cardiogenic shock within four years from their respective clinical endpoint publication dates, but in all cases no later than December 31, 2029.

During the fiscal fourth quarter of 2023, the Company finalized the purchase price allocation. In the fiscal 2023, there were purchase price allocation adjustments netting to approximately $0.2 billion with an offsetting increase to goodwill. The fair value of the acquisition was allocated to assets acquired of $20.1 billion (net of $0.3 billion cash acquired), primarily to goodwill for $11.1 billion, amortizable intangible assets for $6.6 billion, IPR&D for $1.1 billion, marketable securities of $0.6 billion and

liabilities assumed of $3.0 billion, which includes the fair value of the contingent consideration mentioned above for $0.7 billion and deferred taxes of $2.0 billion. The goodwill is primarily attributable to the commercial acceleration and expansion of the portfolio and is not expected to be deductible for tax purposes. The contingent consideration was recorded in Other Liabilities and adjusted to fair value through the fiscal year end 2023 on the Consolidated Balance Sheet.

The amortizable intangible assets were primarily comprised of already in-market products of the Impella® platform with an average weighted life of 14 years. The IPR&D assets were valued for technology programs for unapproved products. The value of the IPR&D was calculated using probability-adjusted cash flow projections discounted for the risk inherent in such projects. The probability of success factor ranged from 52% to 70%. The discount rate applied was 9.5%.

In 2023, the Company recorded acquisition related costs before tax of approximately $0.2 billion, which was primarily recorded in Other (income)/expense. In 2022, the Company recorded acquisition related costs before tax of approximately $0.3 billion, which was recorded in Other (income)/expense.

During fiscal year 2021, the Company did not make any material acquisitions that qualified as a business combination.

In accordance with U.S. GAAP standards related to business combinations, and goodwill and other intangible assets, supplemental pro forma information for fiscal years 2023, 2022 and 2021 is not provided, as the impact of the aforementioned acquisitions did not have a material effect on the Company's results of operations.

Divestitures

During the fiscal year 2023, the Company executed divestitures resulting in approximately $0.2 billion in proceeds resulting in gains or losses that were not material. At fiscal year end 2023, the Company held assets, primarily intangibles, on its Consolidated Balance Sheet that it expects to divest of approximately $0.3 billion primarily related to Acclarent and Ponvory.

During fiscal year 2022, the Company did not make any material divestitures.

During fiscal year 2021, in separate transactions, the Company divested two brands outside the U.S. within the Innovative Medicine segment. The Company recognized a pre-tax gain recorded in Other (income) expense, net, of approximately $0.6 billion.

19. Legal proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability; intellectual property; commercial; indemnification and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of their business.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred, and the amount of the loss can be reasonably estimated. As of December 31, 2023, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25, Contingencies. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; ability to achieve comprehensive multi-party settlements; complexity of related cross-claims and counterclaims; and/or there are numerous parties involved. To the extent adverse awards, judgments or verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution of, or increase in accruals for, one or more of these matters in any reporting period may have a material adverse effect on the Company's results of operations and cash flows for that period.

Matters concerning talc

A significant number of personal injury claims alleging that talc causes cancer have been asserted against Johnson & Johnson Consumer Inc., its successor LTL Management LLC (now known as LLT Management LLC) and the Company arising out of the use of body powders containing talc, primarily JOHNSON'S Baby Powder.

In talc cases that previously have gone to trial, the Company has obtained a number of defense verdicts, but there also have been verdicts against the Company, many of which have been reversed on appeal. In June 2020, the Missouri Court of Appeals reversed in part and affirmed in part a July 2018 verdict of $4.7 billion in Ingham v. Johnson & Johnson, et al., No. ED 207476 (Mo. App.), reducing the overall award to $2.1 billion. An application for transfer of the case to the Missouri Supreme Court was subsequently denied and in June 2021, a petition for certiorari, seeking a review of the Ingham decision by the United States Supreme Court, was denied. In June 2021, the Company paid the award, which, including interest, totaled approximately $2.5 billion. The facts and circumstances, including the terms of the award, were unique to the Ingham decision and not representative of other claims brought against the Company. The Company continues to believe that it has strong legal grounds to contest the other talc verdicts that it has appealed. Notwithstanding the Company's confidence in the safety of its talc products, in certain circumstances the Company has settled cases.

In October 2021, Johnson & Johnson Consumer Inc. (Old JJCI) implemented a corporate restructuring (the 2021 Corporate Restructuring). As a result of that restructuring, Old JJCI ceased to exist and three new entities were created: (a) LTL Management LLC, a North Carolina limited liability company (LTL or Debtor); (b) Royalty A&M LLC, a North Carolina limited liability company and a direct subsidiary of LTL (RAM); and (c) the Debtor's direct parent, Johnson & Johnson Consumer Inc., a New Jersey company (New JJCI). The Debtor received certain of Old JJCI's assets and became solely responsible for the talc-related liabilities of Old JJCI, including all liabilities related in any way to injury or damage, or alleged injury or damage, sustained or incurred in the purchase or use of, or exposure to, talc, including talc contained in any product, or to the risk of, or responsibility for, any such damage or injury, except for any liabilities for which the exclusive remedy is provided under a workers' compensation statute or act (the Talc-Related Liabilities).

In October 2021, notwithstanding the Company's confidence in the safety of its talc products, the Debtor filed a voluntary petition with the United States Bankruptcy Court for the Western District of North Carolina, Charlotte Division, seeking relief under chapter 11 of the Bankruptcy Code (the LTL Bankruptcy Case). All litigation against LTL, Old JJCI, New JJCI, the Company, other of their corporate affiliates, identified retailers, insurance companies, and certain other parties (the Protected Parties) was stayed, although LTL did agree to lift the stay on a small number of appeals where appeal bonds had been filed. The LTL Bankruptcy Case was transferred to the United States Bankruptcy Court for the District of New Jersey. Claimants filed motions to dismiss the LTL Bankruptcy Case and, following a multiple day hearing, the New Jersey Bankruptcy Court denied those motions in March 2022.

The claimants subsequently filed notices of appeal as to the denial of the motions to dismiss the LTL Bankruptcy Case and the extension of the stay to the Protected Parties. On January 30, 2023, the Third Circuit reversed the Bankruptcy Court's ruling and remanded to the Bankruptcy Court to dismiss the LTL bankruptcy.

LTL filed a petition for rehearing of the Third Circuit's decision, which was denied in March 2023. LTL subsequently filed a motion in the Third Circuit to stay the mandate directing the New Jersey Bankruptcy Court to dismiss the LTL bankruptcy pending filing and disposition of a petition for writ of certiorari to the United States Supreme Court. The Third Circuit denied the motion to stay the mandate and issued the mandate.

In April 2023, the New Jersey Bankruptcy Court dismissed the LTL Bankruptcy Case, effectively lifting the stay as to all parties and returning the talc litigation to the tort system. LTL re-filed in the United States Bankruptcy Court for the District of New Jersey seeking relief under chapter 11 of the Bankruptcy Code (the LTL 2 Bankruptcy Case). As a result of the new filing, all talc claims against LTL were again automatically stayed pursuant to section 362 of the Bankruptcy Code. Additionally, the New Jersey Bankruptcy Court issued a temporary restraining order staying all litigation as to LTL, Old JJCI, New JJCI, the Company, identified retailers, and certain other parties (the New Protected Parties).

Also in April 2023, the New Jersey Bankruptcy Court issued a decision that granted limited injunctive relief to the Company and the New Protected Parties (the LTL 2 Preliminary Injunction). The LTL 2 Preliminary Injunction remained in force until late August 2023, following the Bankruptcy Court's extension of the initial LTL 2 Preliminary Injunction in June 2023. Under the LTL 2 Preliminary Injunction, except for in those cases filed in the federal court ovarian cancer multi-district litigation, discovery in all personal injury and wrongful death matters was permitted to proceed.

Furthermore, in April 2023, the Talc Claimants' Committee filed a motion to dismiss the LTL 2 Bankruptcy followed by similar motions from other claimants. Hearings on the motions to dismiss occurred in June 2023. On July 28, 2023, the court dismissed the LTL 2 Bankruptcy case and, the same day, the Company stated its intent to appeal the decision and to continue its efforts to obtain a resolution of the talc claims. In September 2023, the Bankruptcy Court entered an order granting LTL leave to seek a direct appeal to the Third Circuit Court of Appeals. In October 2023, the Third Circuit granted LTL's petition for a direct appeal. Briefing is ongoing.

Following the dismissal of LTL 2, new lawsuits were filed and cases across the country that had been stayed were reactivated. The majority of the cases are pending in federal court, organized in a multi-district litigation (MDL) in the United States District Court for the District of New Jersey. In the MDL, case-specific discovery is proceeding with an expectation that a trial will occur in early 2025. Separately, discovery and pre-trial activity is underway in various individually filed and set cases around the country, with most activity for such cases centralized in New Jersey and California.

In the original bankruptcy case, the Company agreed to provide funding to LTL for the payment of amounts the New Jersey Bankruptcy Court determines are owed by LTL and the establishment of a $2 billion trust in furtherance of this purpose. The Company established a reserve for approximately $2 billion in connection with the aforementioned trust. During the bankruptcy proceedings LTL had been de-consolidated by the Company. In the LTL 2 Bankruptcy Case, the Company had agreed to contribute an additional amount which, when added to the prior $2 billion, would be a total reserve of approximately $9 billion payable over 25 years (nominal value approximately $12 billion discounted at a rate of 4.41%), to resolve all the current and future talc claims. The approximate $9 billion reserve encompasses actual and contemplated settlements, of which approximately one-third is recorded as a current liability. The recorded amount remains the Company's best estimate of probable loss after the dismissal.

The parties have not yet reached a resolution of all talc matters and the Company is unable to estimate the possible loss or range of loss beyond the amount accrued.

A class action advancing claims relating to industrial talc was filed against the Company and others in New Jersey state court in May 2022 (the Edley Class Action). The Edley Class Action asserts, among other things, that the Company fraudulently defended past asbestos personal injury lawsuits arising from exposure to industrial talc mined, milled, and manufactured before January 6, 1989 by the Company's then wholly owned subsidiary, Windsor Minerals, Inc., which is currently a debtor in the Imerys Bankruptcy described hereafter. The Company removed the Edley Class Action to federal court in the District of New Jersey. In October 2022, the Company filed motions to dismiss and to deny certification of a class to pursue the Edley Class Action in the New Jersey District Court. Argument on the motions was heard in November 2023. Thereafter, the Company resolved this matter.

In February 2019, the Company's talc supplier, Imerys Talc America, Inc. and two of its affiliates, Imerys Talc Vermont, Inc. and Imerys Talc Canada, Inc. (collectively, Imerys) filed a voluntary petition for relief under chapter 11 of the United States Code (the Bankruptcy Code) in the United States Bankruptcy Court for the District of Delaware (Imerys Bankruptcy). The Imerys Bankruptcy relates to Imerys's potential liability for personal injury from exposure to talcum powder sold by Imerys. In its bankruptcy, Imerys alleges it has claims against the Company for indemnification and rights to joint insurance proceeds. In its bankruptcy, Imerys proposed a chapter 11 plan (the Imerys Plan) that contemplated all talc-related claims against it being channeled to a trust along with its alleged indemnification rights against the Company. Following confirmation and consummation of the plan, the trust would pay talc claims pursuant to proposed trust distribution procedures (the TDP) and then seek indemnification from the Company.

In February 2021, Cyprus Mines Corporation (Cyprus), which had owned certain Imerys talc mines, filed a voluntary petition for relief under chapter 11 of the Bankruptcy Code and filed its Disclosure Statement and Plan (the Cyprus Plan). The Cyprus Plan contemplates a settlement with Imerys and talc claimants where Cyprus would make a monetary contribution to a trust established under the Imerys Plan in exchange for an injunction against talc claims asserted against it and certain affiliated parties.

The Imerys Plan proceeded to solicitation in early 2021. However, the Imerys Plan did not receive the requisite number of votes to be confirmed after the Bankruptcy Court ruled certain votes cast in favor of the Imerys Plan should be disregarded. Imerys subsequently canceled its confirmation hearing.

Imerys, the Imerys Tort Claimants' Committee, and the Imerys Future Claimants' Representative, along with Cyprus, the Cyprus Tort Claimants' Committee, and the Cyprus Future Claimants' Representative (collectively the Mediation Parties) have been engaged in mediation since shortly after the confirmation hearing was canceled in October 2021. In September 2023, the Bankruptcy Court entered an order extending the term of the mediation among the Mediation Parties through the end of December 2023. The Bankruptcy Court also authorized Imerys and Cyprus to proceed with mediation with certain of their insurers through the end of December 2023.

In September 2023, Imerys and Cyprus filed amended plans of reorganization. The amended plans contemplate a similar construct as the prior Imerys and Cyprus Plans, including all talc claims against Imerys and Cyprus (and certain other protected parties) being channeled to a trust along with Imerys's and Cyprus's alleged indemnification rights against the Company. In January 2024, Imerys and Cyprus filed revised TDP. In February 2024, Imerys and Cyprus filed certain motions related to their Disclosure Statement.

In February 2018, a securities class action lawsuit was filed against the Company and certain named officers in the United States District Court for the District of New Jersey, alleging that the Company violated the federal securities laws by failing to disclose alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S Baby Powder, and that purchasers of the Company's shares suffered losses as a result. In April 2019, the Company moved to dismiss the complaint. In

December 2019, the Court denied, in part, the motion to dismiss. In April 2021, briefing on Plaintiff's motion for class certification was completed. The case was stayed in May 2022 pursuant to the LTL Bankruptcy Case and was reopened in May 2023. In December 2023, the Court granted Plaintiff's motion for class certification. In January 2024, Defendants filed a petition with the Third Circuit under Federal Rule of Civil Procedure 23(f) for permission to appeal the Court's order granting class certification. Fact discovery is proceeding.

A lawsuit was brought against the Company in the Superior Court of California for the County of San Diego alleging violations of California's Consumer Legal Remedies Act (CLRA) relating to JOHNSON'S Baby Powder. In that lawsuit, the plaintiffs allege that the Company violated the CLRA by failing to provide required Proposition 65 warnings. In July 2019, the Company filed a notice of removal to the United States District Court for the Southern District of California and plaintiffs filed a second amended complaint shortly thereafter. In October 2019, the Company moved to dismiss the second amended complaint for failure to state a claim upon which relief may be granted. In response to those motions, plaintiffs filed a third amended complaint. In December 2019, the Company moved to dismiss the third amended complaint for failure to state a claim upon which relief may be granted. In April 2020, the Court granted the motion to dismiss but granted leave to amend. In May 2020, plaintiffs filed a Fourth Amended Complaint but indicated that they would be filing a motion for leave to file a fifth amended complaint. Plaintiffs filed a Fifth Amended Complaint in August 2020. The Company moved to dismiss the Fifth Amended Complaint for failure to state a claim upon which relief may be granted. In January 2021, the Court issued an Order and opinion ruling in the Company's favor and granting the motion to dismiss with prejudice. In February 2021, Plaintiffs filed a Notice of Appeal with the Ninth Circuit. Plaintiffs filed their opening brief in July 2021. The company filed its responsive brief in October 2021. After the Notice of Suggestion of Bankruptcy was filed with the Ninth Circuit, a stay was imposed, and the Court held the reply deadline in abeyance. In September 2023, the stay lifted. With briefing complete, the Court is expected to either schedule oral argument or issue its decision at any time.

In June 2014, the Mississippi Attorney General filed a complaint in Chancery Court of The First Judicial District of Hinds County, Mississippi against the Company and Johnson & Johnson Consumer Companies, Inc. (now known as Johnson & Johnson Consumer Inc.) (collectively, JJCI). The complaint alleges that JJCI violated the Mississippi Consumer Protection Act by failing to disclose alleged health risks associated with female consumers' use of talc contained in JOHNSON'S Baby Powder and JOHNSON'S Shower to Shower (a product divested in 2012) and seeks injunctive and monetary relief. In February 2022, the trial court set the case for trial to begin in February 2023. However, in October 2022, the LTL bankruptcy court issued an order staying the case. In March 2023, the Third Circuit issued the mandate to dismiss the LTL Bankruptcy Case and in April 2023, the New Jersey Bankruptcy Court dismissed the LTL Bankruptcy Case, effectively lifting the stay as to this matter. The State requested a new trial setting. Later in April 2023, the trial court set a new trial date for April 2024. The Company filed summary judgment and Daubert motions. The State filed a limited Daubert motion. The parties agreed to the Court's request for mediation. A pretrial conference is set for February 2024 and trial is scheduled for April 2024. However, the Company is actively engaged in resolution discussions concerning this matter.

In January 2020, the State of New Mexico filed a consumer protection case alleging that the Company deceptively marketed and sold its talcum powder products by making misrepresentations about the safety of the products and the presence of carcinogens, including asbestos. In March 2022, the New Mexico court denied the Company's motion to compel the State of New Mexico to engage in discovery of state agencies and denied the Company's request for interlocutory appeal of that decision. The Company then filed a Petition for Writ of Superintending Control and a Request for a Stay to the New Mexico Supreme Court on the issue of the State of New Mexico's discovery obligations. In April 2022, in view of the efforts to resolve talc-related claims in the LTL Bankruptcy Case, the Company and the State agreed to a 60-day stay of all matters except for the pending writ before the New Mexico Supreme Court, which expired in June 2022. Thereafter, the Company moved to enjoin prosecution of the case in the LTL Bankruptcy Case. In October 2022, the bankruptcy court issued an order staying the case. In December 2022, the State filed an appeal to the Third Circuit concerning the stay order. Separately, in September 2022, the New Mexico Supreme Court granted the Company's request for a stay pending further briefing on the scope of the State of New Mexico's discovery obligations. In March 2023, the Third Circuit issued the mandate to dismiss the LTL Bankruptcy Case and in April 2023, the New Jersey Bankruptcy Court dismissed the LTL Bankruptcy Case, effectively lifting the stay as to this matter. While the State notified the New Mexico Supreme Court of the lifted stay of litigation in April 2023, the Court has not taken any action since being notified of the lifting of the stay and it remains in effect.

Forty-two states and the District of Columbia (including Mississippi and New Mexico) have commenced a joint investigation into the Company's marketing of its talcum powder products. At this time, the multi-state group has not asserted any claims against the Company. Five states have issued Civil Investigative Demands seeking documents and other information. The Company has produced documents to Arizona, North Carolina, Texas, and Washington and entered into confidentiality agreements. The Company has not received any follow up requests from those states. In March 2022, each of the forty-two states agreed to mediation of their claims in the LTL Bankruptcy Case. In July 2022, New Mexico and Mississippi indicated they would no longer voluntarily submit to further mediation in the LTL Bankruptcy and would proceed with their respective cases in state court. In March 2023, the mediation was terminated. In January 2024, the Company reached an agreement in principle with the multi-state group of state Attorneys General, subject to ongoing negotiation of non-monetary terms. The unique procedural history and status of the New Mexico and Mississippi matters specifically have been discussed above.

In addition, the Company has received inquiries, subpoenas, and requests to produce documents regarding talc matters and the LTL Bankruptcy Case from various governmental authorities. The Company has produced documents and responded to inquiries, and will continue to cooperate with government inquiries.

Matters concerning opioids

Beginning in 2014 and continuing to the present, the Company and Janssen Pharmaceuticals, Inc. (JPI), along with other pharmaceutical companies, have been named in close to 3,500 lawsuits related to the marketing of opioids, including DURAGESIC, NUCYNTA and NUCYNTA ER. The majority of the cases have been filed by state and local governments. Similar lawsuits have also been filed by private plaintiffs and organizations, including but not limited to the following: individual plaintiffs on behalf of children born with Neonatal Abstinence Syndrome (NAS); hospitals; and health insurers/payors.

To date, the Company and JPI have litigated two of the cases to judgment and have prevailed in both, either at trial or on appeal.

In October 2019, the Company announced a proposed agreement in principle with a negotiating committee of state Attorneys General to settle all remaining government opioid litigation claims nationwide. Under the final national settlement agreement, which was announced in July 2021, the Company agreed to pay up to $5.0 billion to resolve all opioid lawsuits and future opioid claims by states, cities, counties, local school districts and other special districts, and tribal governments, contingent on sufficient participation by eligible government entities, and with credits back for entities that declined or were ineligible to participate. In July 2021, the Company announced that the terms of the agreement to settle the state and subdivision claims had been finalized and approximately 60% of the all-in settlement was paid by the end of fiscal 2023. The expected payment schedule provides that approximately $0.7 billion of payments are to be paid by the end of fiscal 2024. The agreement is not an admission of liability or wrongdoing, and it provides for the release of all opioid-related claims against the Company, JPI, and their affiliates (including the Company's former subsidiaries Tasmanian Alkaloids Pty, Ltd. and Noramco, Inc.). As of January 2024, the Company and JPI have settled or otherwise resolved the opioid claims advanced by all government entity claimants except the City of Baltimore, a number of school districts and other claimants.

The Company and JPI continue to defend the cases brought by the remaining government entity litigants as well as the cases brought by private litigants, including NAS claimants, hospitals, and health insurers/payors. Counting the private litigant cases, there are approximately 35 remaining opioid cases against the Company and JPI in various state courts, 430 remaining cases in the Ohio MDL, and 4 additional cases in other federal courts. Some of these cases have been dismissed and are being appealed by the plaintiffs and certain others are scheduled for trial in 2024 or 2025.

In addition, the Province of British Columbia filed suit against the Company and its Canadian affiliate Janssen Inc., and many other industry members, in Canada, and is seeking to have that action certified as an opt in class action on behalf of other provincial/territorial and the federal governments in Canada. Additional proposed class actions have been filed in Canada against the Company and Janssen Inc., and many other industry members, by and on behalf of people who used opioids (for personal injuries), municipalities and First Nations bands. These actions allege a variety of claims related to opioid marketing practices, including false advertising, unfair competition, public nuisance, consumer fraud violations, deceptive acts and practices, false claims and unjust enrichment. An adverse judgment in any of these lawsuits could result in the imposition of large monetary penalties and significant damages including, punitive damages, cost of abatement, substantial fines, equitable remedies and other sanctions.

From June 2017 through December 2019, the Company's Board of Directors received a series of shareholder demand letters alleging breaches of fiduciary duties related to the marketing of opioids. The Board retained independent counsel to investigate the allegations in the demands, and in April 2020, independent counsel delivered a report to the Board recommending that the Company reject the shareholder demands and take the steps that are necessary or appropriate to secure dismissal of related derivative litigation. The Board unanimously adopted the recommendations of the independent counsel's report.

In November 2019, one of the shareholders who sent a demand filed a derivative complaint against the Company as the nominal defendant and certain current and former directors and officers as defendants in the Superior Court of New Jersey. The complaint alleges breaches of fiduciary duties related to the marketing of opioids, and that the Company has suffered damages as a result of those alleged breaches. A series of additional derivative complaints making similar allegations against the same and similar defendants were filed in New Jersey state and federal courts in 2019 and 2020. By 2022, all but two state court cases had been voluntarily dismissed. In February 2022, the state court granted the Company's motion to dismiss one of the two cases, and the shareholder that brought the second case filed a notice of dismissal. The shareholder whose complaint was dismissed filed a motion for reconsideration. In May 2022, the state court held oral argument on the motion for reconsideration and subsequently denied the motion. The shareholder has appealed the state court's dismissal order.

Product liability

The Company and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While the Company believes it has substantial defenses, it is not feasible to predict the ultimate outcome of litigation. From time to time, even if it has substantial defenses, the Company considers isolated settlements based on a variety of circumstances. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25, Contingencies. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

The table below contains the most significant of these cases and provides the approximate number of plaintiffs in the United States with direct claims in pending lawsuits regarding injuries allegedly due to the relevant product or product category as of December 31, 2023:

Product or product category	Number of plaintiffs
Body powders containing talc, primarily JOHNSON'S Baby Powder	59,140
DePuy ASR XL Acetabular System and DePuy ASR Hip Resurfacing System	160
PINNACLE Acetabular Cup System	920
Pelvic meshes	6,720
ETHICON PHYSIOMESH Flexible Composite Mesh	370
RISPERDAL	200
ELMIRON	2,150

The number of pending lawsuits is expected to fluctuate as certain lawsuits are settled or dismissed and additional lawsuits are filed. There may be additional claims that have not yet been filed.

MedTech

DePuy ASR XL Acetabular System and ASR Hip Resurfacing System

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR XL Acetabular System and DePuy ASR Hip Resurfacing System (ASR Hip) used in hip replacement surgery. Claims for personal injury have been made against DePuy and the Company. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada, Australia, Ireland, Germany, India and Italy. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR Hip plaintiffs to establish a program to settle claims with eligible ASR Hip patients in the United States who had surgery to replace their ASR Hips, known as revision surgery, as of August 2013. DePuy reached additional agreements in February 2015 and March 2017, which further extended the settlement program to include ASR Hip patients who had revision surgeries after August 2013 and prior to February 15, 2017. This settlement program has resolved more than 10,000 claims, thereby bringing to resolution significant ASR Hip litigation activity in the United States. However, lawsuits in the United States remain, and the settlement program does not address litigation outside of the United States. In Australia, a class action settlement was reached that resolved the claims of the majority of ASR Hip patients in that country. In Canada, the Company has reached agreements to settle the class actions filed in that country. The Company continues to receive information with respect to potential additional costs associated with this recall on a worldwide basis. The Company has established accruals for the costs associated with the United States settlement program and ASR Hip-related product liability litigation.

DePuy PINNACLE Acetabular Cup System

Claims for personal injury have also been made against DePuy Orthopaedics, Inc. and the Company (collectively, DePuy) relating to the PINNACLE Acetabular Cup System used in hip replacement surgery. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Most cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States

District Court for the Northern District of Texas (Texas MDL). Beginning on June 1, 2022, the Judicial Panel on Multidistrict Litigation ceased transfer of new cases into the Texas MDL, and there are now cases pending in federal court outside the Texas MDL. Litigation also has been filed in state courts and in countries outside of the United States. During the first quarter of 2019, DePuy established a United States settlement program to resolve these cases. As part of the settlement program, adverse verdicts have been settled. The Company has established an accrual for product liability litigation associated with the PINNACLE Acetabular Cup System and the related settlement program.

Ethicon Pelvic Mesh

Claims for personal injury have been made against Ethicon, Inc. (Ethicon) and the Company arising out of Ethicon's pelvic mesh devices used to treat stress urinary incontinence and pelvic organ prolapse. The Company continues to receive information with respect to potential costs and additional cases. Cases filed in federal courts in the United States had been organized as a multi-district litigation (MDL) in the United States District Court for the Southern District of West Virginia. In March 2021, the MDL Court entered an order closing the MDL. The MDL Court has remanded cases for trial to the jurisdictions where the case was originally filed and additional pelvic mesh lawsuits have been filed, and remain, outside of the MDL. The Company has settled or otherwise resolved the majority of the United States cases and the estimated costs associated with these settlements and the remaining cases are reflected in the Company's accruals. In addition, class actions and individual personal injury cases or claims seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices have been commenced in various countries outside of the United States, including claims and cases in the United Kingdom, the Netherlands, Belgium, France, Ireland, Italy, Spain and Slovenia and class actions in Israel, Australia, Canada and South Africa. In November 2019, the Federal Court of Australia issued a judgment regarding its findings with respect to liability in relation to the three Lead Applicants and generally in relation to the design, manufacture, pre and post-market assessments and testing, and supply and promotion of the devices in Australia used to treat stress urinary incontinence and pelvic organ prolapse. In September 2022, after exhausting its appeals, the Company reached an in-principle agreement to resolve the two pelvic mesh class actions in Australia and in March 2023 the Federal Court approved the settlement. The class actions in Canada were discontinued in 2020 as a result of a settlement of a group of cases and an agreement to resolve the Israeli class action was reached in May 2021. The parties in the Israeli class action are currently finalizing the terms of the settlement. A motion to approve the settlement was filed with the Court. The Company has established accruals with respect to product liability litigation associated with Ethicon's pelvic mesh products.

Ethicon Physiomesh

Following a June 2016 worldwide market withdrawal of Ethicon Physiomesh Flexible Composite Mesh (Physiomesh), claims for personal injury have been made against Ethicon, Inc. (Ethicon) and the Company alleging personal injury arising out of the use of this hernia mesh device. Cases filed in federal courts in the United States have been organized as a multi-district litigation (MDL) in the United States District Court for the Northern District of Georgia. A multi-county litigation (MCL) also has been formed in New Jersey state court and assigned to Atlantic County for cases pending in New Jersey. In addition to the matters in the MDL and MCL, there are additional lawsuits pending in the United States District Court for the Southern District of Ohio, which are part of the MDL for polypropylene mesh devices manufactured by C.R. Bard, Inc., and lawsuits pending in two New Jersey MCLs formed for Proceed/Proceed Ventral Patch and Prolene Hernia systems, and lawsuits pending outside the United States. In May 2021, Ethicon and lead counsel for the plaintiffs entered into a term sheet to resolve approximately 3,600 Physiomesh cases (covering approximately 4,300 plaintiffs) pending in the MDL and MCL at that time. A master settlement agreement (MSA) was entered into in September 2021 and includes 3,729 cases in the MDL and MCL. All deadlines and trial settings in those proceedings are currently stayed pending the completion of the settlement agreement. Of the cases subject to the MSA, 3,390 have been dismissed with prejudice. Ethicon has received releases from 3,584 plaintiffs, and releases continue to be submitted as part of the settlement process. Post-settlement cases in the Physiomesh MDL and MCL are subject to docket control orders requiring early expert reports and discovery requirements. In May 2023, Ethicon entered an additional settlement to resolve the claims of 292 Physiomesh claimants. That settlement is proceeding, and releases are being returned. As of December 31, 2023, there were 5 Physiomesh cases in the MDL and 3 in the New Jersey MCL which are not included in either settlement and which remain subject to the docket control orders.

Claims have also been filed against Ethicon and the Company alleging personal injuries arising from the PROCEED Mesh and PROCEED Ventral Patch hernia mesh products. In March 2019, the New Jersey Supreme Court entered an order consolidating these cases pending in New Jersey as an MCL in Atlantic County Superior Court. Additional cases have been filed in various federal and state courts in the United States, and in jurisdictions outside the United States.

Ethicon and the Company also have been subject to claims for personal injuries arising from the PROLENE Polypropylene Hernia System. In January 2020, the New Jersey Supreme Court created an MCL in Atlantic County Superior Court to handle such cases. Cases involving this product have also been filed in other federal and state courts in the United States.

In October 2022, an agreement in principle, subject to various conditions, was reached to settle the majority of the pending cases involving Proceed, Proceed Ventral Patch, Prolene Hernia System and related multi-layered mesh products, as well as a number of unfiled claims. All litigation activities in the two New Jersey MCLs are stayed pending effectuation of the proposed settlement. Future cases that are filed in the New Jersey MCLs will be subject to docket control orders requiring early expert reports and discovery requirements.

The Company has established accruals with respect to product liability litigation associated with Ethicon Physiomesh Flexible Composite Mesh, PROCEED Mesh and PROCEED Ventral Patch, and PROLENE Polypropylene Hernia System products.

Innovative Medicine

RISPERDAL

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and the Company arising out of the use of RISPERDAL, and related compounds, indicated for the treatment of schizophrenia, acute manic or mixed episodes associated with bipolar I disorder and irritability associated with autism. Lawsuits primarily have been filed in state courts in Pennsylvania, California, and Missouri. Other actions are pending in various courts in the United States and Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has successfully defended a number of these cases but there have been verdicts against the Company, including a verdict in October 2019 of $8.0 billion of punitive damages related to one plaintiff, which the trial judge reduced to $6.8 million in January 2020. In September 2021, the Company entered into a settlement in principle with the counsel representing plaintiffs in this matter and in substantially all of the outstanding cases in the United States. The costs associated with this and other settlements are reflected in the Company's accruals.

ELMIRON

Claims for personal injury have been made against a number of Johnson & Johnson companies, including Janssen Pharmaceuticals, Inc. and the Company, arising out of the use of ELMIRON, a prescription medication indicated for the relief of bladder pain or discomfort associated with interstitial cystitis. These lawsuits, which allege that ELMIRON contributes to the development of permanent retinal injury and vision loss, have been filed in both state and federal courts across the United States. In December 2020, lawsuits filed in federal courts in the United States, including putative class action cases seeking medical monitoring, were organized as a multi-district litigation in the United States District Court for the District of New Jersey. All cases in the multi-district litigation are in active discussions regarding resolution, and as a result, all activity is stayed. In addition, cases have been filed in various state courts of New Jersey, which have been coordinated in a multi-county litigation in Bergen County, as well as the Court of Common Pleas in Philadelphia, which have been coordinated and granted mass tort designation. No activity has taken place in the New Jersey state court litigation; however, three bellwether trials have been set in Philadelphia for March, April and May 2024. In addition, three class action lawsuits have been filed in Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has established accruals for defense and indemnity costs associated with ELMIRON related product liability litigation.

Intellectual property

Certain subsidiaries of the Company are subject, from time to time, to legal proceedings and claims related to patent, trademark and other intellectual property matters arising out of their businesses. Many of these matters involve challenges to the coverage and/or validity of the patents on various products and allegations that certain of the Company's products infringe the patents of third parties. Although these subsidiaries believe that they have substantial defenses to these challenges and allegations with respect to all significant patents, there can be no assurance as to the outcome of these matters. A loss in any of these cases could adversely affect the ability of these subsidiaries to sell their products, result in loss of sales due to loss of market exclusivity, require the payment of past damages and future royalties, and may result in a non-cash impairment charge for any associated intangible asset.

Innovative Medicine - litigation against filers of abbreviated new drug applications (ANDAs)

The Company's subsidiaries have brought lawsuits against generic companies that have filed ANDAs with the U.S. FDA (or similar lawsuits outside of the United States) seeking to market generic versions of products sold by various subsidiaries of the Company prior to expiration of the applicable patents covering those products. These lawsuits typically include allegations of non-infringement and/or invalidity of patents listed in FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the Orange Book). In each of these lawsuits, the Company's subsidiaries are seeking an order enjoining the defendant from marketing a generic version of a product before the expiration of the relevant patents (Orange Book Listed Patents). In the event the Company's subsidiaries are not successful in an action, or any automatic statutory stay expires before the court rulings are obtained, the generic companies involved would have the ability, upon regulatory approval, to introduce generic versions of their products to the market, resulting in the potential for substantial market share and revenue losses for the applicable products, and which may result in a non-cash impairment charge in any associated intangible asset. In addition, from time to time, the Company's subsidiaries may settle these types of actions

and such settlements can involve the introduction of generic versions of the products at issue to the market prior to the expiration of the relevant patents.

The Inter Partes Review (IPR) process with the United States Patent and Trademark Office (USPTO), created under the 2011 America Invents Act, is also being used at times by generic companies in conjunction with ANDAs and lawsuits to challenge the applicable patents.

XARELTO

Beginning in March 2021, Janssen Pharmaceuticals, Inc.; Bayer Pharma AG; Bayer AG; and Bayer Intellectual Property GmbH filed patent infringement lawsuits in United States district courts against generic manufacturers who have filed ANDAs seeking approval to market generic versions of XARELTO before expiration of certain Orange Book Listed Patents. The following entities are named defendants: Dr. Reddy's Laboratories, Inc.; Dr. Reddy's Laboratories, Ltd.; Lupin Limited; Lupin Pharmaceuticals, Inc.; Taro Pharmaceutical Industries Ltd.; Taro Pharmaceuticals U.S.A., Inc.; Teva Pharmaceuticals USA, Inc.; Mylan Pharmaceuticals Inc.; Mylan Inc.; Mankind Pharma Limited; Apotex Inc.; Apotex Corp.; Auson Pharmaceuticals Inc.; Macleods Pharmaceuticals Ltd; Macleods Pharma USA, Inc.; Indoco Remedies Limited; FPP Holding Company LLC; Umedica Laboratories Pvt. Ltd.; Aurobindo Pharma Limited; Aurobindo Pharma USA, Inc.; Cipla Ltd.; Cipla USA Inc.; and InvaGen Pharmaceuticals, Inc. The following U.S. patents are included in one or more cases: 9,539,218 and 10,828,310.

U.S. Patent No. 10,828,310 was also under consideration by the USPTO in an IPR proceeding. In July 2023, the USPTO issued a final written decision finding the claims of the patent invalid. In September 2023, Bayer Pharma AG filed an appeal to the U.S. Court of Appeals for the Federal Circuit.

OPSUMIT

Beginning in January 2023 Actelion Pharmaceuticals Ltd and Actelion Pharmaceuticals US, Inc. filed patent infringement lawsuits in United States district courts against generic manufacturers who have filed ANDAs seeking approval to market generic versions of OPSUMIT before expiration of certain Orange Book Listed Patents. The following entities are named defendants: Sun Pharmaceutical Industries Limited; Sun Pharmaceutical Industries, Inc.; MSN Laboratories Private Limited; MSN Pharmaceuticals Inc.; and Mylan Pharmaceuticals Inc. The following U.S. patents are included in one or more cases: 7,094,781; and 10,946,015. In November 2023, the Company entered into a confidential settlement agreement with MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. In December 2023, the Company entered into a confidential settlement agreement with Sun Pharmaceutical Industries Limited and Sun Pharmaceuticals Industries, Inc.

INVEGA SUSTENNA

Beginning in January 2018, Janssen Pharmaceutica NV and Janssen Pharmaceuticals, Inc. filed patent infringement lawsuits in United States district courts against generic manufacturers who have filed ANDAs seeking approval to market generic versions of INVEGA SUSTENNA before expiration of the Orange Book Listed Patent. The following entities are named defendants: Teva Pharmaceuticals USA, Inc.; Mylan Laboratories Limited; Pharmascience Inc.; Mallinckrodt PLC; Specgx LLC; Tolmar, Inc.; and Accord Healthcare, Inc. The following U.S. patent is included in one or more cases: 9,439,906.

Beginning in February 2018, Janssen Inc. and Janssen Pharmaceutica NV initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against generic manufacturers who have filed ANDSs seeking approval to market generic versions of INVEGA SUSTENNA before expiration of the listed patent. The following entities are named defendants: Pharmascience Inc. and Apotex Inc. The following Canadian patent is included in one or more cases: 2,655,335.

INVEGA TRINZA

Beginning in September 2020, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV, and Janssen Research & Development, LLC filed patent infringement lawsuits in United States district courts against generic manufacturers who have filed ANDAs seeking approval to market generic versions of INVEGA TRINZA before expiration of the Orange Book Listed Patent. The following entities are named defendants: Mylan Laboratories Limited; Mylan Pharmaceuticals Inc.; and Mylan Institutional LLC. The following U.S. patent is included in one or more cases: 10,143,693. In May 2023, the District Court issued a decision finding that Mylan's proposed generic product infringes the asserted patent and that the patent is not invalid. Mylan has appealed the verdict.

SYMTUZA

Beginning in November 2021, Janssen Products, L.P., Janssen Sciences Ireland Unlimited Company, Gilead Sciences, Inc. and Gilead Sciences Ireland UC filed patent infringement lawsuits in United States district courts against generic manufacturers who have filed ANDAs seeking approval to market generic versions of SYMTUZA before expiration of certain Orange Book Listed Patents. The following entities are named defendants: Lupin Limited; Lupin Pharmaceuticals, Inc.; MSN Laboratories

Private Ltd.; MSN Life Sciences Private Ltd.; MSN Pharmaceuticals Inc.; Apotex Inc.; and Apotex Corp. The following U.S. patents are included in one or more cases: 10,039,718 and 10,786,518.

ERLEADA

Beginning in May 2022, Aragon Pharmaceuticals, Inc., Janssen Biotech, Inc. (collectively, Janssen), Sloan Kettering Institute for Cancer Research (SKI) and The Regents of the University of California filed patent infringement lawsuits in United States district courts against generic manufacturers who have filed ANDAs seeking approval to market generic versions of ERLEADA before expiration of certain Orange Book Listed Patents. The following entities are named defendants: Lupin Limited; Lupin Pharmaceuticals, Inc.; Zydus Worldwide DMCC; Zydus Pharmaceuticals (USA), Inc.; Zydus Lifesciences Limited; Sandoz Inc.; Eugia Pharma Specialities Limited; Aurobindo Pharma USA, Inc.; Auromedics Pharma LLC; Hetero Labs Limited Unit V; and Hetero USA, Inc. The following U.S. patents are included in one or more cases: 9,481,663; 9,884,054; 10,052,314 (which reissued as RE49,353); 10,702,508; 10,849,888; 8,445,507; 8,802,689; 9,388,159; 9,987,261; and RE49,353. In December 2023, Janssen and SKI voluntarily dismissed their case against Lupin Limited and Lupin Pharmaceuticals, Inc.

UPTRAVI

Beginning in November 2022, Actelion Pharmaceuticals US Inc., Actelion Pharmaceuticals Ltd and Nippon Shinyaku Co., Ltd. filed patent infringement lawsuits in United States district courts against generic manufacturers who have filed ANDAs seeking approval to market generic versions of UPTRAVI intravenous before expiration of certain Orange Book Listed Patents. The following entities are named defendants: Alembic Pharmaceuticals Limited, Alembic Pharmaceuticals Inc.; Lupin Ltd.; Lupin Pharmaceuticals, Inc.; Cipla Limited; Cipla USA Inc.; MSN Laboratories Private Ltd.; and MSN Pharmaceuticals Inc. The following U.S. patents are included in one or more cases: 8,791,122 and 9,284,280. In November 2023, the Company entered into a confidential settlement agreement with Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals Inc.

SPRAVATO

Beginning in May 2023, Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV filed patent infringement lawsuits in United States district courts against generic manufacturers who have filed ANDAs seeking approval to market generic versions of SPRAVATO before expiration of certain Orange Book Listed Patents. The following entities are named defendants: Sandoz Inc.; Hikma Pharmaceuticals Inc. USA; Hikma Pharmaceuticals PLC; and Alkem Laboratories Ltd. The following U.S. patents are included in one or more cases: 10,869,844; 11,173,134; 11,311,500; and 11,446,260.

STELARA

In November 2023, Biocon Biologics Inc. filed a Petition for Inter Partes Review with the USPTO seeking review of U.S. Patent No. 10,961,307 related to methods of treating ulcerative colitis with ustekinumab.

MedTech

In March 2016, Abiomed, Inc. (Abiomed) filed a declaratory judgment action against Maquet Cardiovascular LLC (Maquet) in U.S. District Court for the District of Massachusetts seeking a declaration that the Impella does not infringe certain Maquet patents, currently U.S. Patent Nos. 7,022,100 ('100); 8,888,728; 9,327,068; 9,545,468; 9,561,314; and 9,597,437. Maquet counterclaimed for infringement of each of those patents. After claim construction, Maquet alleged infringement of only the '100 patent. In September 2021, the court granted Abiomed's motion for summary judgment of non-infringement of the '100 patent, and in September 2023, the district court entered final judgment in favor of Abiomed on all patents-in-suit. Maquet appealed.

Government proceedings

Like other companies in the pharmaceutical and medical technologies industries, the Company and certain of its subsidiaries are subject to extensive regulation by national, state and local government agencies in the United States and other countries in which they operate. Such regulation has been the basis of government investigations and litigations. The most significant litigation brought by, and investigations conducted by, government agencies are listed below. It is possible that criminal charges and substantial fines and/or civil penalties or damages could result from government investigations or litigation.

MedTech

In July 2018, the Public Prosecution Service in Rio de Janeiro and representatives from the Brazilian antitrust authority CADE inspected the offices of more than 30 companies including Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda. The authorities appear to be investigating allegations of possible anti-competitive behavior and possible improper payments in the medical device industry. The Company continues to respond to inquiries regarding the Foreign

Corrupt Practices Act from the United States Department of Justice and the United States Securities and Exchange Commission.

In July 2023, the U.S. Department of Justice ("DOJ") issued Civil Investigative Demands to the Company, Johnson & Johnson Surgical Vision, Inc., and Johnson & Johnson Vision Care, Inc. (collectively, "J&J Vision") in connection with a civil investigation under the False Claims Act relating to free or discounted intraocular lenses and equipment used in eye surgery, such as phacoemulsification and laser systems. J&J Vision has begun producing documents and information responsive to the Civil Investigative Demands. J&J Vision is in ongoing discussions with the DOJ regarding its inquiry.

Innovative Medicine

In July 2016, the Company and Janssen Products, LP were served with a qui tam complaint pursuant to the False Claims Act filed in the United States District Court for the District of New Jersey alleging the off-label promotion of two HIV products, PREZISTA and INTELENCE, and anti-kickback violations in connection with the promotion of these products. The complaint was filed under seal in December 2012. The federal and state governments have declined to intervene, and the lawsuit is being prosecuted by the relators. The Court denied summary judgment on all claims in December 2021. Daubert motions were granted in part and denied in part in January 2022, and the case is proceeding to trial. Trial is scheduled for May 2024.

In March 2017, Janssen Biotech, Inc. (JBI) received a Civil Investigative Demand from the United States Department of Justice regarding a False Claims Act investigation concerning management and advisory services provided to rheumatology and gastroenterology practices that purchased REMICADE or SIMPONI ARIA. In August 2019, the United States Department of Justice notified JBI that it was closing the investigation. Subsequently, the United States District Court for the District of Massachusetts unsealed a qui tam False Claims Act complaint, which was served on the Company. The Department of Justice had declined to intervene in the qui tam lawsuit in August 2019. The Company filed a motion to dismiss, which was granted in part and denied in part. Discovery is underway.

From time to time, the Company has received requests from a variety of United States Congressional Committees to produce information relevant to ongoing congressional inquiries. It is the policy of Johnson & Johnson to cooperate with these inquiries by producing the requested information.

General litigation

The Company or its subsidiaries are also parties to various proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the Company's agreement to implement remediation activities at designated hazardous waste sites or to reimburse the government or third parties for the costs they have incurred in performing remediation as such sites.

In October 2017, certain United States service members and their families brought a complaint against a number of pharmaceutical and medical devices companies, including Johnson & Johnson and certain of its subsidiaries in United States District Court for the District of Columbia, alleging that the defendants violated the United States Anti-Terrorism Act. The complaint alleges that the defendants provided funding for terrorist organizations through their sales practices pursuant to pharmaceutical and medical device contracts with the Iraqi Ministry of Health. In July 2020, the District Court dismissed the complaint. In January 2022, the United States Court of Appeals for the District of Columbia Circuit reversed the District Court's decision. In June 2023, defendants filed a petition for a writ of certiorari to the United States Supreme Court.

In February 2024, a putative class action was filed against the Company, the Pension & Benefits Committee of Johnson & Johnson, and certain named officers and employees, in United States District Court for the District of New Jersey. The complaint alleges that defendants breached fiduciary duties under the Employee Retirement Income Security Act (ERISA) by allegedly mismanaging the Company's prescription-drug benefits program. The complaint seeks damages and other relief.

MedTech

In October 2020, Fortis Advisors LLC (Fortis), in its capacity as representative of the former stockholders of Auris Health Inc. (Auris), filed a complaint against the Company, Ethicon Inc., and certain named officers and employees (collectively, Ethicon) in the Court of Chancery of the State of Delaware. The complaint alleges breach of contract, fraud, and other causes of action against Ethicon in connection with Ethicon's acquisition of Auris in 2019. The complaint seeks damages and other relief. In December 2021, the Court granted in part and denied in part defendants' motion to dismiss certain causes of action. All claims against the individual defendants were dismissed. The trial was held in January 2024 and the decision is pending.

Innovative Medicine

In June 2019, the United States Federal Trade Commission (FTC) issued a Civil Investigative Demand to the Company and Janssen Biotech, Inc. (collectively, Janssen) in connection with its investigation of whether Janssen's REMICADE contracting practices violate federal antitrust laws. The Company has produced documents and information responsive to the Civil Investigative Demand. Janssen is in ongoing discussions with the FTC staff regarding its inquiry.

In February 2022, the United States Federal Trade Commission (FTC) issued Civil Investigative Demands to Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) in connection with its investigation of whether advertising practices for REMICADE violate federal law. Janssen has produced documents and information responsive to the Civil Investigative Demands. Janssen is in ongoing discussions with the FTC staff regarding the inquiry.

In June 2022, Genmab A/S filed a Notice for Arbitration with International Institute for Conflict Prevention and Resolution (CPR) against Janssen Biotech, Inc. seeking milestones and an extended royalty term for Darzalex FASPRO. In April 2023, the Arbitration Panel ruled in Janssen's favor and dismissed Genmab's claims. In January 2024, Genmab's appeal of this dismissal was denied.

In October 2018, two separate putative class actions were filed against Actelion Pharmaceutical Ltd., Actelion Pharmaceuticals U.S., Inc., and Actelion Clinical Research, Inc. (collectively Actelion) in United States District Court for the District of Maryland and United States District Court for the District of Columbia. The complaints allege that Actelion violated state and federal antitrust and unfair competition laws by allegedly refusing to supply generic pharmaceutical manufacturers with samples of TRACLEER. TRACLEER is subject to a Risk Evaluation and Mitigation Strategy required by the U.S. Food and Drug Administration, which imposes restrictions on distribution of the product. In January 2019, the plaintiffs dismissed the District of Columbia case and filed a consolidated complaint in the United States District Court for the District of Maryland.

In December 2023, a putative class action lawsuit was filed against the Company and Janssen Biotech Inc. (collectively "Janssen") in the United States District Court for the Eastern District of Virginia. The complaint alleges that Janssen violated federal and state antitrust laws and other state laws by delaying biosimilar competition with STELARA through the Janssen's enforcement of patent rights covering STELARA. The complaint seeks damages and other relief.

In June 2022, Janssen Pharmaceuticals, Inc. filed a Demand for Arbitration against Emergent Biosolutions Inc. et al. (EBSI) with the American Arbitration Association, alleging that EBSI breached the parties' Manufacturing Services Agreement for the Company's COVID-19 vaccine. In July 2022, Emergent filed its answering statement and counterclaims. The hearing is scheduled for July 2024.

20. Restructuring

In fiscal 2023, the Company commenced restructuring actions within its Innovative Medicine and MedTech segments. The amounts and details of the current year programs are included below.

In fiscal 2023, the Company completed a prioritization of its research and development (R&D) investment within its Innovative Medicine segment to focus on the most promising medicines with the greatest benefit to patients. This resulted in the exit of certain programs within certain therapeutic areas. The R&D program exits are primarily in infectious diseases and vaccines including the discontinuation of its respiratory syncytial virus (RSV) adult vaccine program, hepatitis and HIV development. Pre-tax Restructuring expenses of $479 million in the fiscal year 2023, included the termination of partnered and non-partnered development program costs and asset impairments. The estimated costs of these total activities is between $500 million - $600 million and is expected to be completed by the end of fiscal year 2024.

In fiscal 2023, the Company initiated a restructuring program of its Orthopaedics franchise within the MedTech segment to streamline operations by exiting certain markets, product lines and distribution network arrangements. The pre-tax restructuring expense of $319 million in the fiscal year 2023 primarily included inventory and instrument charges related to market and product exits. The estimated costs of the total program are between $700 million - $800 million and is expected to be completed by the end of fiscal year 2025.

The following table summarizes the restructuring expenses for the fiscal year 2023:

(Pre-tax Dollars in Millions)	2023
Innovative Medicine Segment[1]	$479
MedTech Segment[2]	319
Total Programs	$798

[1] Included $449 million in Restructuring and $30 million in Cost of products sold on the Consolidated Statement of Earnings

[2] Included $40 million in Restructuring and $279 million in Cost of products sold on the Consolidated Statement of Earnings

Restructuring reserves as of December 31, 2023 and January 1, 2023 were insignificant.

21. Kenvue separation and discontinued operations

On May 8, 2023, Kenvue, completed an initial public offering (the IPO) resulting in the issuance of 198,734,444 shares of its common stock, par value $0.01 per share (the "Kenvue Common Stock"), at an initial public offering of $22.00 per share for net proceeds of $4.2 billion. The excess of the net proceeds from the IPO over the net book value of the Johnson & Johnson divested interest was $2.5 billion and was recorded to additional paid-in capital. As of the closing of the IPO, Johnson & Johnson owned approximately 89.6% of the total outstanding shares of Kenvue Common Stock and at July 2, 2023, the non-controlling interest of $1.3 billion associated with Kenvue was reflected in equity attributable to non-controlling interests in the consolidated balance sheet in the fiscal second quarter of 2023.

On August 23, 2023, Johnson & Johnson completed the disposition of an additional 80.1% ownership of Kenvue Common Stock through an exchange offer, which resulted in Johnson & Johnson acquiring 190,955,436 shares of the Company's common stock in exchange for 1,533,830,450 shares of Kenvue Common Stock. The $31.4 billion of Johnson & Johnson common stock received in the exchange offer is recorded in Treasury stock. Following the exchange offer, the Company owns 9.5% of the total outstanding shares of Kenvue Common Stock that was recorded in other assets within continuing operations at the fair market value of $4.3 billion as of August 23, 2023. Subsequent changes are reflected in other income/expense and amounted to $0.4 billion expense through December 31, 2023.

Johnson & Johnson divested net assets of $11.6 billion as of August 23, 2023, and the accumulated other comprehensive loss attributable to the Consumer Health business at that date was $4.3 billion. Additionally, at the date of the exchange offer, Johnson & Johnson decreased the non-controlling interest by $1.2 billion to record the deconsolidation of Kenvue. This resulted in a non-cash gain on the exchange offer of $21.0 billion that was recorded in Net earnings from discontinued operations, net of taxes in the consolidated statements of earnings for the fiscal third quarter of 2023. This one-time gain includes a gain of $2.8 billion on the Kenvue Common Stock retained by Johnson & Johnson. The gain on the exchange offer qualifies as a tax-free transaction for U.S. federal income tax purposes.

Also in connection with the separation, Johnson & Johnson and Kenvue entered into a separation agreement and also entered into various other agreements that provide for certain transactions to effect the transfer of the assets and liabilities of the Consumer Health business to Kenvue and to govern various interim and ongoing relationships between Kenvue and Johnson & Johnson following the completion of the Kenvue IPO, including transition services agreements (TSAs), transition manufacturing agreements (TMAs), trademark agreements, intellectual property agreements, an employee matters agreement, and a tax matters agreement. Under the TSAs, Johnson & Johnson will provide Kenvue various services and, similarly, Kenvue will provide Johnson & Johnson various services. The provision of services under the TSAs generally will terminate within 24 months following the Kenvue IPO. Additionally, Johnson & Johnson and Kenvue entered into TMAs pursuant to which Johnson & Johnson will manufacture and supply to Kenvue certain products and, similarly, Kenvue will manufacture and supply to Johnson & Johnson certain products. The terms of the TMAs range in initial duration from 3 months to 5 years.

Amounts related to the TSAs and TMAs included in the consolidated statements of earnings were immaterial for the fiscal year 2023. Additionally, the amounts due to and from Kenvue for the above agreements was not material as of December 31, 2023.

The results of the Consumer Health business (previously reported as a separate business segment), as well as the associated gain, have been reflected as discontinued operations in the Company's consolidated statements of earnings as Net earnings from discontinued operations, net of taxes. Prior periods have been recast to reflect this presentation. As a result of the separation of Kenvue, Johnson & Johnson incurred separation costs of $986 million, $1,089 million and $67 million in the fiscal years 2023, 2022 and 2021, respectively, which are also included in Net earnings from discontinued operations, net of taxes. These costs were primarily related to external advisory, legal, accounting, contractor and other incremental costs directly related to separation activities. In the fiscal 2022, as part of the planned separation of the Company's Consumer Health business, the Company recognized approximately $0.5 billion in net incremental tax costs. As of January 1, 2023, the assets and liabilities associated with the Consumer Health business were classified as assets and liabilities of discontinued operations in the consolidated balance sheets.

Details of Net Earnings from Discontinued Operations, net of taxes are as follows:

(Dollars in Millions)	2023[1]	2022	2021
Sales to customers	$10,036	14,953	15,035
Cost of products sold	4,369	6,494	6,452
Gross profit	5,667	8,459	8,583
Selling, marketing and administrative expenses	3,085	4,519	4,542
Research and development expense	258	468	437
Interest Income	(117)	—	—
Interest expense, net of portion capitalized	199	—	—
Other (income) expense, net	1,092	1,060	(37)
(Gain) on separation of Kenvue	(20,984)	—	—
Restructuring	—	46	43
Earnings from Discontinued Operations Before Provision for Taxes on Income	22,134	2,366	3,598
Provision for taxes on income	307	795	521
Net earnings from Discontinued Operations	**$21,827**	**1,571**	**3,077**

[1] The Company ceased consolidating the results of the Consumer Health business on August 23, 2023, the date of the exchange offer, but continued to reflect any separation costs incurred as part of discontinued operations through the end of the fiscal fourth quarter.

The following table presents depreciation, amortization and capital expenditures of the discontinued operations related to Kenvue:

(Dollars in Millions)	2023[1]	2022	2021
Depreciation and Amortization	$383	641	739
Capital expenditures	$162	303	314

Details of assets and liabilities of discontinued operations were as follows:

	January 1, 2023
Assets	
Cash and cash equivalents	$1,238
Accounts receivable trade, less allowances for doubtful accounts	2,121
Inventories	2,215
Prepaid expenses and other receivables	256
Total current assets of discontinued operations	**5,830**
Property, plant and equipment, net	1,821
Intangible assets, net	9,836
Goodwill	9,184
Deferred taxes on income	176
Other assets	390
Total noncurrent assets of discontinued operations	**$21,407**
Liabilities	
Loans and notes payable	$15
Accounts payable	1,814
Accrued liabilities including accrued taxes on income	644
Accrued rebates, returns and promotions	838
Accrued compensation and employee related obligations	279
Total current liabilities of discontinued operations	**3,590**
Long-term debt	2
Deferred taxes on income	2,383
Employee related obligations	225
Other liabilities	291
Total noncurrent liabilities of discontinued operations	**$2,901**

22. Selected quarterly financial data (unaudited)

Selected unaudited quarterly financial data has been recast for discontinued operations for the years 2023 and 2022 and is summarized below:

	2023				2022			
(Dollars in Millions Except Per Share Data)	First Quarter[1]	Second Quarter	Third Quarter[2]	Fourth Quarter[3]	First Quarter[4]	Second Quarter	Third Quarter	Fourth Quarter[5]
Segment sales to customers								
Innovative Medicine	$13,413	13,731	13,893	13,722	12,869	13,317	13,214	13,163
MedTech	7,481	7,788	7,458	7,673	6,971	6,898	6,782	6,776
Total sales	20,894	21,519	21,351	21,395	19,840	20,215	19,996	19,939
Gross profit	14,207	15,057	14,745	14,597	13,822	13,893	13,824	13,855
Earnings (Loss) before provision for taxes on income	(1,287)	6,306	5,217	4,826	5,203	5,144	5,172	3,840
Net earnings (loss) from continuing operations	(491)	5,376	4,309	4,132	4,571	4,262	4,310	3,227
Net earnings (loss) from discontinued operations, net of tax	423	(232)	21,719	(83)	578	552	148	293
Net earnings (loss)	(68)	5,144	26,028	4,049	5,149	4,814	4,458	3,520
Basic net earnings(loss) per share:								
Basic net earnings (loss) per share from continuing operations	(0.19)	2.07	1.71	1.71	1.74	1.62	1.64	1.24
Basic net earnings (loss) per share from discontinued operations	0.16	(0.09)	8.61	(0.03)	0.22	0.21	0.06	0.11
Basic net earnings (loss) per share	(0.03)	1.98	10.32	1.68	1.96	1.83	1.70	1.35
Diluted net earnings (loss) per share:								
Diluted net earnings (loss) per share from continuing operations	(0.19)	2.05	1.69	1.70	1.71	1.60	1.62	1.22
Diluted net earnings (loss) per share from discontinued operations	0.16	(0.09)	8.52	(0.03)	0.22	0.20	0.06	0.11
Diluted net earnings (loss) per share	(0.03)	1.96	10.21	1.67	1.93	1.80	1.68	1.33

(1) The fiscal first quarter of 2023 includes a $6.9 billion charge related to talc matters.

(2) The fiscal third quarter of 2023 includes; a non-cash gain on the exchange offer of $21.0 billion that was recorded in Net earnings from discontinued operations, net of taxes; $0.6 billion related to the unfavorable change in the fair value of the retained stake in Kenvue and $0.4 billion related to the partial impairment of Idorsia convertible debt and the change in the fair value of the Idorsia equity securities held.

(3) The fourth quarter of 2023 includes favorable changes in the fair value of securities of $0.4 billion

(4) In the fiscal first quarter of 2022, the Company recorded an intangible asset impairment charge of approximately $0.6 billion related to an in-process research and development asset, bermekimab (JnJ-77474462).

(5) The fiscal fourth quarter of 2022 includes one-time COVID-19 Vaccine related exit costs of $0.8 billion.

Report of independent registered public accounting firm

To the Board of Directors and Shareholders of Johnson & Johnson

Opinions on the financial statements and internal control over financial reporting

We have audited the accompanying consolidated balance sheets of Johnson & Johnson and its subsidiaries (the "Company") as of December 31, 2023 and January 1, 2023, and the related consolidated statements of earnings, of comprehensive income, of equity and of cash flows for each of the three fiscal years in the period ended December 31, 2023, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and January 1, 2023, and the results of its operations and its cash flows for each of the three fiscal years in the period ended December 31, 2023 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Basis for opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and limitations of internal control over financial reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical audit matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

U.S. pharmaceutical rebate reserves – managed care, medicare and medicaid

As described in Note 1 to the consolidated financial statements, the Company recognizes revenue from product sales when obligations under the terms of a contract with the customer are satisfied. Rebates and discounts provided to customers are accounted for as variable consideration and recorded as a reduction in sales. The liability for such rebates and discounts is recognized within Accrued Rebates, Returns, and Promotions on the consolidated balance sheet. A significant portion of the liability related to rebates is from the sale of pharmaceutical goods within the U.S., primarily the Managed Care, Medicare and Medicaid programs, which amounted to $11.5 billion as of December 31, 2023. For significant rebate programs, which include the U.S. Managed Care, Medicare and Medicaid rebate programs, rebates and discounts estimated by management are based on contractual terms, historical experience, patient outcomes, trend analysis, and projected market conditions in the U.S. pharmaceutical market.

The principal considerations for our determination that performing procedures relating to U.S. pharmaceutical rebate reserves - Managed Care, Medicare and Medicaid is a critical audit matter are the significant judgment by management due to the significant measurement uncertainty involved in developing these reserves and the high degree of auditor judgment, subjectivity and audit effort in performing procedures and evaluating the assumptions related to contractual terms, historical experience, patient outcomes, trend analysis, and projected market conditions in the U.S. pharmaceutical market.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to U.S. pharmaceutical rebate reserves - Managed Care, Medicare and Medicaid, including controls over the assumptions used to estimate these rebates. These procedures also included, among others, (i) developing an independent estimate of the rebates by utilizing third party information on price and market conditions in the U.S. pharmaceutical market, the terms of the specific rebate programs, and the historical experience and trend analysis of actual rebate claims paid; (ii) testing rebate claims processed by the Company, including evaluating those claims for consistency with the contractual and mandated terms of the Company's rebate arrangements; and (iii) comparing the independent estimates to management's estimates.

Litigation contingencies – talc

As described in Notes 1 and 19 to the consolidated financial statements, the Company records accruals for loss contingencies associated with legal matters, including talc, when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. To the extent adverse awards, judgments, or verdicts have been rendered against the Company, management does not record an accrual until a loss is determined to be probable and can be reasonably estimated. For these matters, management is unable to estimate the possible loss or range of loss beyond the amounts accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors, including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; ability to achieve comprehensive multi-party settlements; complexity of related cross-claims and counterclaims; and/or there are numerous parties involved. Management continues to believe that the Company has strong legal grounds to contest the talc verdicts it has appealed. Notwithstanding management's confidence in the safety of the Company's talc products, in certain circumstances the Company has settled cases. The Company has recognized a total provision of approximately $9 billion, of which approximately one-third is recorded as a current liability and which encompasses actual and contemplated settlements. The recorded amount remains the Company's best estimate of probable loss after the dismissal. The parties have not yet reached a full resolution of all talc matters and the Company is unable to estimate the possible loss or range of loss beyond the remaining amount accrued.

The principal considerations for our determination that performing procedures relating to the talc litigation is a critical audit matter are the significant judgment by management when assessing the likelihood of a loss being incurred, when determining whether a reasonable estimate of the loss or range of loss for the future and existing talc claims can be made, and when determining the timing of any settlement payments, which in turn led to a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating management's assessment of the loss contingencies associated with this litigation.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's evaluation of the talc litigation, including controls over determining whether a loss is probable and whether the amount of loss can be reasonably estimated, as well as financial statement disclosures. These procedures also included, among others, (i) gaining an understanding of the Company's process around the accounting and reporting for the talc litigation; (ii) obtaining and evaluating certain executed settlement agreements related to the talc litigation (iii) discussing the status of significant known actual and potential litigation and settlements activity with the Company's in-house legal counsel, as well as external counsel when deemed necessary; (iv) obtaining and evaluating the letters of audit inquiry with internal and external legal counsel for significant litigation; (v) evaluating the reasonableness of management's assessment regarding whether an unfavorable outcome is reasonably possible or probable and reasonably estimable; and (vi) evaluating the sufficiency of the Company's litigation contingencies disclosures.

/s/ **PricewaterhouseCoopers LLP**
Florham Park, New Jersey
February 16, 2024

We have served as the Company's auditor since at least 1920. We have not been able to determine the specific year we began serving as auditor of the Company.

Management's report on internal control over financial reporting

Under Section 404 of the Sarbanes-Oxley Act of 2002, management is required to assess the effectiveness of the Company's internal control over financial reporting as of the end of each fiscal year and report, based on that assessment, whether the Company's internal control over financial reporting is effective.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is designed to provide reasonable assurance as to the reliability of the Company's financial reporting and the preparation of external financial statements in accordance with generally accepted accounting principles.

Internal controls over financial reporting, no matter how well designed, have inherent limitations. Therefore, internal control over financial reporting determined to be effective can provide only reasonable assurance with respect to financial statement preparation and may not prevent or detect all misstatements. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management has assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2023. In making this assessment, the Company used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework (2013)." These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. The Company's assessment included extensive documenting, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

Based on the Company's processes and assessment, as described above, management has concluded that, as of December 31, 2023, the Company's internal control over financial reporting was effective.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2023 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which appears herein.

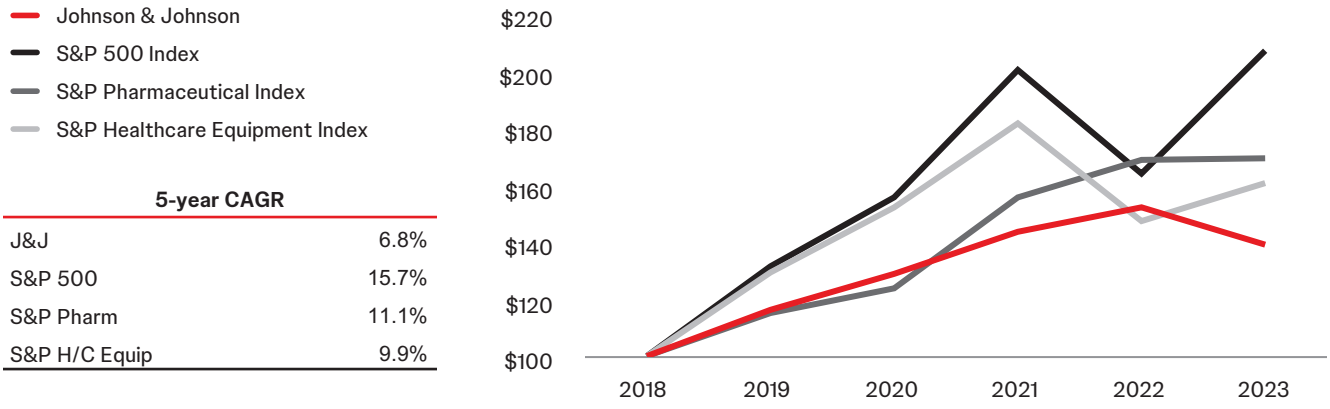
/s/ **J. Duato**
Joaquin Duato
Chairman, Board of Directors
Chief Executive Officer

/s/ **J. J. Wolk**
Joseph J. Wolk
Executive Vice President, Chief Financial Officer

Shareholder return performance graphs

Set forth below are line graphs comparing the cumulative total shareholder return on the Company's Common Stock for periods of five years and ten years ending December 31, 2023, against the cumulative total return of the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Healthcare Equipment Index. The graphs and tables assume that $100 was invested on December 31, 2018 and December 31, 2013 in each of the Company's Common Stock, the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Healthcare Equipment Index and that all dividends were reinvested.

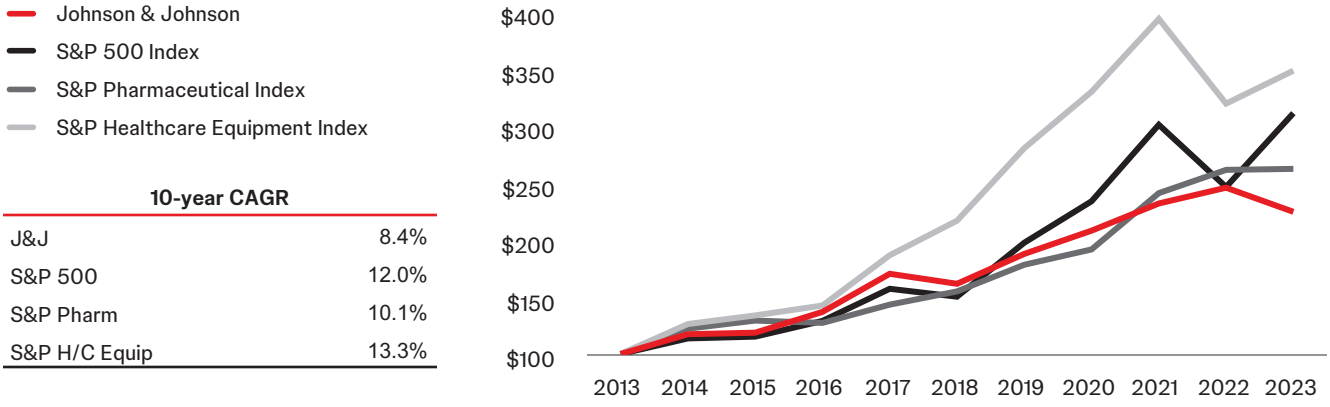
5 Year Shareholder Return Performance J&J vs. Indices



5-year CAGR	
J&J	6.8%
S&P 500	15.7%
S&P Pharm	11.1%
S&P H/C Equip	9.9%

	2018	2019	2020	2021	2022	2023
Johnson & Johnson	$100.00	$116.21	$128.82	$143.57	$152.14	$139.05
S&P 500 Index	$100.00	$131.47	$155.65	$200.29	$163.98	$207.04
S&P Pharmaceutical Index	$100.00	$115.09	$123.75	$155.62	$168.77	$169.33
S&P Healthcare Equipment Index	$100.00	$129.32	$152.12	$181.56	$147.32	$160.64

10 Year Shareholder Return Performance J&J vs. Indices



10-year CAGR	
J&J	8.4%
S&P 500	12.0%
S&P Pharm	10.1%
S&P H/C Equip	13.3%

	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Johnson & Johnson	$100.00	$117.34	$118.69	$136.88	$170.29	$161.54	$187.73	$208.10	$231.92	$245.76	$224.62
S&P 500 Index	$100.00	$113.67	$115.23	$129.00	$157.15	$150.24	$197.53	$233.85	$300.91	$246.37	$311.06
S&P Pharmaceutical Index	$100.00	$122.22	$129.29	$127.27	$143.27	$154.86	$178.23	$191.64	$240.99	$261.37	$262.23
S&P Healthcare Equipment Index	$100.00	$126.28	$133.82	$142.50	$186.53	$216.82	$280.39	$329.83	$393.66	$319.42	$348.30

Item 9. Changes in and disagreements with accountants on accounting and financial disclosure

Not applicable.

Item 9A. Controls and procedures

Disclosure controls and procedures. At the end of the period covered by this Report, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Joaquin Duato, Chairman and Chief Executive Officer, and Joseph J. Wolk, Executive Vice President, Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Duato and Wolk concluded that, as of the end of the period covered by this Report, the Company's disclosure controls and procedures were effective.

Reports on internal control over financial reporting. The information called for by this item is incorporated herein by reference to Management's report on internal control over financial reporting, and the attestation regarding internal controls over financial reporting included in the report of independent registered public accounting firm included in Item 8 of this Report.

Changes in internal control over financial reporting. During the fiscal quarter ended December 31, 2023, there were no changes in the Company's internal control over financial reporting identified in connection with the evaluation required under Rules 13a-15 and 15d-15 under the Exchange Act that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting. The Company continues to monitor and assess the effectiveness of the design and operation of its disclosure controls and procedures.

The Company is implementing a multi-year, enterprise-wide initiative to integrate, simplify and standardize processes and systems for the human resources, information technology, procurement, supply chain and finance functions. These are enhancements to support the growth of the Company's financial shared service capabilities and standardize financial systems. This initiative is not in response to any identified deficiency or weakness in the Company's internal control over financial reporting. In response to this initiative, the Company has and will continue to align and streamline the design and operation of its financial control environment.

Item 9B. Other information

Securities trading plans of Directors and Executive Officers. During the fiscal fourth quarter of 2023, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) informed us of the adoption or termination of a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," each as defined in Item 408 of Regulation S-K.

Item 9C. Disclosure regarding foreign jurisdictions that prevent inspections

Not applicable.

Part III

Item 10. Directors, executive officers and corporate governance

The information called for by this item is incorporated herein by reference to the discussion of the Audit Committee under the caption Item 1. Election of Directors - Board committees; and the material under the captions Item 1. Election of Directors and, if applicable, Delinquent Section 16(a) reporting in the Proxy Statement; and the material under the caption "Executive Officers of the Registrant" in Part I of this Report.

The Company's Code of Business Conduct, which covers all employees (including the Chief Executive Officer, Chief Financial Officer and Controller), meets the requirements of the SEC rules promulgated under Section 406 of the Sarbanes-Oxley Act of 2002. The Code of Business Conduct is available on the Company's website at www.jnj.com/code-of-business-conduct, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code of Business Conduct or any waiver of the Code granted to the Chief Executive Officer, the Chief Financial Officer or the Controller will be posted on the Company's website at www.jnj.com/code-of-business-conduct within five business days (and retained on the website for at least one year).

In addition, the Company has adopted a Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers. The Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers is available on the Company's website at www.investor.jnj.com/governance/corporate-governance-overview/code-of-business-conduct--ethics, and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code or any waiver of the Code granted to any member of the Board of Directors or any executive officer will be posted on the Company's website at www.investor.jnj.com/governance/corporate-governance-overview/code-of-business-conduct--ethics within five business days (and retained on the website for at least one year).

Item 11. Executive compensation

The information called for by this item is incorporated herein by reference to the material under the captions Item 1. Election of Directors – Director compensation, and Item 2. Compensation Committee report, Compensation discussion and analysis and Executive compensation tables in the Proxy Statement.

The material incorporated herein by reference to the material under the caption Compensation Committee report in the Proxy Statement shall be deemed furnished, and not filed, in this Report and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, as a result of this furnishing, except to the extent that the Company specifically incorporates it by reference.

Item 12. Security ownership of certain beneficial owners and management and related stockholder matters

The information called for by this item is incorporated herein by reference to the material under the caption Item 1. Stock ownership in the Proxy Statement; and Note 16 Common stock, stock option plans and stock compensation agreements of the Notes to Consolidated Financial Statements in Item 8 of this Report.

Equity compensation plan information

The following table provides certain information as of December 31, 2023 concerning the shares of the Company's Common Stock that may be issued under existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights	Weighted Average Exercise Price of Outstanding Options and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans[2][3]
Equity Compensation Plans Approved by Security Holders[1]	127,211,785	$123.41	130,112,007
Equity Compensation Plans Not Approved by Security Holders	—	—	—
Total	**127,211,785**	**$123.41**	**130,112,007**

(1) Included in this category are the following equity compensation plans which have been approved by the Company's shareholders: 2012 Long-Term Incentive Plan and 2022 Long-Term Incentive Plan.

(2) This column excludes shares reflected under the column "Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights."

(3) The 2012 Long-Term Incentive Plan expired April 26, 2022. All options and restricted shares granted subsequent to that date were under the 2022 Long-Term Incentive Plan.

Item 13. Certain relationships and related transactions, and director independence

The information called for by this item is incorporated herein by reference to the material under the captions Item 1. Election of Directors - Related person transactions & Director independence in the Proxy Statement.

Item 14. Principal accountant fees and services

The information called for by this item is incorporated herein by reference to the material under the caption Item 3. Ratification of appointment of independent registered public accounting firm in the Proxy Statement.

Part IV

Item 15. Exhibits and financial statement schedules

The following documents are filed as part of this report:

1. *Financial Statements*

   Consolidated balance sheets at end of fiscal years 2023 and 2022

   Consolidated statements of earnings for fiscal years 2023, 2022 and 2021

   Consolidated statements of comprehensive income for Fiscal Years 2023, 2022 and 2021

   Consolidated statements of equity for fiscal years 2023, 2022 and 2021

   Consolidated statements of cash flows for fiscal years 2023, 2022 and 2021

   Notes to Consolidated Financial Statements

   Report of independent registered public accounting firm

All schedules are omitted because they are not applicable or the required information is included in the financial statements or notes.

2. *Exhibits required to be filed by item 601 of regulation S-K*

   The information called for by this item is incorporated herein by reference to the Exhibit Index in this Report.

Item 16. Form 10-K summary

Registrants may voluntarily include a summary of information required by Form 10-K under this Item 16. The Company has elected not to include such summary information.

Signatures

Pursuant to the requirements of Section 13 of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 16, 2024

JOHNSON & JOHNSON
(Registrant)

By /s/ **J. Duato**
J. Duato, Chairman of the Board
and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ **J. Duato** **J. Duato**	Chairman of the Board Chief Executive Officer (Principal Executive Officer)	February 16, 2024
/s/ **J. J. Wolk** **J. J. Wolk**	Chief Financial Officer (Principal Financial Officer)	February 16, 2024
/s/ **R. J. Decker Jr.** **R. J. Decker Jr.**	Controller and Chief Accounting Officer (Principal Accounting Officer)	February 16, 2024
/s/ **D. Adamczyk** **D. Adamczyk**	Director	February 16, 2024
/s/ **M. C. Beckerle** **M. C. Beckerle**	Director	February 16, 2024
/s/ **D. S. Davis** **D. S. Davis**	Director	February 16, 2024
/s/ **J. A. Doudna** **J. A. Doudna**	Director	February 16, 2024

Signature	Title	Date
/s/ M. A. Hewson M. A. Hewson	Director	February 16, 2024
/s/ P. A. Johnson P. A. Johnson	Director	February 16, 2024
/s/ H. Joly H. Joly	Director	February 16, 2024
/s/ M. B. McClellan M. B. McClellan	Director	February 16, 2024
/s/ A. M. Mulcahy A. M. Mulcahy	Director	February 16, 2024
/s/ M. A. Weinberger M. A. Weinberger	Director	February 16, 2024
/s/ N. Y. West N. Y. West	Director	February 16, 2024
/s/ E. A. Woods E. A. Woods	Director	February 16, 2024

Exhibit index

Reg. S-K Exhibit Table Item No.	Description of Exhibit
2(i)	Agreement and Plan of Merger, dated as of October 31, 2022, by and among Johnson & Johnson, Athos Merger Sub, Inc. and ABIOMED, Inc. – Incorporated herein by reference to Exhibit 2.1 of the Registrant's Form 8-K Current Report filed November 1, 2022.†
3(i)	Restated Certificate of Incorporation effective February 19, 2016 — Incorporated herein by reference to Exhibit 3(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.
3(ii)	Certificate of Amendment to the Certificate of Incorporation of Johnson & Johnson effective April 30, 2020 — Incorporated herein by reference to Exhibit 3.1 of the Registrant's Form 8-K Current Report filed April 29, 2020.
3(iii)	By-Laws of the Company, as amended effective June 9, 2020 — Incorporated herein by reference to Exhibit 3.1 of the Registrant's Form 8-K Current Report filed June 10, 2020.
4(a)	Upon the request of the Securities and Exchange Commission, the Registrant will furnish a copy of all instruments defining the rights of holders of long-term debt of the Registrant.
4(b)	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 — Incorporated herein by reference to Exhibit 4.1 of the Registrant's Form 8-K Current Report filed August 12, 2020.
10(a)	2012 Long-Term Incentive Plan — Incorporated herein by reference to Appendix A of the Registrant's Proxy Statement filed on March 15, 2012.*
10(b)	Form of Stock Option Certificate under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.2 of the Registrant's Form 10-Q Quarterly Report for the quarter ended April 1, 2012.*
10(c)	Form of Restricted Share Unit Certificate under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.3 of the Registrant's Form 10-Q Quarterly Report for the quarter ended April 1, 2012.*
10(d)	Form of Performance Share Unit Certificate under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.4 of the Registrant's Form 10-Q Quarterly Report for the quarter ended April 1, 2012.*
10(e)	Global NonQualified Stock Option Award Agreement under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended April 1, 2018.*
10(f)	Global Restricted Share Unit Award Agreement under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.2 of the Registrant's Form 10-Q Quarterly Report for the quarter ended April 1, 2018.*
10(g)	Global Performance Share Unit Award Agreement under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.3 of the Registrant's Form 10-Q Quarterly Report for the quarter ended April 1, 2018.*
10(h)°	Global Restricted Share Unit Award Agreement granted to John Reed on May 1, 2023 under the 2022 Long-Term Incentive Plan — Filed with this document.*
10(i)	Domestic Deferred Compensation (Certificate of Extra Compensation) Plan — Incorporated herein by reference to Exhibit 10(g) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2003.*
10(j)	Amendments to the Certificate of Extra Compensation Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(j) of the Registrant's Form 10-K Annual Report for the year ended December 28, 2008.*
10(k)	2009 Certificates of Long-Term Performance Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 27, 2009.*
10(l)	Amended and Restated Deferred Fee Plan for Directors (Amended as of January 17, 2012) — Incorporated herein by reference to Exhibit 10(k) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 1, 2012.*

Reg. S-K Exhibit Table Item No.	Description of Exhibit
10(m)	The Johnson & Johnson Executive Income Deferral Plan Amended and Restated Effective January 1, 2010 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.*
10(n)	The Johnson & Johnson Excess Savings Plan (amended and restated as of January 1, 2022) — Incorporated herein by reference to Exhibit 10(l) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 1, 2023.*
10(o)	Excess Benefit Plan of Johnson & Johnson and Affiliated Companies (amended and restated as of January 1, 2020) — incorporated by reference to Exhibit 10(n) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2021.*
10(p)**	Executive Life Plan Agreement — Incorporated herein by reference to Exhibit 10(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 1993.*
10(q)	Executive Life Plan Agreement Closure Letter — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended March 29, 2015.*
10(r)	2022 Long-Term Incentive Plan — Incorporated by reference to Appendix A of the Registrant's Proxy Statement filed on March 16, 2022.*
10(s)	Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies, Amended and Restated as of October 1, 2014 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 28, 2014.*
10(t)	First Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended June 28, 2015.*
10(u)	Second Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10(x) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.*
10(v)	Contingent Value Rights Agreement, dated as of December 22, 2022, by and between Johnson & Johnson and American Stock Transfer & Trust Company, LLC – Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 8-K Current Report filed December 22, 2022.†
10(w)	Separation Agreement, dated as of May 3, 2023, by and between Johnson & Johnson and Kenvue Inc.
10(x)	Tax Matters Agreement, dated as of May 3, 2023, by and between Johnson & Johnson and Kenvue Inc.
10(y)	Employee Matters Agreement, dated as of May 3, 2023, by and between Johnson & Johnson and Kenvue Inc.
10(z)	Intellectual Property Agreement, dated as of May 3, 2023, by and between Johnson & Johnson and Kenvue Inc.
10(aa)	Trademark Phase-Out License Agreement, dated as of April 3, 2023, by and between Johnson & Johnson and Johnson & Johnson Consumer Inc.
10(ab)	Transition Services Agreement, dated as of May 3, 2023, by and between Johnson & Johnson and Kenvue Inc.
10(ac)	Transition Manufacturing Agreement, dated as of May 3, 2023, by and between Johnson & Johnson and Kenvue Inc.
10(ad)	Registration Rights Agreement, dated as of May 3, 2023, by and between Johnson & Johnson and Kenvue Inc.
10(ae)	Johnson & Johnson Deferred Compensation Plan*
10(af)	Global Performance Share Unit Award Agreement*

Reg. S-K Exhibit Table Item No.	Description of Exhibit
10(ag)	Global Restricted Share Unit Award Agreement*
10(ah)	Global Nonqualified Stock Option Award Agreement*
10(ai)	Amendment One to the Johnson & Johnson Excess Savings Plan (amended and restated effective as of January 1, 2022) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended October 1, 2023.*
10(aj)	Johnson & Johnson Executive Incentive Plan (Amended as of September 7, 2023) — Incorporated herein by reference to Exhibit 10.2 of the Registrant's Form 10-Q Quarterly Report for the quarter ended October 1, 2023.*
19°	Johnson & Johnson Stock Trading Policy for Directors, Executive Officers and Insiders (Amended as of April 27, 2023) — Filed with this document.
21°	Subsidiaries — Filed with this document.
23°	Consent of Independent Registered Public Accounting Firm — Filed with this document.
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.
32.1	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
32.2	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.
97°	Johnson & Johnson Clawback Policy (effective as of August 8, 2023) — Filed with this document.
Exhibit 101:	
EX-101.INS	Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
EX-101.SCH	Inline XBRL Taxonomy Extension Schema
EX-101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
EX-101.LAB	Inline XBRL Taxonomy Extension Label Linkbase
EX-101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
EX-101.DEF	Inline XBRL Taxonomy Extension Definition Document
Exhibit 104:	Cover Page Interactive Data File––the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

* Management contract or compensatory plan.

** Paper filing.

† Certain exhibits and schedules have been omitted pursuant to Item 601(b)(2)(ii) or 601(b)(10)(iv) of Regulation S-K, as applicable.

° Omitted from the printed version of this 2023 Annual Report.

A copy of any of the Exhibits listed above will be provided without charge to any shareholder submitting a written request specifying the desired exhibit(s) to the Secretary at the principal executive offices of the Company. Pursuant to Item 601(b)(4)(iii)(A) of Regulation S-K, the Company has not filed as exhibits to this Form 10-K certain long-term debt instruments, including indentures, under which the total amount of securities authorized does not exceed 10% of the total assets of the Company and its subsidiaries on a consolidated basis. The Company hereby agrees to furnish a copy of any such instrument to the SEC upon request.

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT

I, Joaquin Duato, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (the "report") of Johnson & Johnson (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter (the Company's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

/s/ Joaquin Duato

Joaquin Duato

Chief Executive Officer

Date: February 16, 2024

CERTIFICATION OF CHIEF FINANCIAL OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT

I, Joseph J. Wolk certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (the "report") of Johnson & Johnson (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter (the Company's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

/s/ Joseph J. Wolk
Joseph J. Wolk
Chief Financial Officer

Date: February 16, 2024

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT

The undersigned, Joaquin Duato, the Chief Executive Officer of Johnson & Johnson, a New Jersey corporation (the "Company"), pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certifies that, to the best of my knowledge:

(1) the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (the "Report") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Joaquin Duato
Joaquin Duato
Chief Executive Officer

Dated: February 16, 2024

This certification is being furnished to the SEC with this Report on Form 10-K pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section.

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT

The undersigned, Joseph J. Wolk, the Chief Financial Officer of Johnson & Johnson, a New Jersey corporation (the "Company"), pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certifies that, to the best of my knowledge:

(1) the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (the "Report") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Joseph J. Wolk
Joseph J. Wolk
Chief Financial Officer

Dated: February 16, 2024

This certification is being furnished to the SEC with this Report on Form 10-K pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section.

The tables below are provided to reconcile certain non-GAAP financial disclosures in the 2023 Chairman's Letter.

Reconciliation of Non-GAAP Financial Measures

(Dollars in Millions Except Per Share Data)	2023	2022	% change
Net Earnings from Continuing Operations, after tax- as reported	**$ 13,326**	**$ 16,370**	
Pre-tax Adjustments			
Litigation related	7,152	866	
Intangible Asset Amortization expense	4,532	3,944	
COVID-19 Vaccine related costs	663	1,474	
Restructuring related	798	372	
Medical Device Regulation	311	296	
Acquisition, integration and divestiture related	339	196	
(Gains)/losses on securities	641	690	
IPR&D impairments	313	783	
Other	—	(7)	
Tax Adjustments			
Tax impact on special item adjustments	(2,694)	(1,294)	
Tax legislation and other tax related	28	106	
Adjusted Net Earnings from Continuing Operations, after tax	**$ 25,409**	**$ 23,796**	
Average shares outstanding (Diluted)	2,560.4	2,663.9	
Adjusted net earnings per share from Continuing Operations (Diluted)	**$ 9.92**	**$ 8.93**	**11.1%**

Sales Growth % 2023 vs. 2022	Total	Operational	Currency
Worldwide as reported	6.5%	7.4%	(0.9)%
COVID-19 Vaccine impact	(1.5)	(1.6)	0.1
Worldwide excluding COVID-19 Vaccine	8.0	9.0	(1.0)

Board of Directors

JOAQUIN DUATO*
Chairman, Board of Directors

DARIUS ADAMCZYK
Executive Chairman, Honeywell International

MARY C. BECKERLE
Chief Executive Officer, Huntsman Cancer Institute at the University of Utah; Distinguished Professor of Biology, College of Science, University of Utah

D. SCOTT DAVIS
Former Chairman and Chief Executive Officer, United Parcel Service, Inc.

JENNIFER A. DOUDNA
Professor of Chemistry; Professor of Biochemistry & Molecular Biology; Li Ka Shing Chancellor's Professor in Biomedical and Health, University of California, Berkeley

MARILLYN A. HEWSON
Former Chair and Chief Executive Officer, Lockheed Martin Corporation

PAULA A. JOHNSON
President, Wellesley College

HUBERT JOLY
Former Chairman and Chief Executive Officer, Best Buy Co., Inc.

MARK B. McCLELLAN
Director, Duke-Robert J. Margolis, MD, Center for Health Policy, Duke University

ANNE M. MULCAHY
Former Chairman and Chief Executive Officer, Xerox Corporation

MARK A. WEINBERGER
Former Chairman and Chief Executive Officer, Ernst & Young

NADJA Y. WEST
Former Lieutenant General, U.S. Army

EUGENE A. WOODS
Chief Executive Officer, Advocate Health

Senior Management

JOAQUIN DUATO*
Chief Executive Officer

VANESSA BROADHURST*
Executive Vice President, Global Corporate Affairs

ROBERT J. DECKER JR.
Corporate Controller; Chief Accounting Officer

PETER M. FASOLO*
Executive Vice President, Chief Human Resources Officer

ELIZABETH FORMINARD*
Executive Vice President, General Counsel

WILLIAM N. HAIT*
Executive Vice President, Chief External Innovation and Medical Officer

MARC LARKINS
Corporate Secretary; Worldwide Vice President, Corporate Governance

JOHN REED*
Executive Vice President, Innovative Medicine, R&D

TIM SCHMID*
Executive Vice President, Worldwide Chairman, MedTech

JAMES SWANSON*
Executive Vice President, Chief Information Officer

JENNIFER TAUBERT*
Executive Vice President, Worldwide Chairman, Innovative Medicine

DUANE VAN ARSDALE
Treasurer

KATHRYN E. WENGEL*
Executive Vice President, Chief Technical Operations & Risk Officer

JOSEPH J. WOLK*
Executive Vice President, Chief Financial Officer

* Member, Executive Committee

Principal office

One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
(732) 524-0400

2024 Annual Meeting of Shareholders

Thursday, April 25, 2024
10:00 a.m. (Eastern Standard Time)

Meeting held virtually at *www.virtualshareholdermeeting.com/JNJ2024.*

All shareholders as of the record date of February 27, 2024 are invited to attend.

A formal Notice of Annual Meeting, Proxy Statement and proxy have been made available to shareholders.

2023 Annual Report on Form 10-K and 2024 Proxy Statement

Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 is included in this Annual Report in its entirety, with the exception of certain exhibits. The Form 10-K, complete with all of its exhibits, is available on our website at *www.investor.jnj.com/financials/sec-filings,* and the SEC's website at *www.sec.gov.*

Shareholders may also obtain copies of the exhibits, our 2023 Annual Report on Form 10-K and our 2024 Proxy Statement, without charge, upon written request to the Office of the Corporate Secretary at our principal office address, or by calling (800) 950-5089.

Electronic delivery notification

The 2024 Proxy Statement and our 2023 Annual Report are available on our website *investor.jnj.com/asm.* Shareholders who receive paper copies of our Proxy Statement and Annual Report by mail can elect to receive instead an email message with a link to those documents on the Internet. Registered shareholders may enroll in electronic delivery at: *www.computershare-na.com/green*. Beneficial shareholders (who hold shares of Johnson & Johnson Common Stock through a bank, broker or other holder of record) generally can enroll for electronic delivery at: *enroll.icsdelivery.com/jnj.*

Stock listing

Johnson & Johnson Common Stock
Listed on New York Stock Exchange
Stock Symbol: JNJ

Shareholder relations contact

Marc Larkins
Corporate Secretary
(732) 524-2455

Investor Relations contact

Jessica Moore
Vice President, Investor Relations
(800) 950-5089
investor-relations@its.jnj.com

Stock transfer agent and registrar

Questions regarding stock holdings, certificate replacement/transfer, dividends and address changes should be directed to our stock transfer agent and registrar at:

Computershare Trust Company, N.A.
P.O. Box 3006
Providence, RI 02490-3006

Overnight mail:
Computershare Trust Company, N.A.
150 Royal Street, Suite 101
Canton, MA 02021
(800) 328-9033 or (781) 575-2718

Shareholder website:
www.computershare.com/investor

Dividend reinvestment plan

The Plan allows for full or partial dividend reinvestment and additional cash investments up to $50,000 per year in Johnson & Johnson Common Stock without per share or service charges on stock purchases. If you are interested in participating in the Plan and need an enrollment form and/or more information, please call the Plan administrator, Computershare Trust Company, N.A. at (800) 328-9033 or (781) 575-2718 (outside the U.S.) or access online at *www.computershare.com/investor.*

Hearing impaired

Shareholders who have inquiries regarding stock-related matters can communicate directly with Computershare Trust Company, N.A. via a telecommunications device (TDD). The telephone number for this service is (800) 952-9245 or (781) 575-2692 (outside the U.S.).

Johnson & Johnson online

Our website: www.jnj.com

http://www.jnj.com/media-center

www.facebook.com/jnj

www.twitter.com/JNJNews
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Exhibit “J21”

This is Exhibit “J21” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

Federal Court Cour fédérale

Date: 20230717

Docket: T-2627-22

Citation: 2023 FC 870

Ottawa, Ontario, July 17, 2023

PRESENT: The Honourable Madam Justice Aylen

BETWEEN:

JANSSEN INC.

Applicant

and

THE MINISTER OF HEALTH AND THE ATTORNEY GENERAL OF CANADA

Respondents

PUBLIC JUDGMENT AND REASONS
(Confidential version issued on June 21, 2023)

[1] The Applicant, Janssen Inc [Janssen], seeks judicial review of a decision of the Office of Submissions and Intellectual Property [OSIP] on behalf of the Minister of Health dated November 15, 2022. OSIP determined that Canadian Patent No. 3,113,837 [837 Patent] was not eligible to be added to the Patent Register against STELARA® with respect to two supplementary new drug submissions.

[2] While Janssen has raised a number of issues on this application, of central importance are the following two issues: (i) whether OSIP's decision that a supplemental new drug submission approved for additional safety data that could provide a clinician more confidence in prescribing a drug long-term is not a "change in use of the medicinal ingredient" as prescribed by subsection 4(3) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [*PMNOC Regulations*] if the approved indication never included a temporal restriction on its use was reasonable; and (ii) whether the Canadian patent filing date requirement in subsection 4(6) of the *PMNOC Regulations* is *ultra vires* the *Patent Act*.

[3] For the reasons that follow, I am not satisfied that Janssen has demonstrated that there is any basis for the Court's intervention. Accordingly, the application for judicial review shall be dismissed in its entirety, with costs.

I. Background

A. *Drug Approval under the Food and Drug Regulations*

[4] Drug manufacturers who wish to advertise or sell a new drug in Canada must first obtain a Notice of Compliance [NOC] pursuant to the *Food and Drug Regulations*, CRC, c 870, by filing a drug submission with the Minister.

[5] The *Food and Drug Regulations* refer to several types of drug submissions, including a new drug submission [NDS] and a supplemental new drug submission [SNDS]. An NDS is

typically filed by the innovator drug manufacturer in order to obtain an NOC. An NDS contains a variety of clinical, non-clinical, chemistry and manufacturing data relating to the safety, efficacy and quality of the drug. The Minister evaluates this information to determine whether the drug meets the regulatory requirements in order to initially approve the drug for sale on the Canadian market. After an NOC for an NDS is issued, a manufacturer will typically continue to file information about the drug. Significant changes made to the information or material contained in the NDS are made by filing an SNDS. An NOC is also issued by the Minister for each approved SNDS.

B. *Product Monographs*

[6] As part of the drug review process for an NDS or SNDS, Health Canada reviews a Product Monograph which is a factual, scientific document that describes a drug product's properties, claims, indications, contra-indications, conditions, dosage, administration and any other relevant information that may be required for the optimal, safe and effective use of the drug. The "Indications and Clinical Use" section of a Product Monograph, among other things, lists the uses for which the drug has been approved through the issuance of an NOC.

C. *The PMNOC Regulations*

[7] The *PMNOC Regulations*, which were enacted in 1993 and have subsequently been amended on a number of occasions, were promulgated pursuant to the authority granted to the Governor in Council by subsection 55.2(4) the *Patent Act*, RSC 1985, c P-4, which provides:

The Governor in Council may make regulations respecting the infringement of any patent that, directly or indirectly, could result or results from the making, construction, use or sale of a patented invention in accordance with subsection (1), including regulations

(a) respecting the conditions that must be fulfilled before a document — including a notice, certificate or permit — concerning any product to which a patent may relate may be issued to any person under any Act of Parliament that regulates the manufacture, construction, use or sale of that product, in addition to any conditions provided for by or under that Act;

(b) respecting the earliest day on which such a document may be issued to a person and the earliest day on which it may take effect, and respecting the manner in which each day is to be determined;

(c) respecting the issuance, suspension or revocation of such a document in circumstances where, directly or indirectly, the document's issuance could result or results in the infringement of a patent;

(d) respecting the prevention and resolution of disputes with respect to the day on which such a document may be issued or take effect;

(e) respecting the prevention and resolution of disputes with respect to the infringement of a patent that could result directly or indirectly from the manufacture, construction, use or sale of a product referred to in paragraph (a);

Le gouverneur en conseil peut, par règlement, régir la contrefaçon de tout brevet qui résulte ou pourrait résulter, de façon directe ou autrement, de la fabrication, de la construction, de l'utilisation ou de la vente, au titre du paragraphe (1), d'une invention brevetée, et notamment :

a) régir les conditions complémentaires nécessaires à la délivrance à quiconque, relativement à un produit auquel peut se rapporter un brevet, de tout titre — avis, certificat, permis ou autre — en vertu de lois fédérales régissant la fabrication, la construction, l'utilisation ou la vente d'un tel produit;

b) régir la première date à laquelle un tel titre peut être délivré et celle à laquelle il peut prendre effet, ainsi que la manière de fixer chacune de ces dates;

c) régir la délivrance, la suspension ou la révocation d'un tel titre lorsque la délivrance de celui-ci entraîne ou pourrait entraîner, de façon directe ou autrement, la contrefaçon d'un brevet;

d) régir la prévention et le règlement de différends portant sur la date à laquelle un tel titre peut être délivré ou prendre effet;

e) régir la prévention et le règlement de différends portant sur la contrefaçon d'un brevet qui pourrait résulter, de façon directe ou autrement, de la fabrication, de la construction, de l'utilisation ou de la vente d'un produit visé à l'alinéa a);

f) régir le règlement de différends portant sur la contrefaçon d'un brevet qui résulte, de façon directe ou autrement, de la fabrication, de la

(f) respecting the resolution of disputes with respect to the infringement of a patent that results directly or indirectly from the manufacture, construction, use or sale of such a product;

(g) conferring rights of action with respect to disputes referred to in any of paragraphs (d) to (f);

(h) restricting or excluding the application of other rights of action under this Act or another Act of Parliament to disputes referred to in any of paragraphs (d) to (f);

(i) designating the court of competent jurisdiction in which a proceeding with respect to rights of action referred to in paragraph (g) is to be heard;

(j) respecting such proceedings, including the procedure of the court in the matter, the defences that may be pleaded, the remedies that may be sought, the joinder of parties and of rights of action and the consolidation of other proceedings, the decisions and orders the court may make and any appeals from those decisions and orders; and

(k) specifying who may be an interested person for the purposes of subsection 60(1) with respect to disputes referred to in paragraph (e).

construction, de l'utilisation ou de la vente d'un tel produit;

g) conférer des droits d'action concernant les différends visés à l'un ou l'autre des alinéas d) à f);

h) limiter ou interdire le recours à d'autres droits d'action prévus par toute loi fédérale concernant les différends visés à l'un ou l'autre des alinéas d) à f);

i) désigner le tribunal compétent à l'égard des procédures résultant de l'exercice des droits d'action visés à l'alinéa g);

j) régir ces procédures, notamment la procédure devant ce tribunal, les moyens de défense qui peuvent être invoqués, les conclusions qui peuvent être recherchées, la jonction de parties, la réunion de droits d'action ou d'autres procédures, les décisions et ordonnances qui peuvent être rendues ainsi que les appels de ces décisions et ordonnances;

k) préciser qui peut être un intéressé pour l'application du paragraphe 60(1) dans le cadre des différends visés à l'alinéa e).

[8] As confirmed by the Supreme Court of Canada in *AstraZeneca Canada Inc v Canada (Minister of Health)*, 2006 SCC 49 at paragraph 12, the *PMNOC Regulations* lie at the intersection of two regulatory systems with sometimes conflicting objectives – (i) the law governing the approval of new drugs (*Food and Drug Act*) with the objective of encouraging the bringing of safe

and effective medicines to market to advance the nation's health; and (ii) patent protection provided to innovators under the *Patent Act*.

[9] The Regulatory Impact Analysis Statement [RIAS] related to the 2006 amendments to the *PMNOC Regulations* describes the balancing function as follows:

> The Government's pharmaceutical patent policy seeks to balance effective patent enforcement over new and innovative drugs with the timely market entry of their lower priced generic competitors. The current manner in which that balance is realized was established in 1993, with the enactment of Bill C-91, the *Patent Act Amendment Act*, 1992, S.C. 1993, c. 2.
>
> On the one end of the balance lies subsection 55.2(1) of the *Patent Act*, better known as the "early-working" exception. In the pharmaceutical industry, early-working allows second and subsequent entry drug manufacturers (typically generic drug companies) to use a patented innovative drug for the purpose of seeking approval to market a competing version of that drug. Normally, conduct of this kind would constitute patent infringement but an exception has been made so that generic drug companies can complete Health Canada's regulatory approval process while the equivalent innovative drug is still under patent, in order to be in a position to enter the market as soon as possible after patent expiry. The generic pharmaceutical industry estimates that early-working can accelerate the market entry of its products in Canada by some three to five years.
>
> The PM(NOC) Regulations represent the other half of the balance. As explained in the original Regulatory Impact Analysis Statement (RIAS) which accompanied their passage in 1993, in creating the early-working exception, Bill C-91 removed an exclusive right otherwise available to patentees and the PM(NOC) Regulations are therefore required "…to ensure that this new exception to patent infringement is not abused by generic drug applicants seeking to sell their products during the term of the competitor's patent…" The PM(NOC) Regulations do this by linking Health Canada's ability to approve a generic drug to the patent status of the equivalent innovative product the generic seeks to copy. Under the current scheme, a generic drug company which compares its product directly or indirectly with a patented, innovative drug in order to

> establish the former's safety and efficacy and secure marketing approval from Health Canada (which comes in the form of a "notice of compliance" or 'NOC") must make one of two choices. It can either agree to await patent expiry before obtaining its NOC or make an allegation justifying immediate market entry that is either accepted by the innovator or upheld by the court.
>
> Thus, while early-working is intended to promote the timely market entry of generic drugs by allowing them to undergo the regulatory approval process in advance of patent expiry, the PM(NOC) Regulations are intended to provide effective patent enforcement by ensuring the former does not result in the actual issuance of a generic NOC until patent expiry or such earlier time as the court or innovator considers justified having regard to the generic company's allegations. Despite their seemingly competing policy objectives, it is important that neither instrument be considered in isolation as the intended policy can only be achieved when the two operate in a balanced fashion.

D. ***The Patent Register***

[10] The Minister maintains a Patent Register, which is a list of patents and certifications of supplementary protection associated with each approved drug. Pursuant to subsections 3(2) to 3(8) of the *PMNOC Regulations*, the Minister has the discretion to maintain the Patent Register, including the ability to add or delete patents in various prescribed circumstances.

[11] A "first person" who files an NDS or SNDS may, pursuant to subsection 4(1) of the *PMNOC Regulations*, submit to the Minister a patent for listing on the Patent Register in respect of the drug for which approval is sought. A patent will only be added to the Patent Register if the Minister is satisfied that the relevant regulatory criteria are met.

[12] In the case of an SNDS, paragraph 4(3)(c) sets out the product specificity requirements that must be met for a patent to be listed on the Patent Register:

(3) A patent on a patent list in relation to a supplement to a new drug submission is eligible to be added to the register if the supplement is for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient, and […] (c) in the case of a change in use of the medicinal ingredient, the patent contains a claim for the changed use of the medicinal ingredient that has been approved through the issuance of a notice of compliance in respect of the supplement.	(3) Est admissible à l'adjonction au registre tout brevet, inscrit sur une liste de brevets, qui se rattache au supplément à une présentation de drogue nouvelle visant une modification de la formulation, une modification de la forme posologique ou une modification de l'utilisation de l'ingrédient médicinal, s'il contient, selon le cas : c) dans le cas d'une modification d'utilisation de l'ingrédient médicinal, une revendication de l'utilisation modifiée de l'ingrédient médicinal, l'utilisation ayant été approuvée par la délivrance d'un avis de conformité à l'égard du supplément.

[13] Subsection 4(4) of the *PMNOC Regulations* prescribe what must be included in a patent list:

A patent list shall contain the following: (a) an identification of the new drug submission or the supplement to a new drug submission to which the list relates; (b) the medicinal ingredient, brand name, dosage form, strength, route of administration and use set out in the new drug submission or the	La liste de brevets comprend : a) l'identification de la présentation de drogue nouvelle ou du supplément à la présentation de drogue nouvelle qui s'y rattachent; b) l'ingrédient médicinal, la marque nominative, la forme posologique, la concentration, la voie d'administration et l'utilisation prévus à la

supplement to a new drug submission to which the list relates;

(c) for each patent on the list, the patent number, the filing date of the patent application in Canada, the date of grant of the patent and the date on which the term limited for the duration of the patent will expire under section 44 or 45 of the Patent Act;(d) for each patent on the list, a statement that the first person who filed the new drug submission or the supplement to a new drug submission to which the list relates

is the owner of the patent,

has an exclusive licence to the patent or to a certificate of supplementary protection in which that patent is set out, or

(iii) has obtained the consent of the owner of the patent to its inclusion on the list;

(e) the address in Canada for service, on the first person, of a notice of allegation referred to in paragraph 5(3)(a) or the name and address in Canada of another person on whom service may be made with the same effect as if service were made on the first person; and

(f) a certification by the first person that the information submitted under this subsection is accurate and that each patent on the list meets the eligibility requirements of subsection (2) or (3).

présentation ou au supplément qui s'y rattachent;

c) à l'égard de chaque brevet qui y est inscrit, le numéro de brevet, la date de dépôt de la demande de brevet au Canada, la date de délivrance de celui-ci et la date d'expiration du brevet aux termes des articles 44 ou 45 de la *Loi sur les brevets*;

d) à l'égard de chaque brevet qui y est inscrit, une déclaration portant que la première personne qui a déposé la présentation de drogue nouvelle ou le supplément à une présentation de drogue nouvelle qui s'y rattache :

(i) soit en est le propriétaire,

(ii) soit en détient la licence exclusive ou détient une telle licence à l'égard d'un certificat de protection supplémentaire qui mentionne ce brevet,

(iii) soit a obtenu le consentement du propriétaire pour l'inscrire sur la liste;

e) l'adresse au Canada de la première personne aux fins de signification de l'avis d'allégation visé à l'alinéa 5(3)a) ou les nom et adresse au Canada d'une autre personne qui peut en recevoir signification comme s'il s'agissait de la première personne elle-même;

f) une attestation de la première personne portant que les renseignements fournis aux termes du présent paragraphe

sont exacts et que chaque brevet qui y est inscrit est conforme aux conditions d'admissibilité prévues aux paragraphes (2) ou (3).

[14] The *PMNOC Regulations* also prescribe timing requirements related to patent listing, which depend on when the patent is issued. Specifically, subsections 4(5) and (6) provide:

(5) Subject to subsection (6), a first person who submits a patent list must do so at the time the person files the new drug submission or the supplement to a new drug submission to which the patent list relates.

(6) A first person may, after the date of filing of a new drug submission or a supplement to a new drug submission, and within 30 days after the issuance of a patent that was issued on the basis of an application that has a filing date in Canada that precedes the date of filing of the submission or supplement, submit a patent list, including the information referred to in subsection (4), in relation to the submission or supplement.

(5) Sous réserve du paragraphe (6), la première personne qui présente une liste de brevets doit le faire au moment du dépôt de la présentation de drogue nouvelle ou du supplément à une présentation de drogue nouvelle qui s'y rattachent.

(6) La première personne peut, après la date de dépôt de la présentation de drogue nouvelle ou du supplément à une présentation de drogue nouvelle et dans les trente jours suivant la délivrance d'un brevet faite au titre d'une demande de brevet dont la date de dépôt au Canada est antérieure à celle de la présentation ou du supplément, présenter une liste de brevets, à l'égard de cette présentation ou de ce supplément, qui contient les renseignements visés au paragraphe (4).

[15] As such, only patents that have a filing date in Canada before the filing date of an SNDS are eligible to be added to the Patent Register.

[16] For the purpose of the administration of the patent list, the Minister utilizes a form entitled "Form IV" that the Minister requires be completed by each first person. Form IV states in its header in bold to "COMPLETE ONE FORM PER PATENT PER SUBMISSION".

[17] Having a patent listed on the Patent Register in relation to a particular drug affords significant protections to an innovator. If a second person files a drug submission that directly or indirectly compares their drug with, or makes reference to, a first person's drug that is marketed in Canada under an NOC and which has one or more patents listed on the Patent Register, the second person must, pursuant to subsection 5(1) and (2.1) of the *PMNOC Regulations*, address each listed patent. One manner of addressing a listed patent is to serve on the first person a notice of allegation [NOA], pursuant to subsection 5(2.1)(c), alleging that the listed patent is invalid or would not be infringed by the second person making, constructing, using or selling their drug product. The first person then has the right, within 45 days of being served with a NOA, to bring an action against the second person pursuant to subsection 6(1) seeking a declaration that making, constructing, using or selling of the second person's drug product in accordance with the second person's drug submission would infringe the listed patent(s) addressed in the NOA. When such an action is brought, the Minister is prohibited from issuing a NOC to the second person for 24 months from the date of commencement of the action or such other periods of time prescribed by subsection 7(1) of the *PMNOC Regulations*.

[18] However, not all patents will receive the aforementioned protection afforded by the regulatory regime simply by relating to a drug for which an NOC has been issued. Only those

patents that meet the product specificity and timing requirements of the *PMNOC Regulations* will benefit from the regime's protections.

E. STELARA®

[19] STELARA® is a Schedule D biologic drug containing the medicinal ingredient ustekinumab [STELARA]. First approved in Canada in December of 2008 for the treatment of psoriasis, STELARA has since gained approvals for several other indications including its use to treat plaque psoriasis, active psoriatic arthritis and moderately to severely active Crohn's disease.

[20] There are currently no patents listed on the Patent Register in respect of STELARA. Canadian Patent No. 2,418,961 was previously listed on November 17, 2009, but expired on August 9, 2021.

[21] Health Canada's "Submissions Under Review" page shows at least one company has filed a submission for approval of a biosimilar of STELARA in January of 2023.

(1) SNDS 244739

[22] On February 15, 2019, the Applicant filed SNDS 224739 [SNDS 739] seeking approval for a new use of STELARA for the treatment of adult patients with moderately to severely active ulcerative colitis and updates to the Product Monograph. Supporting studies were submitted, including approximately one year of data (44 weeks) from a UNIFI-M maintenance study.

[23] On January 23, 2020, the Minister approved the use of STELARA for the treatment of ulcerative colitis, issuing an NOC for SNDS 739. The NOC stated, under the heading "Reasons for Supplement":

> New indication: The treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies.

[24] The "Dosage and Administration" section of the approved Product Monograph included a recommended induction treatment regimen for ulcerative colitis, as well as a recommended maintenance dose regimen. No temporal limitation on the duration of treatment was included in the Product Monograph. Put differently, the NOC for SNDS 739 did not approve the use of STELARA to treat ulcerative colitis for a limited period of time.

(2) SNDS 244670

[25] On October 1, 2020, Janssen filed SNDS 244670 [SNDS 670] seeking to update the Product Monograph of STELARA with updated two-year safety and efficacy data (96 weeks) from the same on-going UNIFI-M study on its use for ulcerative colitis (which use had been previously approved with SNDS 739).

[26] The Clinical Evaluation Executive Summary notes, under the heading "Subject", that SNDS 670 is to "update the product monograph to include results from the long-term extensions

of two Phase 3 studies for the treatment of adult patients with moderately to severely active Crohn's disease or ulcerative colitis".

[27] Both the General Note to Reviewer and Regulatory Executive Summary notes the purpose of the submission was to provide data on safety and efficacy of STELARA through five years of treatment in subjects with Crohn's disease and two years of treatment in subjects with ulcerative colitis, including relevant data in regard to a post-marketing adverse drug reaction for hypersensitivity vasculitis.

[28] Janssen indicated in the Product Information Regulatory Process Form for SNDS 670 that "there [were] no changes to the indication/Use/Dosage (including the maximum daily dose)".

[29] On September 9, 2021, Health Canada issued an NOC for SNDS 670. Under the heading "Reason for Supplement", the NOC states "Updates to the Product Monograph". The approval resulted in two changes to the Product Monograph, as shown in bold and underlined below:

Product Monograph (SNDS 739)	**Product Monograph (SNDS 670)**
(1) In the "Clinical Trial Adverse Drug Reactions" section addressing adverse drug reactions reported in studies related to ulcerative colitis, on page 12:	
The safety of STELARA®/STELARA® I.V. was evaluated in two randomized, double-blind, placebo-controlled studies (UNIFI-I and UNIFI-M) in 960 adult patients with moderately to severely active ulcerative colitis. The overall safety profile was similar for patients	The safety of STELARA®/STELARA® I.V. was evaluated in two randomized, double-blind, placebo-controlled studies (UNIFI-I and UNIFI-M) in 960 adult patients with moderately to severely active ulcerative colitis. The overall safety profile was similar for patients with psoriasis, psoriatic

with psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis.	arthritis, Crohn's disease and ulcerative colitis. **The safety profile remaining generally consistent throughout the Week 96 safety analysis.**
(2) In the "Study and Demographics and Trial Design" section on page 58:	
The maintenance study (UNIFI-M), evaluated 523 patients who achieved clinical response at Week 8 following the administration of STELARA® I.V. in UNIFI-I. These patients were randomized to receive a subcutaneous maintenance regimen of either 90 mg of STELARA® every 8 weeks, 90 mg STELARA® every 12 weeks or placebo for 44 weeks. Randomization was stratified by clinical remission status at maintenance baseline (yes/no), oral corticosteroid use at maintenance baseline (yes/no), and induction treatment. The primary endpoint was the proportion of patients in clinical remission at Week 44. Secondary endpoints included the proportion of patients maintaining clinical response through Week 44, the proportion of patients with improvement of endoscopic appearance of the mucosa at Week 44, the proportion of patients with corticosteroid-free clinical remission at Week 44, and the proportion of patients maintaining clinical remission through Week 44 in patients who achieved clinical remission 8 weeks after induction.	The maintenance study (UNIFI-M), evaluated 523 patients who achieved clinical response at Week 8 following the administration of STELARA® I.V. in UNIFI-I. These patients were randomized to receive a subcutaneous maintenance regimen of either 90 mg of STELARA® every 8 weeks, 90 mg STELARA® every 12 weeks or placebo for 44 weeks. Randomization was stratified by clinical remission status at maintenance baseline (yes/no), oral corticosteroid use at maintenance baseline (yes/no), and induction treatment. The primary endpoint was the proportion of patients in clinical remission at Week 44. Secondary endpoints included the proportion of patients maintaining clinical response through Week 44, the proportion of patients with improvement of endoscopic appearance of the mucosa at Week 44, the proportion of patients with corticosteroid-free clinical remission at Week 44, and the proportion of patients maintaining clinical remission through Week 44 in patients who achieved clinical remission 8 weeks after induction. **Patients who completed the maintenance study through Week 44 were eligible to continue treatment through Week 96.**

(3) The 837 Patent

[30] On September 24, 2019, Janssen filed in Canada a patent application for the 837 Patent. The 837 Patent, entitled "Safe and effective method of treating ulcerative colitis with anti-IL 12/IL23 antibody", claims priority from three U.S. provisional patents applications, the earliest one having been filed on September 24, 2018.

[31] The 837 Patent contains 68 claims generally directed toward the use of an anti-IL-12/IL-23p40 antibody (including ustekinumab) for the treatment of moderately to severely active ulcerative colitis, where the subject failed to respond to or was intolerant of at least one enumerated therapy or the subject demonstrated corticosteroid dependence and compositions for use in such treatment.

[32] The claims of the 837 Patent are directed to the treatment of ulcerative colitis, including numerous claims where the clinical response of the subject "continues at least 44 weeks after week 0".

[33] The 837 Patent was issued on July 12, 2022.

[34] On July 25, 2022, Janssen sought to list the 837 Patent in relation to SNDS 670 by submitting three Form IVs for the 837 Patent (one for each DIN).

[35] No Form IV was ever submitted for the 837 Patent in relation to SNDS 739. The deadline by which Janssen could have submitted a patent list for SNDS 739 (as prescribed by subsection 4(6) of the *PMNOC Regulations*) was August 11, 2022. There is no evidence in the record as to why this was not done.

F. OSIP's Preliminary Decision

[36] By letter dated July 29, 2022, OSIP acknowledged receipt of Janssen's patent lists for the 837 Patent in relation to SNDS 670. OSIP advised Janssen, in detail, of the basis for its preliminary view that SNDS 670 was not approved for a change in use of the medicinal ingredient and as such, SNDS 670 did not provide a basis to list the 837 Patent. Even if SNDS was considered to be approved for a change in use of a medicinal ingredient, OSIP advised that its preliminary view was that the 837 Patent did not contain a claim to the very change sought for approval in the submission.

[37] OSIP also noted the existence of SNDS 739 and that had a patent list been submitted in respect of the 837 Patent and SNDS 739, it would not meet the timing requirements of subsection 4(6), as the filing date for SNDS 739 was February 15, 2019 and the date of filing in Canada of the 837 Patent was subsequent to that date.

[38] OSIP requested that Janssen provide representations as to the eligibility of the 837 Patent for listing on the patent register in respect of SNDS 670.

G. Janssen's Response to the Preliminary Decision

[39] By letter dated September 14, 2022, Janssen provided detailed submissions in response to OSIP's request. With respect to SNDS 670, Janssen asserted that the 837 Patent claims [redacted] are a new method of use approved through SNDS 670, which is the submission against which Janssen originally sought listing on July 19, 2022. Janssen asserted that it was of the view that the 837 Patent is also listable as against SNDS 739 and that there are in fact no timing issues under subsection 4(6) as the only rational date to be used is the claim date and not the Canadian filing date. Janssen asserted that the use of the Canadian filing date in the *PMNOC Regulations* was illogical, arbitrary and *ultra vires* the scheme of the *Patent Act* and of the *PMNOC Regulations* themselves. Janssen asserted that OSIP ought to apply the intent of the *PMNOC Regulations* with respect to the timing of the patent and the submission under subsection 4(6) and when the claim date is properly applied, the 837 Patent is listable.

[40] In relation to Janssen's request that the 837 Patent also be listed in relation to SNDS 739, Janssen stated at footnote 2 of its submission:

> As a patent list was already submitted with respect to the '837 Patent within the requisite 30 days of its issuance we trust that the OPML will not consider this request to be out of time under subsection 4(6) of the *Regulations*. Further, we understand that the OPML has already considered the listing of the '837 Patent against SNDS 224739, as reflected in the Letter. If the OPML rejects this request, then we respectfully request that the OPML advise us of the reason and allow us an opportunity to respond.

[41] For reasons unknown to the Court, Janssen did not include a Form IV with its submission in relation to SNDS 739 and the 837 Patent.

[42] In support of its assertion that the 837 Patent claims [redacted] are a new method of use approved through SNDS 670, Janssen asserted that a clinician reviewing the new Product Monograph approved with SNDS 670 would change their prescribing practices, especially a clinician who may have been otherwise hesitant to prescribe STELARA beyond 44 weeks. Janssen supported this assertion regarding a clinician's understanding of the new additions to the Product Monograph with an expert statement from Dr. Brian Feagan and two publications.

[43] With respect to the publications, Janssen made the following submissions:

> A clinician's understanding of the additions to the Product Monograph is also reflected in publications reporting on the data collected for the treatment of patients with ustekinumab up to Week 96, including Panaccione R, et al. Ustekinumab is effective and safe for ulcerative colitis through 2 years of maintenance therapy. *Aliment Pharmacol Ther*. 2020; **52**: 1658-1675 ("Pannaccione (2020)"; enclosed). Panaccione (2020) concluded that the "efficacy of ustekinumab in patients with [ulcerative colitis] was sustained through 92 weeks" (abstract), that "[r]ates of symptomatic remission were maintained from Week 44 through Week 92" (page 1671), and that "[t]he results reported here in patients with moderately-to-severely active [ulcerative colitis], together with both clinical trial and registry data confirm the positive long-term efficacy and safety profile of ustekinumab-treated patients" (page 1672). With respect to safety, Panaccione (2020) concluded that "[n]o new safety signals were observed" (abstract) and that "[t]he safety profile observed for ustekinumab in the second year of maintenance treatment was consistent with that reported through the first year during the maintenance study and with the established ustekinumab safety profile" (page 1672). […]
>
> The importance of safety data for ustekinumab beyond one year was also stated in an integrated safety study, Sandborn WJ, et al. Safety

> of Ustekinumab in Inflammatory Bowel Disease: Pooled Safety Analysis Results from Phase 2/3 Studies. *Inflamm Bowel Dis*. 2021; **27(7)**: 994-1007 ("Sandborn (2021)", enclosed). Sandborn (2021) pooled data from six studies, including the UNIFI study for ulcerative colitis, through one year. The authors concluded (pages 1006-7):
>
> > Though these and previously reported findings are reassuring, longer-term longitudinal data and larger (eg, real-world observational) studies are ongoing to confirm current findings of no increased malignancy risk with IL-12/23 inhibition.
> >
> > …
> >
> > There are several limitations to this study. In a lifetime disease, 1 year of treatment is relatively short; longer-term data will be needed to further support these findings. This may limit comparisons, especially for long latency events like malignancies or certain infections. Although the data contained in this article are only from clinical trials, limitations on interpretation may differ from outcomes observed in real-world.
>
> The information added to the Stelara Product Monograph via SNDS 24470 thus provided clinicians with support of the safety findings made one year after that Sandborn (2021) indicated was required.
>
> [Emphasis in original.]

[44] With respect to the expert statement of Dr. Feagan, Dr. Feagan is a gastroenterologist at London Health Sciences Centre and a Professor of Medicine at the Schulich School of Medicine and Dentistry at Western University, with a research focus on the design, conduct and execution of large-scale randomized controlled trials in Crohn's disease and ulcerative colitis. Dr. Feagan's mandate was to: (i) provide brief background information on ulcerative colitis and its treatment options (including STELARA); and (ii) to advise how, if at all, a clinician's prescribing practices would be influenced by the additions to the STELARA Product Monograph arising from the NOC

for SNDS 670. Dr. Feagan provided no evidence in relation to the aforementioned publications relied upon by Janssen.

[45] While Janssen did not make specific submissions related to Dr. Feagan's evidence (other than as detailed in paragraph 42 above), Dr. Feagan opined that community gastroenterologists (who are gastroenterologists not located in a teaching or research hospital) would "take comfort" in the additional information (as it would "alleviate fears relating to potential side effects") and would be more willing to prescribe or be more comfortable prescribing STELARA based on the additional information contained in the Product Monograph.

II. The Decision under Review

[46] On November 15, 2022, OSIP provided Janssen with its final decision. OSIP found that SNDS 670 was not approved for a change in formulation, change in dosage form or change in use of the medicinal ingredient and did not present an opportunity to list a patent on the Patent Register in accordance with subsection 4(3) of the *PMNOC Regulations*. OSIP noted that SNDS 670 amended STELARA's Product Monograph to include updated safety and efficacy data generated through an on-going study, which was the very same on-going study that had been previously included in the Product Monograph for SNDS 739. OSIP considered the text, context and purpose of subsection 4(3) of the *PMNOC Regulations*, the relevant jurisprudence and the submissions of Janssen, before concluding that updating the safety information in the product monograph did not result in a change in use in SNDS 670.

[47] OSIP went on to examine whether the 837 Patent would have been eligible for listing if one were to assume that SNDS 670 was in fact for a change in use. However, OSIP found that the 837 Patent did not contain a claim to the very change that Janssen alleged was approved by the NOC for SNDS 670 as required by subsection 4(3).

[48] In relation to SNDS 739, OSIP determined that Janssen had not filed a patent list to add the 837 Patent to the Patent Register against SNDS 739. The OSIP went on to find that, even if Janssen had submitted a patent list to add the 837 Patent against SNDS 739, Janssen would not have met the timing requirements in subsection 4(6) of the *PMNOC Regulations,* as the 837 Patent application was filed in Canada after the filing date of SNDS 739. OSIP held that to consider the claim date/priority date (as opposed to the Canadian filing date) as the appropriate date when assessing the application of subsection 4(6) as urged by Janssen would be to ignore the clear words of the *PMNOC Regulations*, circumvent the strict timing requirements and undo the balance struck by the *PMNOC Regulations* and subsection 55.2(1) of the *Patent Act*.

III. Issue and Standard of Review

[49] This application raises the following issues:

A. Whether OSIP's decision not to add the 837 Patent to the Patent Register in relation to SNDS 670 and SNDS 739 was unreasonable and in particular:

i. Whether OSIP's determination that SNDS 670 was not approved for a change in use of the medicinal ingredient was unreasonable;

ii. Whether OSIP's determination that the 837 Patent was not eligible to be added to the Patent Register as it did not meet the product specificity requirements of paragraph 4(3)(c) was unreasonable; and

iii. Whether OSIP's determination that Janssen failed to provide a patent list in relation to SNDS 739 was unreasonable.

B. Whether the Canadian filing date requirement in subsection 4(6) of the *PMNOC Regulations* is *ultra vires* the *Patent Act*.

[50] The parties agree and I concur that the first issue is reviewable on a standard of reasonableness. When reviewing for reasonableness, the Court must determine whether the decision under review, including both its rationale and outcome, is transparent, intelligible and justified. A reasonable decision is one that is based on an internally coherent and rational chain of analysis and that is justified in relation to the facts and law that constrain the decision-maker [see *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at paras 15, 85]. The Court must be able to trace the decision maker's reasoning without encountering any fatal flaws in the overarching logic and the Court must be satisfied that there is a line of analysis within the given reasons that could reasonably lead the decision maker from the evidence before it to the conclusion at which it arrived [see *Vavilov, supra* at para 102].

[51] A number of elements will generally be relevant in evaluating whether a given decision is reasonable, including the governing statutory scheme, other relevant statutory or common law, the principles of statutory interpretation, the evidence before the decision maker and facts of which the decision maker may take notice, the submissions of the parties, the past practices and decisions of the decision maker and the potential impact of the decision on the individual to whom it applies [see *Vavilov, supra* at para 106].

[52] Where a decision involves a matter of statutory interpretation, the Court does not undertake a *de novo* analysis of the question. Rather, the Court still undertakes a reasonableness review, examining the administrative decision as a whole, including the reasons provided and the outcome reached. An administrative decision maker's task is to interpret the contested provision in a manner consistent with the text, context and purpose, applying its particular insight into the statutory scheme at issue. The modern principles of statutory interpretation apply equally when an administrative decision maker interprets a provision. Where the meaning of a statutory provision is disputed in administrative proceedings, the decision maker must demonstrate in its reasons that it was alive to these essential elements [see *Vavilov, supra* at para 115-116, 120, 121].

[53] The Court will intervene only if it is satisfied there are sufficiently serious shortcomings in the decision such that it cannot be said to exhibit the requisite degree of justification, intelligibility and transparency [see *Adenjij-Adele v Canada (Minister of Citizenship and Immigration)*, 2020 FC 418 at para 11].

[54] With respect to the second issue, both parties agree that the issue of whether the Canadian filing date requirement in subsection 4(6) of the *PMNOC Regulations* is *ultra vires* the *Patent Act* is reviewable on a reasonableness standard. However, they disagree as to whether, as the Respondent asserts, the pre-*Vavilov* case law (and in particular, *Katz Group Canada Inc v Ontario (Health and Long-Term Care)*, 2013 SCC 64) remains instructive and applicable to *vires* challenges to regulations.

[55] Prior to *Vavilov*, the Supreme Court of Canada outlined the method to determine if regulations were *ultra vires* in *Katz*, *supra* at paragraphs 24 to 28. The *Katz* approach requires the party challenging the *vires* of the regulations to show that the regulations (which benefit from a presumption of validity) are inconsistent with the purposes and objectives of the enabling statute or the scope of the statutory mandate when read as a whole. The three parts to the *Katz* rule are: (1) the challenging party bears the burden of proof; (2) the Court is directed to take a broad and purposive approach to interpreting the challenged regulation and the enabling statute, consistent with general guidance on statutory interpretation; and (3) the challenging party must overcome the presumption that the regulations are valid, which can only be done by establishing that the regulations are irrelevant, extraneous or completely unrelated to objectives of the governing statute. In particular, the Supreme Court directs that a *vires* challenge does not involve assessing the policy merits of the regulations as the motives or other considerations (political, economic, social or partisan) are irrelevant.

[56] After *Vavilov* established a general framework for review of administrative decisions, this prompted a debate regarding the extent to which the principles established in *Katz* were affected

by *Vavilov.* Some decisions of this Court continued to be guided by the *Katz* approach, mindful of this debate [see *Innovative Medicines Canada v Canada (Attorney General)*, 2020 FC 725 at paras 66-72; *Bertrand v Acho Dene Koe First Nation*, 2021 FC 287 at paras 73-76].

[57] The Federal Court of Appeal weighed into this debate in *Portnov v Canada (Attorney General)*, 2021 FCA 171. Justice Stratas, writing for the Court, explained how the approach outlined in *Katz* had been overtaken by *Vavilov* and thus, the Federal Court of Appeal did not follow the guidance of *Katz* but applied reasonableness review as per *Vavilov* [see *Portnov, supra* at paras 18-28].

[58] The Federal Court of Appeal weighed in again in *International Air Transport Association v Canadian Transportation Agency*, 2022 FCA 211, also considering the jurisprudence on whether courts reviewing the validity of regulations should apply a *Vavilov* standard of review analysis or the *ultra vires* doctrine from *Katz*. In *International Air Transport Association*, the appellant challenged numerous provisions of new regulations (in particular, challenging the Minister's Direction requiring the Agency to make regulations in respect of tarmac delays of three hours or less) on the basis that they exceeded the Agency's authority under the *Canada Transportation Act*. The Federal Court of Appeal discussed the analytical framework in the *Dunsmuir* era, wherein the reviewing court interpreted the statutory grant of authority to determine whether it fell within or outside its ambit. Justice de Montigny, writing for the Court, goes on to discuss the judicial review framework that was later applied in cases such as *Katz*, concluding that *Vavilov* did not bring clarity to the confusion around what framework to apply in the context of delegated legislation. Further, the *References re Greenhouse Gas Pollution Pricing Act*, 2021 SCC 11, wherein the

Supreme Court reviewed the validity of regulations at issue, made no mention of the *ultra vires* doctrine or *Vavilov* and reasonableness review. The Federal Court of Appeal noted that the issue is far from settled:

> [188] Unfortunately, *Vavilov* did not bring much clarity to that confusion. Because the Supreme Court purported to adopt the reasonableness standard as the default standard of review to all administrative actions, most intermediate appeal courts adopted the view that delegated legislation would henceforth be reviewed against that standard: see, for example, *1193652 B.C. Ltd. v. New Westminster (City)*, 2021 BCCA 176 at paras. 48-59; *Portnov v. Canada (Attorney General)*, 2021 FCA 171; *Canadian Association of Refugee Lawyers v. Canada (Citizenship and Immigration)*, 2020 FCA 196 [2021] 1 F.C.R. 271; Paul Daly, "Regulations and Reasonableness Review" (January 29, 2021), online (blog): *Administrative Law Matters* <https://www.administrativelawmatters.com/blog/2021/01/29/regulations-and-reasonableness-review/and the cases cited therein>.
>
> [189] This approach, however, has not been followed unanimously: see, for example, *Hudson's Bay Company ULC v. Ontario (Attorney General)*, 2020 ONSC 8046, 154 O.R. (3d) 103; *Friends of Simcoe Forest Inc. v. Minister of Municipal Affairs and Housing*, 2021 ONSC 3813 at para. 25. Indeed, the reasonableness standard review is fraught with difficulties, not the least of which is that it assumes the body or person that has been granted the power to adopt delegated legislation has also been vested with the power to decide questions of law and to determine the proper interpretation of the habilitating statute; yet, this is obviously not always the case: see John M. Evans, "Reviewing Delegated Legislation After *Vavilov*: *Vires* or Reasonableness?" (2021) 34:1 Can. J. Admin. L.& P. 1.
>
> [190] More recently, the Supreme Court has brought grist to the mill of those who support the view that the *Vavilov* judicial review framework does not apply to delegated legislation. In *References re Greenhouse Gas Pollution Pricing Act*, 2021 SCC 11, 455 D.L.R. (4th) 1 [*Ref re Greenhouse Gas*], the Court reviewed the validity of the regulations at issue on the basis of its own interpretation of the enabling statute, without expressing any deference to Cabinet on the interpretative issue. It is true that the majority (in contrast to the dissenting opinion of Rowe J.) made no mention of the *ultra*

> *vires* doctrine, but neither did it refer to *Vavilov* nor to reasonableness review. On the contrary, the majority took it upon itself to interpret the scope of the regulation-making powers found in the *Greenhouse Gas Pollution Pricing Act*, S.C. 2018, c. 12. While this is clearly not the last word on the subject, it signals at the very least that the issue is far from settled.
>
> [191] That being said, and whether we assess the validity of the Direction and of section 8 of the Regulations through the lens of the reasonableness standard of review or through the more exacting prism of the ultra vires doctrine, the result would be the same. For the appellants to succeed with their argument that subsection 86.11(2) of the CTA does not encompass the power to issue the *Direction* (and section 8 of the Regulations) because it relates to matters covered at paragraph 86.11(1)(f), they would have to show either that the Direction: 1) is irrelevant, extraneous or completely unrelated to the statutory purpose (*Katz* at para. 28; *Shell Canada Products Ltd. v. Vancouver (City)*, [1994] 1 S.C.R. 231, 1994 CanLII 115 (SCC) at p. 280), or 2) rests on an unreasonable interpretation of subsection 86.11(2). If the *Direction* (and section 8 of the CTA) satisfies the more exacting *ultra vires* framework, it will obviously meet the less stringent reasonableness standard of review analysis.

[59] However, in its most recent decision in *Innovative Medicines Canada v Canada (Attorney General)*, 2022 FCA 210, Justice Stratas, writing on behalf of the Court, held that *Portnov*, a unanimous and binding decision of this Court, binds future panels of the Federal Court of Appeal (and thus this Court), such that the methodology to be used to assess a regulation is that set out in *Vavilov*, not *Katz* [see *Innovative Medicines, supra,* at paras 26-27].

[60] The Federal Court of Appeal offers specific guidance in *Innovative Medicines, supra,* to the review of regulations enacted by the Governor in Council:

> [39] …Under *Vavilov*, the broader the regulation-making power in a statute, particularly in matters of policy that are quintessentially the preserve of the executive, the less constrained the regulation-

> maker will be in enacting the regulation: *Entertainment Software Association v. Society of Composers, Authors and Music Publishers of Canada*, 2020 FCA 100, [2021] 1 F.C.R. 374 at para. 28 (applying *Vavilov* and earlier cases consistent with it), aff'd 2022 SCC 30.
>
> [40] This is especially so for the Governor in Council. The Governor in Council is "at the apex of the executive", serves as "the grand co-ordinating body for the divergent provincial, sectional, religious, racial and other interests throughout the nation", and represents "different geographic, linguistic, religious, and ethnic groups": *Canada (Citizenship and Immigration) v. Canadian Council for Refugees*, 2021 FCA 72, 458 D.L.R. (4th) 125 at paras. 36-38. Thus, subject to limiting statutory language passed by our elected representatives, the Governor in Council's regulation-making power is often relatively unconstrained. The key is the limiting statutory language. *Vavilov* goes straight to that key, focusing on what meanings the language of the regulation-making power can reasonably bear. *Katz* doesn't. […]

[61] In conducting a reasonableness review, the Court is to assess the constraints on the administrative decision-maker (the primary constraint being the empowering legislation) and whether the decision maker has remained within them. The Court is entitled to look at the reasons offered by the decision maker, associated documents that shed light on the reasoning process, any submissions made to the decision maker and the record before the decision maker. In the case of decisions of the Governor in Council, reasoned explanations can often be found in the text of the legal instrument it is issuing, prior legal instruments related to it and any associated RIAS. Express explanations can be quite brief, yet still "pass muster" [see *Portnov*, *supra* at paras 33-34; *Innovative Medicines, supra* at para 44].

[62] I am satisfied that in this case, as no exception set out in *Vavilov* to reasonableness review applies, the standard of review is reasonableness and that the Court is to be guided by *Vavilov* (not

Katz) and the cases of the Federal Court of Appeal that apply *Vavilov* in conducting its reasonableness review.

IV. Analysis

A. OSIP's decision not to add the 837 Patent to the Patent Register for SNDS 670 and SNDS 739 was reasonable

[63] Paragraph 4(3)(c) of the *PMNOC Regulations* sets out the relevant product specificity requirement that must be met for a patent to be listed on the Patent Register in relation to an SNDS. A patent is eligible to be added to the Patent Register if: (i) the SNDS is for a "change in use of the medicinal ingredient"; and (ii) the patent contains a claim for the changed use of the medicinal ingredient that has been approved through the issuance of an NOC in respect of the SNDS.

[64] In relation to SNDS 670, Janssen takes issue with OSIP's determination that: (a) SNDS 670 was not for a change of use of a medicinal ingredient; and (b) that the 837 Patent does not contain a claim for the alleged changed use of the medicinal ingredient. I will address those issues in turn.

[65] In relation to SNDS 739, Janssen takes issue with OSIP's determination that no patent list to add the 837 Patent was filed by Janssen in relation to SNDS 739. The *vires* of the filing date requirement in subsection 4(6) of the *PMNOC Regulations* and its impact on Janssen's ability to add the 837 Patent to the Patent Register in relation to SNDS 739 is addressed separately below.

(1) OSIP's determination that SNDS 670 was not approved for a change in use of the medicinal ingredient was reasonable

[66] Before turning to Janssen's submissions and a consideration of the decision under review, I want to begin by looking at any prior consideration (judicial or otherwise) of the phrase "a change in use of the medicinal ingredient".

[67] The phrase "change in the use of a medicinal ingredient" is not defined in the *Patent Act* or the *PMNOC Regulations*.

[68] One can have reference to subsection 2(1) of the *PMNOC Regulations* which defines a "claim for the use of the medicinal ingredient". Subsection 4(1) permits a first person to submit a patent list in relation to an NDS and paragraph 4(2)(d) provides that a patent on a patent list in relation to an NDS is eligible to be added to the register if the patent contains a "claim for the use of the medicinal ingredient" and the use has been approved through the issuance of an NOC in respect of the NDS. While the focus of paragraph 4(2)(d) is on whether the patent contains a claim for the changed use of a medicinal ingredient, it is focused on the "use of the medicinal ingredient" that is later sought to be "changed" in paragraph 4(3)(c). A "claim for the use of the medicinal ingredient" is defined in subsection 2(1) to mean "a claim for the use of the medicinal ingredient for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms".

[69] In *Abbott Laboratories Ltd v Canada (Attorney General)*, 2008 FCA 244, one of the issues before the Court was whether the patent at issue contained a claim for the very change in use that was approved by the issuance of an NOC with respect to an SNDS. In that case, it was not disputed that a new indication for a drug (to treat NSAID ulcers) constituted a change in use in the medicinal ingredient.

[70] In *Solvay Pharma Inc v Canada (Attorney General)*, 2009 FC 102, this Court dismissed an application for judicial review of a decision of the Minister refusing to add Solvay's patent to the Patent Register pursuant to paragraph 4(3)(c). The Minister had refused to add the patent as the SNDS against which listing was sought did not approve a change in use of the medicinal ingredient. The drug in question, AndroGel, had initially been approved on the basis of safety and efficacy information from a clinical trial following patients to whom the drug was administered for six months. Solvay filed an SNDS to provide additional safety and efficacy information following the extension of that clinical trial to 42 months, including making associated updates to the Product Monograph. An NOC issued in connection with the SNDS and indicated that the reason for the SNDS was to "Update PM with long term extension study results".

[71] Solvay asserted that the SNDS approved a change in use of the medicinal ingredient "as the safe and effective duration of use is extended and important changes to the implied use of the product, as authorized to be described in the Product Monograph, are clearly the essential subject of the SNDS". The Minister rejected this argument and also found that the patent did not contain a claim for the changed use introduced in the Product Monograph by way of the SNDS. Specifically, the Minister held that the patent did not contain "a claim for the changed use of the

medicinal ingredient, for the long term use and relative safety of AndroGel". Rather, the Minister held that the uses of AndroGel are the same uses that were previously approved by an earlier SNDS.

[72] The Court found that the evidence supported the Minister's conclusion that Solvay did not meet either requirement for the listing of its patent on the Patent Register. With respect to the first requirement – that the SNDS represent a change in use of the medicinal ingredient – the Court held:

> [79] The evidence in the record satisfies me that the SNDS, filed on March 11, 2005, did not represent a change in use of the medicinal ingredient of AndroGel testosterone in the form of topical gel. The jurisprudence supports the proposition that "change in use" as that term is used in subsection 4(3) of the NOC Regulations is measured by the approved use in AndroGel's product monograph, as approved by Health Canada, which is described in the Indications and Clinical Use section of that document. AndroGel is indicated for hormone replacement therapy in men suffering from conditions associated with a testosterone deficiency. No change of indication and use was made to Solvay's AndroGel product monograph as a result of the 2006 NOC.

[73] In discussing the amendments to the *PMNOC Regulations* in 2006, the 2006 RIAS also provides some insight into the intended meaning of the phrase "a change in use of the medicinal ingredient", where it states:

> The amendments to section 4 also formally confirm the right to list new patents on the basis of SNDS filings and introduce listing requirements governing that right. Under these requirements, a patent which had been applied for prior to the filing of an SNDS may be submitted in relation to that SNDS provided the purpose of the latter is to obtain approval for a change in use of the medicinal

> ingredient (i.e. a new method of use or new indication), a change in formulation or a change in dosage form and the patent contains a claim to the formulation, dosage form or use so changed…
>
> [Emphasis added.]

(a) ***Janssen's submissions***

[74] Janssen asserts that OSIP's determination that SNDS 670 was not approved for a change in use is an improper fettering of OSIP's decision making power and is unreasonable. If a clinician's change in treatment duration or in prescribing practices would be changed by an SNDS, Janssen asserts that this should be sufficient to establish a change in use.

[75] Janssen asserts that OSIP's decision was unreasonable in light of the evidence before them – namely, the expert statement of Dr. Feagan and the two studies. In relation to Dr. Feagen, Janssen asserts that his evidence clearly demonstrated that the additional safety data would change prescribing practices of a community gastroenterologist. In the absence of any competing evidence procured by OSIP, Janssen asserts that there is no reasonable basis upon which OSIP could conclude that the approved health and safety data regarding the 96-week treatment and safety profile of STELARA in SNDS 670 is not a change in use.

[76] Janssen also points to the Sandborn and Panaccione studies, in which Janssen asserts the authors commented on the need for longer-term data to confirm findings of no increased malignancy risk with IL-12/23 inhibition. Janssen asserts that SNDS 670 provided that longer-term safety data that the authors called for and that Dr. Feagan stated would bring comfort or

confidence to Canadian clinicians to prescribe STELARA beyond 44 weeks. While OSIP held that a clinician who was "up to date" on ulcerative colitis research could have referred to either of the two studies before the approval of SNDS 670 to obtain information and "comfort" regarding prescribing STELARA for a longer period of time, Janssen says that this is irrelevant and does not change the fact that the addition of safety data to the approved Product Monograph is a change in use. Moreover, Janssen asserts that OSIP's finding is unsupported by any expert evidence and importantly, would not apply to clinicians who are not up to date on ulcerative colitis research, which is the sector of clinicians that Dr. Feagan was opining about. Janssen notes that there is no requirement in paragraph 4(3)(c) that all physicians change their prescribing practices, rather simply that there be a change in use and that Janssen has demonstrated such a change.

[77] Janssen further asserts that OSIP unreasonably applied *Solvay* to conclude that the addition of safety data can never be a change in use, whereas there is no express exclusion of safety data from the possible changes in use that can be covered by paragraph 4(3)(c) of the *PMNOC Regulations*. At the hearing, Janssen argued that OSIP was "blinded" by the *Solvay* decision and it tainted the entirety of OSIP's assessment of the meaning of "change in use".

[78] Moreover, Janssen asserts that the *Solvay* decision was guided by the evidentiary record before OSIP and in this case, the evidentiary record is distinguishable. Specifically:

A. In *Solvay*, there was no evidence before the Minister to support the conclusion that the SNDS contained a change in use, whereas in this case, the Minister had the evidence of Dr. Feagan and the two studies.

B. In *Solvay*, the Office of Patent Submissions and Liaison had sought the opinion of Health Canada experts, who concluded that there was no change in use, whereas in this case, the Minister did not adduce any of its own expert evidence or contradict Janssen's expert evidence.

C. In *Solvay*, the Court held that the patent claims contain no limitation on the duration of use and that the patent did not address the issue of the duration of testosterone therapy, whereas in this case, the nexus to the patent is present as the 837 Patent [redacted]

[79] Janssen asserts that OSIP failed to take into consideration these distinctions and that each of the aforementioned points of distinction alone undermines OSIP's "strong reliance" on *Solvay* and establish that OSIP's decision was based on a misapprehension of the law and evidence, thus rendering it unreasonable.

[80] Janssen further asserts that OSIP's interpretation of the product specificity requirement of a "change in use of the medicinal ingredient" is inconsistent with the context, language and purpose of the *Patent Act* and the *PMNOC Regulations*. Janssen asserts that the Governor in Council enacted paragraph 4(3)(c) with the broad terminology of change in use and the 2006 RIAS confirms an intention that a change in use was broad enough to include a new indication and a new method of use. Janssen asserts that the RIAS supports an understanding that change in use is not

to be restricted to changes to particular sections of the Product Monograph and that a change in use includes changes in the duration of treatment.

[81] Janssen asserts that the *PMNOC Regulations* must be read in line with the purpose of the *Patent Act* and should be considered in light of the societal imperative of encouraging new and better medical therapies and the difficulties associated with protecting pharmaceutical patent rights by way of conventional infringement litigation. Janssen asserts that the *PMNOC Regulations* are intended to protect that which the innovator has invested time and money to test and have approved for sale (or put different, to protect the patentee's contribution to the public through skill and ingenuity). The clinical trial data in SNDS 670 is the result of time and money invested by Janssen to obtain safety data for STELARA in patients with moderately or severely active ulcerative colitis, the exact type of substantive change intended to be protected by the *PMNOC Regulations*. By adopting an unduly restrictive meaning to change in use, Janssen asserts that it is being improperly denied the full benefit of the patent protection it should be provided as part of the balance of the early working exception. Such an unduly restrictive meaning also, according to Janssen, reduces incentives to research the safety and efficacy of existing medicinal ingredients because it stands in the way of listing patents tied to such research.

[82] Moreover, Janssen notes that the product specificity requirements were intended to prevent the listing of patents in respect of SNDSs for purely administrative changes (such as changes of manufacturer) and asserts that SNDS 670 is not akin to an administrative change.

(b) ***Consideration of Janssen's submissions***

[83] In interpreting a "change in use of the medicinal ingredient", the 2006 RIAS provides guidance that a change in use can be a new indication or a new method of use, but cannot be an administrative change (such as a change in drug or company name). There is no dispute that SNDS 670 was not for a new indication, as the treatment of ulcerative colitis was added to the Product Monograph by SNDS 739.

[84] The question then becomes whether, on the record before OSIP and considering the text, context and purpose of section 4(3)(c) of the *PMNOC Regulations*, the guidance provided by the RIAS, this Court's decision in *Solvay* and Janssen's submissions, OSIP reasonably determined that SNDS 670 was not approved for a change in use.

[85] In reaching their decision, OSIP considered the following evidence that was before them:

A. The existing Product Monograph as approved in relation to SNDS 739 approved STELARA to be used to treat adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies. That approved use did not include a limitation on the duration of time STELARA could be used to treat ulcerative colitis (notwithstanding that the clinical trial data was limited to 44 weeks). Moreover, SNDS 670 did not seek to add a limitation on the duration of time STELARA could be used to treat ulcerative colitis.

B. The relevant NOC stated that SNDS 670 was approved for updates to the Product Monograph.

C. SNDS 670 did not result in any changes to the "Indications and Clinical Use" section of the product monograph, but rather only added safety and efficacy date to the "Clinical Trial Adverse Drug Reaction" and "Study Demographics and Trial Design" sections of the Product Monograph.

D. Dr. Feagan's evidence was that community gastroenterologists would "take comfort" in the additional information and would be more willing to prescribe or be more comfortable prescribing STELARA based on the additional information contained in the Product Monograph. However, he did not state that community gastroenterologists (or any other gastroenterologists) would not have prescribed STELARA for longer than 44 weeks based on the prior Product Monograph.

E. In Janssen's Product Information Regulatory Enrollment Process form, Janssen wrote (as opposed to checking a box) in relation to SNDS 670 that "there are no changes to the indication/Use/Dosage (including the maximum daily dose)".

[86] OSIP properly considered the aforementioned evidence, the text, context and purpose of the *PMNOC Regulations* (which I will address more fully below), considered the guidance provided in the 2006 RIAS, considered this Court's decision in *Solvay* (which I will also address in more detail below) and considered the submissions of Janssen before concluding as follows:

The OSIP recognizes that a change to the method of use of a medicinal ingredient can be reflected in sections of the product monograph other than the "Indications and Clinical Use" section. For example, the "Contraindications", "Warning and Precautions", and "Dosage and Administration" sections. However, the OSIP disagrees with Janssen's characterization that SNDS 244670 was approved for such a change. Rather, as detailed above, the OSIP is of the view that SNDS 244670 was approved for updates to the product monograph to include results from the long-term extensions of two Phase 3 studies for the treatment of adult patients with moderately to severely active Crohn's disease or ulcerative colitis.

Following the approval of SNDS 224739, STELARA (I.V.) could be used in the treatment of ulcerative colitis for an indefinite period of time. Both Janssen and Dr. Feagan submit that a clinician would change their prescribing practices upon reading the two sentences added to the STELARA (I.V.) product monograph following the approval of SNDS 244670. It is the position of Janssen and Dr. Feagan that the clinician practice would have changed given their increased comfort in prescribing STELARA (I.V.) beyond 44 weeks. However a clinician's reluctance to prescribe a drug is not a limitation on the approved use of that drug.

Clinicians were not prevented from prescribing the drug for the long-term use in treating ulcerative colitis. Dr. Feagan states at paragraph 21 that a community gastroenterologist may not be up to date on ulcerative colitis research and would have concerns about the potential for issues to arise after one year's administration of STELARA (I.V.). Therefore, a clinician who was up to date on ulcerative colitis could have referred to either of the two studies enclosed in Janssen's representations before the approval of SNDS 244670 and could have obtained the comfort needed to change their prescribing practices in accordance with the use for which SNDS 224739 was approved. In any event, a submission approved for additional data that could provide a clinician more confidence in prescribing a drug long-term is not sufficient for the submission to be considered as having been approved for a change in use of the drug if the indication never included a temporal restriction on its use.

Implicit in Janssen's position is the idea that the use of STELARA (I.V.) was limited by the period of time during which ustekinumab was administered to patients in the clinical trials underlying the approval of SNDS 224739. Janssen had made this position explicit on page 7 of its representations, where it states that the use set out in SNDS 224739 is for the treatment of ulcerative colitis "for up to 44 weeks". The OSIP disagrees with Janssen's position that the

> length of time for which STELARA (I.V.) could be used was limited. No such limitation was provided in the STELARA (I.V.) product monograph. As STELARA (I.V.) was approved for the use in treating ulcerative colitis for an indefinite period of time, the inclusion of updates to the product monograph to include results from the long-term extension of two Phase 3 studies could not have changed the approved use of STELARA (I.V.), irrespective of any additional confidence the information may provide clinicians.
>
> As noted above, the Federal Court considered substantially similar facts in *Solvay* and held that the inclusion of safety and efficacy information into the product monograph following an extension of a clinical trial did not constitute a change to the use of the medicinal ingredient as required by paragraph 4(3)(c) of the *PM(NOC) Regulations*. Similarly, the inclusion of updates to the STELARA (I.V.) product monograph to include results from the long-term extensions of two Phase 3 studies does not meet the requirements of paragraph 4(3)(c) of the *PM(NOC) Regulations*.
>
> [Emphasis added.]

[87] I find that OSIP's decision is based on an internally coherent and rational chain of analysis and is justified in relation to the facts and law that constrain OSIP. I see nothing unreasonable about OSIP's focus, in its interpretation and application of paragraph 4(3)(c), on the actual approved use of STELARA (i.e. the use as approved by the Minister) and not the prescribing practices of clinicians, as that which is being "changed" in subsection 4(3) is the use as previously approved by the Minister.

[88] I will now turn to address the specific arguments raised by Janssen.

[89] Turning first to the evidence of Dr. Feagan, OSIP clearly considered Dr. Feagan's evidence and did not dispute his statements regarding the influence that the additional safety and efficacy data would have on certain gastroenterologists. However, OSIP's decision turned on their

determination that STELARA was approved for use to treat ulcerative colitis with no temporal limitation on its use and that a clinician's reluctance to prescribe a drug is not a limitation on the approved use of that drug. Similarly, OSIP considered the two studies and regardless of whether a clinician may or may not have read the studies, OSIP found that a submission approved for additional data that could provide a clinician more confidence in prescribing a drug long-term is not sufficient for the submission to be considered as having been approved for a change in use of the drug if the indication never included a temporal restriction on its use. I see no error on OSIP's part in reaching these conclusions.

[90] With respect to *Solvay*, I reject Janssen's characterization of OSIP's treatment of the decision. On a fair reading, OSIP's reasons do not state that the addition of safety data can never be a change in use. Rather, OSIP considered this Court's decision in *Solvay*, outlined the facts of that case and summarized the Court's findings. OSIP noted the factual similarities between this case and *Solvay* and noted that its finding was supported by the Court's reasoning in *Solvay*.

[91] Janssen's suggestion that OSIP was "blinded" by *Solvay* and that *Solvay* tainted the entirety of OSIP's decision is baseless. OSIP is obligated to follow applicable precedents originating from this Court [see *Bank of Montreal v Li*, 2020 FCA 22 at para 37] and given the factual similarities between the two cases, it was reasonable for OSIP to rely on *Solvay* as an influential precedent. Moreover, a fair reading of OSIP's 23-page decision reveals that OSIP considered all relevant factors in interpreting and applying paragraph 4(3)(c), not just *Solvay*.

[92] While Janssen has attempted to distinguish *Solvay* and faults OSIP for failing to take into account the factual differences between the two cases, I would note that Janssen did not raise *Solvay* with OSIP or put any of its purported distinguishing facts to OSIP to suggest that OSIP should not follow *Solvay*. In any event, I am not satisfied that the factual differences identified by Janssen render OSIP's reliance on *Solvay* unreasonable. OSIP did not state that the two cases were identical, but rather that they were similar and the presence or absence of expert evidence did not play a central role in OSIP's determination that there had not been a change in use in either case. As for Janssen's third argument, that argument relates to the next issue and thus I will address it there.

[93] Moreover, while Janssen made much of the fact that Dr. Feagan's evidence was uncontradicted and that OSIP had failed to secure its own expert evidence on the issue of change of use, this ignores the fact that the burden rested on Janssen to demonstrate that it meets the product specificity requirements of the *PMNOC Regulations*. OSIP was under no obligation to produce an expert statement in response to Dr. Feagan or that otherwise addressed the issue of change in issue. As noted by the Respondent, the only obligation on OSIP was to make a reasonable and procedurally fair determination of the issues before them and in doing so, OSIP was entitled to rely on OSIP's own expertise.

[94] I also reject Janssen's submissions that OSIP's interpretation of the product specificity requirement is inconsistent with the context, language and purpose of the *Patent Act* and *PMNOC Regulations*. I begin by noting that there is no express inconsistency between OSIP's interpretation

of subsection 4(3) and the *Patent Act*. Rather, what Janssen asserts is that there is a "conceptual" inconsistency between the two.

[95] It must be recalled that OSIP agreed with Janssen's interpretation of subsection 4(3) in part, expressly acknowledging that a change in use of a medicinal ingredient includes a change to the method of use (as recognized in the 2006 RIAS) and that a change to the method of use can be reflected in sections of the Product Monograph other than the "Indications and Clinical Use" section. Where OSIP and Janssen part ways is on the question of whether a change in use of the medicinal ingredient in subsection 4(3) includes the "change" asserted by Janssen.

[96] It is clear from a review of OSIP's reasons that OSIP was very much alive to the dispute between OSIP and Janssen as to the interpretation of subsection 4(3). In considering the reasonableness of OSIP's interpretation of subsection 4(3), the Court is guided by the following commentary of the Federal Court of Appeal in *Canada (Minister of Citizenship and Immigration) v Mason*, 2021 FCA 156:

> [16] *Hillier* begins by reminding reviewing courts of three basic things they should appreciate when conducting reasonableness review. First, in many cases, administrators may have a range of interpretations of legislation open to them based on the text, context and purpose of the legislation. Second, in particular cases, administrators may have a better appreciation of that range than courts because of their specialization and expertise. And, third, the legislation--the law on the books that reviewing courts must follow--gives administrators the responsibility to interpret the legislation, not reviewing courts.
>
> [17] For these reasons, *Hillier* tells reviewing courts to conduct themselves in a way that gives administrators the space the legislator intends them to have, yet still hold them accountable. Reviewing courts can do this by conducting a preliminary analysis of the text,

context and purpose of the legislation just to understand the lay of the land before they examine the administrators' reasons. But the lay of the land is as far as they should go. They should not make any definitive judgments and conclusions themselves. That would take them down the road of creating their own yardstick and measuring the administrator's interpretation to make sure it fits.

[18] Instead, *Hillier* recommends (at para. 16) that a reviewing court should "focus on the administrator's interpretation, noting what the administrator invokes in support of it and what the parties raise for or against it", trying to understand where the administrator was coming from and why it ruled the way it did: *Hillier* at paragraph 16.

[19] Under this approach, the reviewing court does not act in an "external" way, i.e., "arrive at a definitive conclusion about the best way to read the statutory provision under review before considering how the [administrator's] interpretation matched up with [the] preferred reading". Rather, as Professor Daly has observed, the reviewing court acts in an "internal" way, i.e., "a relatively cursory examination of the provision at issue, with a view to analyzing the robustness of the [administrator's] interpretation". See Paul Daly, "Waiting for Godot: Canadian Administrative Law in 2019" (online: https://canlii.ca/t/t23p at 11).

[20] By necessary implication, *Vavilov* supports the *Hillier* approach. *Vavilov* warns us that even though reviewing courts are accustomed in other contexts to interpret legislative provisions themselves, when conducting reasonableness review of administrative interpretations they should avoid that. Reviewing courts must not "ask how they themselves would have resolved [the] issue", "undertake a *de novo* analysis", "ask itself what the correct decision would have been" or "[decide] the issue themselves": *Vavilov,* at paragraphs 75, 83 and 116. In other words, reviewing courts must not "make [their] own yardstick and then use that yardstick to measure what the administrator did": *Vavilov,* at paragraph 83, citing *Delios,* at paragraph 28. Instead, reviewing courts must exercise "judicial restraint" and respect "the distinct role of administrative decision makers": *Vavilov,* at paragraph 75. They are to do this by examining the administrator's reasons with "respectful attention" and by "seeking to understand the reasoning process": *Vavilov,* at paragraph 84.

[97] Determining the meaning of “change in use of the medicinal ingredient” very much falls within OSIP’s area of expertise. In arriving at their interpretation of that phrase, OSIP considered the plain wording of subsection 4(3) and related provisions of the *PMNOC Regulations* and the intent of the 2006 amendments to subsection 4(3) as reflected in the 2006 RIAS (as cited above) and as acknowledged by the Court of Appeal in *GD Searle & Co v Canada (Health)*, 2009 FCA 35. I see nothing unreasonable with that approach and OSIP’s reasons allow the Court to understand how the text, context and purpose of the *PMNOC Regulations* factored into its reasoning process in arriving at its interpretation of subsection 4(3).

[98] There is no dispute between the parties as to the purpose of the *Patent Act* and the protections that it affords to innovators. However, I reject Janssen’s assertion that OSIP’s interpretation improperly denies Janssen the full benefit of the patent protection it should be provided as part of the balance of the early working exception. As stated above, the *PMNOC Regulations* seek to balance the patent rights associated with innovative drugs against the timely market entry of lower-priced competitor drugs [see *Fresenius Kabi Canada Ltd* v *Canada (Health)*, 2020 FC 1013]. In striking that balance, the product specificity requirements reflected in section 4 inherently acknowledge that not every patent is eligible for listing on the Patent Register, notwithstanding the time and money invested by the innovator. As noted by this Court in *Solvay*, supra at paragraph 69:

> …Under the heading Patent Listing Requirements, the RIAS states, at page 1511, that the NOC Regulations "are intended to operate as a very potent patent enforcement mechanism", citing the 24-month automatic stay when an innovator launches a prohibition application, adding that "it is this very potency which calls for moderation in the application" with the result that "[o]nly those

> patents which meet the current timing, subject matter and relevance requirements set out in section 4 of the regulations are entitled to be added to ... register and to the concurrent protection of the 24-month stay."
>
> [Emphasis added.]

[99] It must also be recalled that Janssen is not without the protections of the *Patent Act* under OSIP's interpretation, retaining the right to bring a patent infringement action outside of the PMNOC regime.

[100] Subsection 4(3) limits the subset of patents eligible for listing and I am not satisfied that Janssen has demonstrated how OSIP's interpretation unreasonably denies Janssen the patent protection intended by the balance struck by the *PMNOC Regulations*.

[101] Having determined that OSIP's decision that SNDS 670 did not meet the first product specificity requirement of paragraph 4(3)(c) was reasonable, Janssen's application in relation to the listing of the 837 patent in relation to SNDS 670 cannot succeed. While I need not do so, I will nonetheless go on to consider whether OSIP's determination in relation to the second product specificity requirement was reasonable.

(2) OSIP's determination that the 837 Patent was not eligible to be added to the Patent Register as it did not meet the product specificity requirements of paragraph 4(3)(c) was reasonable

[102] In considering whether the patent sought to be listed in relation to a particular SNDS meets the product specificity requirement of paragraph 4(3)(c) of the *PMNOC Regulations*, OSIP was

required to apply what is known as the *Abbott* test, as originally set out by Justice Hughes in *Abbott Laboratories Limited v Canada (Attorney General)*, 2008 FC 700 and later affirmed in *Canada (Attorney General) v Abbott Laboratories Limited*, 2008 FCA 354 and applied by the Federal Court of Appeal in a number of other cases, such as *Searle*, *supra*, *Purdue Pharma v Canada (Attorney General)*, 2011 FCA 132, *Gilead Sciences Canada Inc v Canada (Health)*, 2012 FCA 254 and *Eli Lilly Canada Inc v Canada (Attorney General)*, 2015 FCA 166.

[103] Pursuant to the *Abbott* test, OSIP was required to consider the following three questions: (i) what does the 837 Patent claim? (ii) what is the change approved by SNDS 670? and (iii) does the 837 Patent claim the very change approved in SNDS 670?

[104] The current version of the *PMNOC Regulations* makes product specificity between the patent claims and the NOC for the approved drug a key requirement for a patent to be considered eligible for listing on the patent register [see *Gilead*, *supra* at para 33]. Under the prior version of the *PMNOC Regulations*, if the patent claims were shown merely to be "relevant to" the approved drug, the submitted patents were generally accepted for listing. The wording of the current *PMNOC Regulations*, as well as their object and purpose, suggest that the product specificity requirement sets a high threshold of consistency between the patent claims and the NOC [see *Gilead*, *supra* at para 40].

[105] In *Canada* (*Attorney General*) *v Abbott Laboratories Limited*, 2008 FCA 244, leave to appeal refused, [2008] SCCA No 408, [2008] 3 SCR v (*Abbott Prevacid*) [*Abbott 244*], Justice Pelletier commented on the level of specificity required under paragraph 4(3)(*c*). The debate there

concerned the eligibility for listing of a patent in relation to an NOC issued pursuant to an SNDS approving a new use. The Federal Court concluded that the patent was eligible for listing because the patent could be construed as including the new approved use notwithstanding that it was not explicitly claimed in the patent. The Federal Court of Appeal disagreed, stating at paragraphs 47 and 49:

> It stands to reason that if a patent must contain a claim for the changed use identified in Abbott's SNDS, that patent cannot simply claim the use which formed the basis of the original submission. Such a patent does not specifically claim the changed use, even though the changed use may come within the claims of the patent. In other words, the Regulations envisage as a condition of listing a patent in respect of a change in the use of a medicinal ingredient that the patent specifically claims the changed use as opposed to non-specific claims which are wide enough to include the changed use.
>
> […]
>
> I conclude that paragraph 4(3)(*c*) of the Regulations requires, as a condition of listing a patent on the Patent Register, that the patent must specifically claim the very change in use which was approved by the issuance of a Notice of Compliance with respect to an SNDS.
>
> [Emphasis added.]

[106] Before turning to Janssen's submission on this application, I note that before OSIP, Janssen asserted:

> Further and contrary to the clear wording of the *Regulations*, which simply requires "a claim for the changed use … that has been approved", in its Letter, the OPML instead identified what it framed as the very change approved in SNDS 244670 and asked whether the '837 Patent claims the "very change" approved in SNDS 244670. In doing so, the OPML's approach was too narrow and required a nexus between the change approved in SNDS 244670 and

> the ‘837 Patent that is more stringent than what is in fact required by the *Regulations*.

[107] Janssen’s aforementioned description of the product specificity requirement for the 837 Patent as prescribed by subsection 4(3) is reflective of the approach prior to the 2006 amendments to the *PMNOC Regulations* and inconsistent with the clear enunciation of the applicable test as affirmed repeatedly by the Federal Court of Appeal.

[108] Before this Court, Janssen persists with this position in part, refusing in its written submissions to agree with OSIP’s interpretation of subsection 4(3) and its application of the *Abbott* test, yet taking no issue with the application of the *Abbott* test at the hearing. There is no merit to any suggestion that OSIP has misconstrued the applicable legal test and I find that OSIP properly formulated and applied the *Abbott* test by requiring that the 837 Patent claim the “very change in use” approved for SNDS 670.

[109] Without agreeing with OSIP’s interpretation of the requirements of subsection 4(3), Janssen asserts that OSIP’s decision is unreasonable as the 837 Patent meets the “very change in use” standard, as the 837 Patent contains claims covering the [redacted].

[110] [redacted] do not take issue with OSIP’s determination in relation to step one of the *Abbott* test and [redacted], in simple terms, the 837 Patent claims the use of the antibody to treat ulcerative colitis for at least 44 weeks after week zero or for 44 weeks and after.

[111] For step two of the *Abbott* test, one would have to presume that the change in use is as proposed by Janssen (albeit rejected by OSIP) – namely, the addition of longer term safety data up to 96 weeks that changes prescribing practise so as to prescribe STELARA beyond 44 weeks.

[112] It is at step three of the *Abbott* test that the parties' positions regarding the reasonableness of OSIP's determination greatly diverge. I will begin with OSIP's reasons for decision on step three, which provide as follows:

> The '837 Patent does not contain a claim to the very change for which SNDS 244670 was approved. In particular, the '837 patent does not contain a claim directed toward the use of ustekinumab for the treatment of moderately to severely active ulcerative colitis wherein ustekinumab is administered for 96 weeks as maintenance therapy.
>
> As explained above and as set out by the Federal Court of Appeal in *Abbott FCA* and *Searle FCA*, in order to meet the requirements of paragraph 4(3)(c) of the *PM(NOC) Regulations*, the patent must contain a claim to the very changed use. While the '837 patent contains claims directed towards the use of ustekinumab for the treatment of moderately to severely active ulcerative colitis, the duration of time within which the use of ustekinumab is claimed as a maintenance therapy is not limited to 96 weeks. The OSIP is of the view that reference at page 52 of the '837 patent description that the anti-IL-12/IL-23p40 antibody, which may be ustekinumab, could be administered for a total of two years does not restrict the duration of time within which the anti-IL-12/IL-23p40 antibody could be used in any of the 837 patent claims.

[113] Janssen asserts that OSIP unreasonably imposed a standard of "exact matching" between claim language. Janssen asserts that it was sufficient that the claims of the 837 Patent include [redacted]

[114] Janssen asserts that OSIP placed unreasonable reliance on *Abbott 244*, which Janssen asserts is distinguishable from this case. Janssen asserts that in *Abbott 244*, the issue was whether a patent with claims to the treatment of ulcers generally claimed the very change in an SNDS approved for a new use of a drug to treat ulcers caused by non-steroidal anti-inflammatory drugs. In that case, the Court held that the patent did not specifically claim the changed use even though the changed use may come within the claims of the patent. By contrast, Janssen asserts that at least some of the 837 Patent's claims provide the required specificity [redacted]

[115] Janssen further asserts that *Solvay* is distinguishable, as none of the claims of the patent at issue contained a claim directed to the duration of treatment. By contrast, Janssen asserts that the 837 Patent has "claims that include [redacted]

[116] Janssen urged the Court to find that the circumstances in *Eli Lilly Canada Inc v Canada (Attorney General)*, 2015 FCA 166, were more akin to those in this case and that OSIP should have followed *Eli Lilly* rather than *Abbott 244* (despite Janssen not raising either authority with OSIP). In *Eli Lilly*, one of the issues before the Federal Court of Appeal was whether this Court had erred in determining whether the formulation claimed in the relevant patent was the formulation found in the appellant's drug submission for Trifexis. Janssen asserts that *Eli Lilly* is instructive as the Federal Court of Appeal held that a claim to a broader class of compound includes a specific compound in that class.

[117] I am not satisfied that Janssen has established that OSIP's determination regarding step three of the *Abbott* test is unreasonable. Rather, what Janssen urges the Court to do is to reassess the issue and come to a different result, which is not the role of the Court on an application for judicial review.

[118] I find that there was nothing unreasonable in OSIP's reliance on *Abbott 244*, which was a paragraph 4(3)(c) case. While Janssen urges the Court to find that *Eli Lilly* has somehow "overtaken" *Abbott 244*, I am not satisfied that that is the case. *Eli Lilly* was a change in formulation case, not a change in use case and on that basis alone, I find that it is distinguishable. More specifically, I agree with the Respondent that in *Eli Lilly*, at the first step of the *Abbott* test, the Federal Court of Appeal found that the general class of compounds that the patent claimed actually included the very specific formulation that was approved in the NDS. The Federal Court of Appeal found that in such circumstances, this Court was unreasonable in requiring identical wording at step three of the *Abbott* test. The circumstances in this case are distinct.

[119] As confirmed in *Abbott 244*, the *PMNOC Regulations* require that a patent specifically claim the change in use, as opposed to broader claims that are wide enough to subsume the specific change in use. With that principle in mind, I see nothing unreasonable in OSIP's determination that a patent having broad "temporal features" (as described by Janssen) for the use of ustekinumab for an indefinite period of time (for 44 weeks or more) is not the very change in use approved in relation to SNDS 670 (even on Janssen's interpretation thereof) which specifically included safety data to only 96 weeks.

[120] With respect to *Solvay*, I note that OSIP did not refer to *Solvay* in its reasons for decision on this issue.

[121] Accordingly, even if Janssen had established that OSIP's decision in relation to a "change in use of the medicinal ingredient" was unreasonable, Janssen's application in relation to the listing of the 837 patent in relation to SNDS 670 could not succeed on this ground either.

(3) OSIP's determination that Janssen failed to provide a patent list in relation to SNDS 739 was reasonable

[122] Janssen asserts that OSIP's determination that Janssen failed to file a patent list for the 837 Patent in relation to SNDS 739 was unreasonable as a patent list was filed for the 837 Patent within 30 days of the issuance of the 837 Patent and Janssen sought, by way of its September 14, 2022 submission, to add SNDS 739 to an already submitted patent list, given that it had been raised by OSIP in its preliminary decision letter. Janssen asserts that subsection 4(7) of the *PMNOC Regulations* obligates a first person to keep their patent list up to date, so the Minister clearly contemplated amendments to a patent list.

[123] Moreover, Janssen asserts that the *PMNOC Regulations* do not contain a requirement to add to a patent list by using Form IV, but rather only that a first person must provide all of the information set out in subsection 4(4). Janssen submits that its September 14, 2022 submission provided all of the necessary information prescribed by subsection 4(4). As such, to refuse to add the 837 Patent to the Patent Register on the basis that Janssen did not provide the same information

by way of a Form IV would be an unreasonably harsh result and an extreme example of "form over substance".

[124] Turning to OSIP's reasons for decision, OSIP held:

> The *PM(NOC) Regulations* do not permit a patent list to be submitted in relation to multiple submissions. As noted above, subsection 4(1) of the *PM(NOC) Regulations* allows a first person to seek to add a patent to the Patent Register by submitting a patent list to the Minister. The content of a patent list is prescribed by subsection 4(4). Notably, paragraph 4(4)(a) of the *PM(NOC) Regulations* requires that the patent list identify the submissions to which the patent list relates. The patent list submitted in accordance with 4(6) provides a section dedicated for this purpose and allows the first person to identify the submission in relation to which it submits the patent list.
>
> The patent lists submitted by Janssen seeking to add the '837 patent to the Patent Register identified SNDS 244670. Janssen did not seek to add the '837 patent to the Patent Register against SNDS 224739. Janssen's suggestion that the submission in relation to which a patent list was filed can shift after its receipt would ignore the operation of paragraph 4(4)(a) of the *PM(NOC) Regulations*. The statements made on page 7 of Janssen's representations purporting to change the submission in relation to which its patent lists were submitted are not akin to filing a patent list in accordance with subsection 4(1). As such, the OSIP is of the view that no patent list was filed in relation to SNDS 224739 and that Janssen has not met the requirements to seek to add the '837 patent against SNDS 224739.
>
> In addition, the OSIP disagrees with Janssen's view that the '837 patent was considered for addition to the Patent Register against SNDS 224739 in its preliminary decision letter dated July 29, 2022. Rather, the OSIP is of the view that the use for which SNDS 224739 was approved was included in its preliminary decision letter to contextualize the change for which SNDS 244670 was approved.

[125] I see nothing unreasonable in OSIP's analysis and determination of this issue. OSIP properly considered the requirements of subsection 4(4) of the *PMNOC Regulations*, noting that the regulations prescribe one SNDS per patent list (as also set out in Form IV) and to permit Janssen to add a second SNDS to a pre-existing patent list would run afoul of the express mandatory language of paragraph 4(4)(a), which limits a patent list to one SNDS.

[126] Moreover, I find nothing unreasonable in OSIP's determination that Janssen's attempt to change/amend the SNDS in relation to which its patent lists for the 837 Patent were submitted was not akin to filing a patent list. Janssen was well aware of the requirement to file one patent list per SNDS, given that it had already filed multiple Form IVs in relation to STELARA and given the language of paragraph 4(4)(a). Why Janssen did not file a patent list for SNDS 739 in relation to the 837 Patent is unknown, but Janssen is bound by the consequences of that decision.

[127] While not expressly addressed by OSIP, I would note that, even if I were inclined to find that Janssen's September 14, 2022 submission could constitute a patent list for the 837 Patent, Janssen's September 14, 2022 submission did not, in fact, contain all of the information required by subsection 4(4) of the *PMNOC Regulations*. For example, the submission does not set out the Canadian patent filing date, the patent issue date, the patent expiry date or the address for service of the first person of a NOA. While that information might otherwise be available to OSIP in other documents, there is no obligation on the part of OSIP to search for missing information. Rather, the obligation rested on Janssen to clearly identify all of the information required by subsection 4(4) in its "patent list" [see *Hoffmann-La Roche Ltd v Canada (Health)*, 2005 FC 1415 at para 21].

[128] As acknowledged by Janssen in its written submissions, the Minister has the discretion to determine the manner in which a patent list is to be submitted and the Minister has done so by requiring the use of Form IV. Form IV requires that, in completing the form, a first person provide all of the mandatory information required by subsection 4(4) of the *PMNOC Regulations*. Janssen has pointed to nothing that is unreasonable about the Minister's adoption of Form IV or the Minister's requirement that it be completed by first persons. Rather, Janssen appears to be inviting the Court to find that it was open to the Minister to accept a deviation to the Minister's practices, but without pointing to any error made by the Minister or any lack of coherent and rational chain of analysis in the Minister's determination.

[129] Janssen further asserts that in footnote 2 of its September 14, 2022 submission, Janssen requested that if OSIP rejected their request to add SNDS 739 to the patent list for the 837 Patent, that Janssen be advised of the reason and given an opportunity to respond. Janssen asserts that their procedural fairness rights were breached as OSIP never gave them a chance to address the issue. I reject this assertion. I am not satisfied that OSIP was under any duty to alert Janssen as to its views on Janssen's failure to file a Form IV patent list for SNDS 739 and to provide Janssen an opportunity to make further submissions on the issue. The burden rested on Janssen to take the appropriate steps to submit a patent list for the 837 Patent in relation to each of its SNDSs within the time limits prescribed by the *PMNOC Regulations* and in any event, by September 14, 2022, the deadline for submission of a patent list for the 837 Patent for SNDS 739 had already passed.

[130] In its reply oral submissions, Janssen asserted that it also relied on section 32 of the *Interpretation Act*, RSC 1985, c I-21, which provides that "where a form is prescribed, deviations

from that form, not affecting the substance or calculated to mislead, do not invalidate the form used" and identified two decisions of the Federal Court addressing section 32. This argument, and the related statute and case law, were not raised by Janssen in its memorandum of fact and law filed in this proceeding (nor were they raised in Janssen's submissions before OSIP) and did not arise from something unexpectedly raised by the Respondent in their oral submissions. In the circumstances, it is not open to Janssen to raise the argument now and most certainly inappropriate to attempt to raise it only in reply. Accordingly, I will not consider this portion of Janssen's submission, as to do so would be unfair to the Respondent.

[131] For the reasons stated above, I am not satisfied that Janssen has demonstrated that OSIP's determination that Janssen did not file a patent list for the 837 Patent for SNDS 739 was unreasonable. While I appreciate that Janssen views the impact of OSIP's determination of this issue as unreasonably harsh, the *PMNOC Regulations* contain numerous mandatory requirements (such as the 30 day requirement in subsection 4(6)) that result in harsh consequences when not met. This is a function of the nature of the regulatory regime [see *Fournier Pharma Inc v Canada (Attorney General)*, [1999] 1 FC 327; *Immunex Corporation v Canada (Health)*, 2008 FC 1409; *Merck Canada Inc v Canada (Minister of Health)*, 2021 FC 345].

[132] My finding on this issue is sufficient to dispose of Janssen's application for judicial review in relation to OSIP's refusal to list the 837 Patent in relation to SNDS 739. Notwithstanding, I will nonetheless go on to consider whether the Canadian filing date requirement in subsection 4(6) of the *PMNOC Regulations* is *ultra vires* the *Patent Act*.

B. The Canadian Filing Date Requirement in Subsection 4(6) of the *PMNOC Regulations* is *intra vires* the *Patent Act*

[133] Notwithstanding OSIP's determination that no patent list had been filed for the 837 Patent in relation to SNDS 739, OSIP went on to consider whether the 837 Patent could have been listed against SNDS 739 if such a patent list had been provided. OSIP determined that Janssen would not have met the timing requirement in subsection 4(6) as the 837 Patent was filed in Canada after SNDS 739 was filed. OSIP further determined that the consideration of the claim date or priority date of the 837 Patent when assessing the application of subsection 4(6) would be to ignore the clear wording of the *PMNOC Regulations* (which states "filing date in Canada"), circumvent the strict timing requirements and undo the balance struck by the *PMNOC Regulations* and subsection 55.2(1) of the *Act*.

[134] Janssen does not take issue with OSIP's interpretation of subsection 4(6) and acknowledges that the filing date requirement in subsection 4(6) refers to the date that the patent application was filed in Canada, rather than the claim date or priority date. Rather, Janssen asserted before OSIP and now before this Court that the filing date requirement in subsection 4(6) is *ultra vires*.

[135] In the alternative, Janssen asserts that the Canadian filing date is an illogical, irrational and/or arbitrary date to employ in subsection 4(6). However, Janssen did not, in its written submissions and at the hearing, develop these arguments and as such, I will not consider them separately. Rather, I will consider the arguments as they were advanced by Janssen.

[136] In conducting a reasonableness review of this issue, the Court is to determine the constraints on the Governor in Council and whether the Governor in Council remained within them, with the focus on any reasons given by the Governor in Council.

[137] In this case, the parties agree that the primary constraint on the Governor in Council is subsection 55.2(4) of the *Patent Act* (as set out above), which contains the Governor in Council's regulation making authority. Section 55.2(4) of the *Patent Act* provides for a broad grant of authority for the making of such regulations as the Governor in Council "considers necessary for preventing the infringement of a patent" by any person who makes use of the early working exception. The specific authority outlined in paragraphs (a) to (e) is said not to limit the generality of the initial grant. Rather, the only limitation lies in the limited purpose for which regulations may be made – the prevention of infringement by those who use the patented invention for the early working exception [see *Apotex Inc v Merck & Co Inc*, 2009 FCA 187 at para 40]. As such, in enacting the *PMNOC Regulations*, the Governor in Council had to interpret the scope of its regulation making power and enact a regulation (subsection 4(6)) that, in its reasonable view, was within that power [see *Innovative Medicines*, *supra* at para 44].

[138] In considering Janssen's submissions, I note that Janssen does not assert that including a reference to a filing date of the patent in subsection 4(6), in and of itself, exceeds the Governor in Council's regulation making authority. In that regard, I note that Janssen originally sought to quash the entirety of subsection 4(6) but, at the hearing, substantially modified the relief sought and now only seeks the quashing of the words "that has a filing date in Canada". This is an important point, as Janssen concedes that the Governor in Council has the authority to enact a regulation that

includes a filing date requirement. This is not necessarily surprising given this Court's determination in *Fournier*, *supra* at para 20, that the Governor in Council's authority and discretion in subsection 55.2(4) are sufficiently broad to embrace the enactment of subsections 4(3) and 4(4) of the *PMNOC Regulations*, which impose time limits on the registration of patent lists.

[139] On Janssen's wording, section 4(6) would read as follows:

> A first person may, after the date of filing of a new drug submission or a supplement to a new drug submission, and within 30 days after the issuance of a patent that was issued on the basis of an application that precedes the date of filing of the submission or supplement, submit a patent list, including the information referred to in subsection (4), in relation to the submission or supplement.

[140] Janssen's argument therefore boils down to an assertion that the specific choice of the Canadian filing date over the claim date or priority date is *ultra vires*. In that regard, Janssen asserts that the Canadian filing date requirement does not conform with the purpose of the *Patent Act* and the *PMNOC Regulations*.

[141] Turning to the purpose of the *Patent Act*, Justice Manson described its purpose as follows in *Innovative Medicines*:

> [76] The policy rationale underlying the *Patent Act* is the patent bargain, or *quid pro quo*. The patent bargain encourages innovation by offering an inventor exclusive rights in a new and useful invention for a limited period in exchange for disclosure of the invention so that society can benefit from this knowledge (*Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60, [2012] 3 S.C.R.

> 625, at paragraph 32). Two central objectives of the *Patent Act* as a whole are to "advance research and development and to encourage broader economic activity" (*Free World Trust v Électro Santé Inc*, 2000 SCC 66, [2000] 2 S.C.R. 104 at paragraph 42; *Harvard College v Canada (Commissioner of Patents)*, 2002 SCC 76, [2002] 4 S.C.R. 45 (Harvard College) at paragraph 185).
>
> [77] As acknowledged by both the applicants and the respondent, patent monopoly rights are not unlimited, and Parliament has at times balanced promotion of ingenuity against other considerations (*Harvard College*, above, at paragraph 185)…

[142] The purpose of the *PMNOC Regulations*, as noted previously, is to balance effective patent enforcement over new and innovative drugs with the timely market entry of their lower priced generic competitors.

[143] Only limited information is known about the rationale for the Governor in Council's choice to use the Canadian patent filing date. The 2006 RIAS indicates that the Government was aware that "an increasing number of court decisions interpreting the PM(NOC) Regulations have given rise to the need to clarify the patent listing requirements" and that these decisions addressed issues of timing and relevance.

[144] Among those decisions was Justice Blanchard's decision in *Pfizer Canada Inc v Canada (Attorney General) (TD)*, 2002 FCT 706, in which the Court was considering an earlier version of subsection 4(4) of the *PMNOC Regulations* which provided:

> A first person may, after the filing of a submission for a notice of compliance and within 30 days after the issuance of a patent that was issued on the basis of an application that has a filing date that precedes the date of filing of the submission, submit a patent list, or

> an amendment to an existing patent list, that includes information referred to in subsection (2).

[145] The issue before the Court was whether the "filing date" in subsection 4(4) should be interpreted to be the priority filing date (in that case, the date of filing in the United States) or the Canadian filing date. The Minister had determined that "filing date" meant the Canadian filing date. The Applicants advanced a number of arguments in support of their assertion that "filing date" meant the priority filing date, including that the Minister's interpretation would place patentees who file their patent applications first in a country other than Canada at a disadvantage compared to patentees who choose to file first in Canada and results in a loss of rights during the priority period. In rejecting the Applicant's submissions, Justice Blanchard stated:

> [50] At the risk of stating the obvious, the *Patent Act* is Canadian legislation and provides for the grant of a patent to an inventor, "if an application for the patent in Canada is filed" (see subsection 27(1) [as am. *idem*, s. 31] of the *Patent Act*). Moreover, the *Patent Act* specifically defines "filing date" to be the Canadian filing date. In my view, any reference to "filing date" in the Act, or in the Regulations thereunder, must be read with regard to this definition. Such an interpretation is consistent with other provisions of the *Patent Act* and the Regulations which, for the most part, explicitly set out, in the context of the specific section, when "filing date" is meant as a date other than the Canadian filing date.

[146] Given the *Pfizer* decision, the Government was accordingly well aware of the issue raised by stakeholders as to the use of the Canadian filing date and the consequences thereof and engaged in consultations with stakeholders prior to the enactment of the current version of subsection 4(6) during which submissions could be made by stakeholders on this issue. The Governor in Council ultimately decided, in enacting subsection 4(6), to expressly include the Canadian filing date.

[147] With respect to subsection 4(6), the only commentary thereon in the 2006 RIAS provides as follows:

> By stipulating that the application filing date of the patent precede the date of the corresponding drug submission, the timing requirement promotes a temporal connection between the invention sought to be protected and the product sought to be approved. This ensures that patents for inventions discovered after the existence of a product do not pre-empt generic competition on that product.

[148] No express rationale is given in the 2006 RIAS as to why the Canadian filing date was specifically chosen. In its reasons for decision, OSIP notes that the Governor in Council chose for subsection 4(6) to refer to the first date of a patent term, as opposed to a date relevant to considerations of novelty, inventiveness or prior use and that this was a deliberate choice.

[149] Janssen asserts that the choice of the Canadian filing date is inconsistent with the aforementioned purpose of the timing requirement (namely, to prevent patents for inventions discovered after the existence of a product from pre-empting generic competition on that product), as the date of the invention's discovery is actually the claim date and not the Canadian filing date. Janssen stresses that the claim date (which is defined in sections 2 and 28.1 of the *Patent Act*) is the relevant date in several sections of the *Patent Act*, including those directed at novelty, inventiveness and the prior use defence, which are concepts at the core of an invention, and demonstrate that within the overall scheme of the *Patent Act*, the invention sought to be protected is linked to the claim date.

[150] Further, Janssen asserts that the selection of the Canadian filing date fails to advance effective enforcement of patents that would be infringed by the use of the early-working exception, such that there is no rational connection between the early-working exception and the requirement that a Canadian patent application be filed before a drug submission to be listed.

[151] I am not convinced by Janssen's submissions. While the 2006 RIAS expresses a rationale for subsection 4(6), the expressed rationale is in regard to why the filing of the patent application must occur before the submission of the SNDS. It was about the sequencing of the patent application and the SNDS, not about the rationale for picking the Canadian filing date over the claim date.

[152] The Governor in Council was well aware that since 1998, the Minister has "sought to apply the amendments on timing and relevance in order to place reasonable limits on the ability of innovator drug companies to list new patents on the basis of SNDS filings" [see 2006 RIAS] and that:

> It is recognized that there may be instances where a patent which does not qualify for the protection of the PM(NOC) Regulations is ultimately infringed by the fact of generic market entry. However, the Government's view is that where the patent fails to meet the listing requirements described above, policy considerations tip the balance in favour of immediate approval of the generic drug, and the matter is better left to the alternative judicial recourse of an infringement action. It follows that the continued viability of the regime greatly depends upon the fair and proper application of these listing requirements.
>
> [Emphasis added.]

[153] The Governor in Council made a choice that struck a particular balance between the PMNOC regime's competing objectives. The enactment of subsection 4(6) was within the Governor in Council's regulation making authority. As recognized by the Federal Court of Appeal in *Innovative Medicines*, having acted within the limits of the statutory language, the Governor in Council's regulation-making power is relatively unconstrained and it certainly falls within Governor in Council's purview to make policy-based choices such as this when deciding the balance to be struck. Could the Governor in Council have chosen to use the claim date in subsection 4(6)? Certainly. But the balance chosen by the date selected need not be perfect and it is not the role of the Court on this application to consider whether a different balance (as urged by Janssen) could have or ought to have been struck [see *Sanofi-Aventis Canada Inc v Teva Canada Limited*, 2012 FC 551 at para 24]. The burden rested on Janssen to demonstrate that the inclusion of the Canadian filing date was not in pursuance of and connected with the prevention of patent infringement and I am not satisfied that they have done so. Rather, I am satisfied that requiring that a patent meet certain timing requirements based on its Canadian filing date, which ensures timely market entry of subsequent generic drugs, is reasonably in keeping with the balance of the competing policy interests at issue.

[154] In some circumstances, the operation of the regulatory regime may benefit a subsequent entry drug manufacturer and in others, the innovator, depending on when the innovator choses to file their patent application in Canada. However, I am not satisfied that this renders subsection 4(6) *ultra vires* or otherwise arbitrary, illogical or irrational. I agree with the Respondent that, in Janssen's view, the language chosen by the Governor in Council must be the most beneficial to innovators in order to be rationally connected to the purpose of the *Patent Act* and the *PMNOC*

Regulations. But such an approach ignores the balancing of interests that must be undertaken. Moreover, it also ignores that innovators (whose patents benefit from a priority application) who chose to file their Canadian patent after their SNDS retain their right to bring patent infringement actions under the *Patent Act* regime and are not deprived of the benefit of their priority date in such actions.

[155] Janssen bears the burden of demonstrating that the Governor in Council's inclusion of the Canadian filing date in subsection 4(6) was unreasonable. For the reasons stated above, I am not satisfied that they have done so.

V. Conclusion

[156] Having found that Janssen has failed to demonstrate that any aspect of OSIP's decision is unreasonable and that the Canadian filing date requirement in subsection 4(6) of the *PMNOC Regulations* is *ultra vires*, illogical, irrational or arbitrary, the application for judicial review shall be dismissed.

VI. Costs

[157] At the hearing of the application, the parties advised that they agreed that the successful party should be awarded their costs fixed in the amount of $7,500.00. As the Respondents were

successful on the application, they shall be awarded their costs in accordance with the parties' agreement.

JUDGMENT in T-2627-22

THIS COURT'S JUDGMENT is that:

1. The application for judicial review is dismissed.

2. The Applicant shall pay to the Respondents their costs of this application fixed in the amount of $7,500.00, inclusive of disbursements and taxes.

"Mandy Aylen"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-2627-22
STYLE OF CAUSE:	JANSSEN INC. v THE MINISTER OF HEALTH AND THE ATTORNEY GENERAL OF CANADA
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	MAY 25, 2023
JUDGMENT AND REASONS:	AYLEN J.
DATED:	JULY 17, 2023

APPEARANCES:

Sana Halwani Jordana Sanft Allison Jandura	FOR THE APPLICANT
Elizabeth Koudys Leah Bowes	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

Lenczner Slaght LLP Barristers Toronto, Ontario	FOR THE APPLICANT
Attorney General of Canada Toronto, Ontario	FOR THE RESPONDENTS

Exhibit “J22”

This is Exhibit “J22” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

Court File No.

FEDERAL COURT

B E T W E E N:

(Court Seal)

JANSSEN INC.

Applicant

- and -

THE MINISTER OF HEALTH and ATTORNEY GENERAL OF CANADA

Respondents

APPLICATION UNDER sections 18 and 18.1 of the *Federal Courts Act*, R.S.C. 1985, c. F-7, as amended.

NOTICE OF APPLICATION

TO THE RESPONDENTS:

A PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the Applicant. The relief claimed by the Applicant appears below.

THIS APPLICATION will be heard by the Court at a time and place to be fixed by the Judicial Administrator. Unless the Court orders otherwise, the place of hearing will be as requested by the Applicant. The Applicant requests that this application be heard at Toronto, Ontario.

IF YOU WISH TO OPPOSE THIS APPLICATION, to receive notice of any step in the application or to be served with any documents in the application, you or a solicitor acting for you must file a notice of appearance in Form 305 prescribed by the *Federal Courts Rules* and serve it on the Applicant's solicitor or, if the Applicant is self-represented, on the Applicant, WITHIN 10 DAYS after being served with this notice of application.

Copies of the *Federal Courts Rules*, information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-992-4238) or at any local office.

IF YOU FAIL TO OPPOSE THIS APPLICATION, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

Date _____ Issued by _____
(Registry Officer)

Address of
local office: 180 Queen Street West, Suite 200
Toronto, Ontario
M5V 3L6

TO: **THE ADMINISTRATOR**
Federal Court

AND TO: **THE MINISTER OF HEALTH**
c/o Health Products and Food Branch
Resource Management and Operations Directorate
Office of Submissions and Intellectual Property
Finance Building
101 Tunney's Pasture Driveway
Postal Locator 0201A1
Ottawa ON
K1A 0K9

(service to be effected by filing duplicate copies in the Registry pursuant to s. 133 of the *Federal Courts Rules* and s. 48 of the *Federal Courts Act)*

ATTORNEY GENERAL OF CANADA
Ontario Regional Office
Department of Justice Canada
Suite 400
120 Adelaide Street West
Toronto ON
M5H 1T1

(service to be effected by filing duplicate copies in the Registry pursuant to s. 133 of the *Federal Courts Rules* and s. 48 of the *Federal Courts Act)*

APPLICATION

This is an Application for judicial review pursuant to sections 18 and 18.1 of the *Federal Courts Act*, R.S.C. 1985, c. F-7, as amended, in respect of a decision of the Office of Submissions and Intellectual Property ("**OSIP**"), on behalf of the Minister of Health (the "**Minister**"). By letter dated November 15, 2022, the Minister advised the Applicant that its patent list for submission nos. 224739 and 244670 for Canadian Patent No. 3,113,837 (the "'**837 Patent**") and the drug STELARA® (including STELARA I.V.) ("**STELARA**") are not eligible for listing on the Patent Register for failing to meet the listing provisions under subsections 4(3) and/or 4(6) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended (the "***PM(NOC) Regulations***") (the "**Decision**").

THE APPLICANT MAKES APPLICATION FOR:

1. The Applicant seeks relief as follows:

   (a) An order quashing or setting aside the Minister's Decision refusing to list the '837 Patent on the Patent Register in respect of STELARA;

   (b) A declaration that the '837 Patent is/was eligible for listing on the Patent Register in respect of STELARA as of:

      (i) July 19, 2022;

      (ii) In the alternative, September 14, 2022; or

      (iii) In the further alternative, the date of the decision of this Court on this Application;

(c) A declaration pursuant to subsection 4.1(2) of the *PM(NOC) Regulations* that the patent list be carried forward and the ’837 Patent be listed on the Patent Register in respect of any supplementary new drug submissions (“**SNDS**”) filed for STELARA;

(d) An order directing the Minister to list the ’837 Patent on the Patent Register in respect of STELARA, as of the date determined in (b);

(e) In the alternative to (b), (c) and (d), an order referring the matter back to the Minister for redetermination on proper principles as to whether the ’837 Patent is eligible for listing on the Patent Register in respect of STELARA;

(f) An order in the nature of *certiorari* quashing section 4(6) of the *PM(NOC) Regulation* on the basis that it is *ultra vires* the authority granted to the Governor General in Council by the *Patent Act*, and is without any legal force or effect to the extent that it refers to a patent’s “filing date” as opposed to its “claim date”;

(g) Costs of this application; and

(h) Such further and other relief as counsel may advise and this Honourable Court may permit.

THE GROUNDS FOR THE APPLICATION ARE:

A. Overview

2. The Minister’s decision that the ’837 Patent is ineligible for listing on the Patent Register in respect of STELARA was unreasonable.

3. The Minister erred in determining that the ’837 Patent did not satisfy product specificity requirements in subsection 4(3) of the *PM(NOC) Regulations*, in respect of SNDS 244670. The Minister also erred in determining that the ’837 Patent did not satisfy the timing requirements in subsections 4(6) of the *PM(NOC) Regulations*, in respect of SNDS 224739.

4. In addition and/or in the alternative, in respect of SNDS 224739, subsection 4(6) is *ultra vires* the scheme and purpose of the *Patent Act* and *PM(NOC) Regulations,* and is without any legal force or effect to the extent that it refers to a patent’s “filing date” as opposed to its “claim date”.

5. The ’837 Patent is listable in respect of SNDS 224739 and SNDS 244670. SNDS 224739 added the ulcerative colitis indication to STELARA. SNDS 244670 added safety data relevant to the ulcerative colitis indication that – according to an expert statement – changed prescribing practices of clinicians with respect to STELARA. Both submissions therefore contain a change in use that allows for the listing of a patent on the Patent Register under subsection 4(3).

6. Further, the ’837 Patent contains claims to the change in use in both SNDS 224739 and SNDS 244670. The ’837 Patent thus meets the product specificity requirements in subsection 4(3) of the *PM(NOC) Regulations*, which require that the patent contain a claim for the medicinal ingredient, formulation or use which has been approved through the issuance of a Notice of Complaince (“**NOC**”) in respect of a submission. There is no dispute that the ’837 Patent meets the timing requirements in subsection 4(6) of the *PM(NOC) Regulations* in respect of SNDS 244670. Therefore, the Minister’s Decision not to list the ’837 Patent in respect of SNDS 244670 is unreasonable and should be overturned.

7. In addition and/or in the alternative, in respect of SNDS 224739, subsection 4(6) is *ultra vires* the scheme and purpose of the *Patent Act* and *PM(NOC) Regulations* because the designation of the "filing date" in subsection 4(6) of the *PM(NOC) Regulations* bears no rational connection with the object of the *Patent Act.* The appropriate date is the claim date of a patent, as defined in sections 2 and 28.1 of the *Patent Act*.

8. The claim date of the '837 Patent meets the timing requirements in subsection 4(6) of the *PM(NOC) Regulations* in respect of SNDS 224739.

9. Accordingly, the '837 Patent should be found eligible for listing on the Patent Register in respect of STELARA.

B. STELARA

10. STELARA is a Schedule D biologic drug containing the medicinal ingredient ustekinumab. STELARA was first approved in Canada in December 2008 for the treatment of psoriasis.

11. Since that time, STELARA has gained approvals for several other important indications and is now used to treat plaque psoriasis, active psoriatic arthritis, moderately to severely active Crohn's disease and moderately to severely active ulcerative colitis.

12. Most relevant to this Application is the indication relating to ulcerative colitis, i.e. the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies.

13. There are currently no patents listed on the Patent Register for STELARA pursuant to the *PM(NOC) Regulations*. Canadian Patent No. 2,418,961 ("'**961 Patent**") was previously listed on

the Patent Register in respect of STELARA until its expiry on August 9, 2021. The ’961 Patent did not contain any claims for use of ustekinumab for the treatment of ulcerative colitis. No other patents have previously been listed against STELARA.

14. As there are no patents currently listed on the Patent Register in respect of STELARA (and STELARA no longer benefits from data protection) there is an increased need for the ’837 Patent to be listed on the Patent Register quickly. Under the current circumstances, the Applicant cannot benefit from the rights provided by the *Patent Act* and the *PM(NOC) Regulations* when a subsequent entrant seeks market approval. In addition, the public – including any subsequent entrant – currently has no notice that the ’837 Patent is sought to be listed on the Patent Register in respect of STELARA. As such the Applicant seeks to expedite this Judicial Review.

C. The ’837 Patent

15. The ’837 Patent is entitled “Safe and effective method of treating ulcerative colitis with anti-IL12/IL23 antibody”. The ’837 Patent application was filed on September 24, 2019 and issued on July 12, 2022, and it was submitted for listing on the Patent register on July 25, 2022. It claims priority from three U.S. applications, the earliest of which was filed on September 24, 2018, and is the relevant claim date. It will expire on September 24, 2039.

16. The ’837 Patent is generally directed to the use of an anti-IL-12/IL-23p40 antibody, including ustekinumab, for the treatment of moderately to severely active ulcerative colitis in a subject in need thereof, wherein the subject may have previously failed or was intolerant of at least one enumerated therapy or the subject had demonstrated corticosteroid dependence.

17. The ’837 Patent describes a long-term study extension that will continue through Week 220 (page 73, lines 27-29) and claims the use of ustekinumab wherein the subject experiences

clinical remission, healing and clinical response in accordance with the enumerated measures "at least 44 weeks after week 0" (for example, claims 10-18, 44-52).

D. The SNDSs Against Which the '837 Patent is Sought to be Listed

18. The '837 Patent is sought to be listed in respect of SNDS 224739 and/or SNDS 244670.

(i) SNDS 224739

19. The indication for the treatment of moderately to severely active ulcerative colitis was first approved in SNDS 224739.

20. SNDS 224739 was filed on February 15, 2019 and approved on January 23, 2020 (a revised NOC was issued on February 20, 2020). Thus, SNDS 224739 was filed *before* the filing of the '837 Patent (September 24, 2019) but *after* the relevant claim date (September 24, 2018).

(ii) SNDS 244670

21. SNDS 244670 was approved for updates to the Product Monograph for STELARA. SNDS 244670 was submitted, *inter alia*, to provide data on safety and efficacy of STELARA through two years of treatment in subjects with moderately to severely active ulcerative colitis.

22. SNDS 244670 was filed on October 1, 2020 and approved on September 9, 2021. Thus, SNDS 244670 was filed after both the filing date and the relevant claim date of the '837 Patent.

23. The Product Monograph approved as part of SNDS 244670 (date of revision September 21, 2020) includes additional data relating to the ulcerative colitis indication that is the subject matter of claims of the '837 Patent and described in the specification. The additions to the Product Monograph address treatment with and safety of ustekinumab in ulcerative colitis patients beyond 44 weeks.

E. The Governing Statute: The *Patent Act*

24. The object and purpose of the *Patent Act* is to promote innovation by granting patentees a time limited monopoly. The monopoly granted pursuant to the *Patent Act* provides a patentee with the exclusive right and liberty to make, use and sell the invention during the term of the patent in exchange for disclosure of new and useful innovations. Patents are granted for new, useful and inventive subject matter, including incremental inventions. Once issued, patents are presumed to be valid.

25. The *Patent Act* provides for protection of inventions from the earliest date upon which the applicant can claim priority to the claimed invention. As such, section 28.1 of the *Patent Act* defines claim date as the filing date, or if a priority application exists, the priority date.

26. The ability of patentees to claim and benefit from priority is critical to the patent bargain, and central to the *Patent Act*. It must therefore be maintained in any subordinate legislation like the *PM(NOC) Regulations.*

F. The Patent-Regulatory Linkage for Drugs

27. The policy purpose of the *PM(NOC) Regulations* is set out in Health Canada's Guidance Document and includes: "The PM(NOC) Regulations provide the balance, through a patent enforcement mechanism, to ensure that the early working exception is not abused by linking the regulatory approval of a generic drug to the patent status of the innovative product." (https://www.canada.ca/content/dam/hc-sc/documents/services/drug-health-product-review-approval/drug-products/guidance-documents/pm-noc-regulations-guid-ld-eng.pdf, p. 7).

28. Section C.08.002(1)(b) of the *Food and Drug Regulations* addresses regulatory approval of a drug and provides that no person "shall sell or advertise a new drug" unless the Minister has

issued an NOC pursuant to subsections C.08.004 or C.08.004.01. If a patent is listed on the Patent Register in respect of a drug product, the *PM(NOC) Regulations* prohibit the Minister from issuing an NOC for a generic drug unless certain circumstances are met. Those circumstances include the timing and product specificity requirements set out in sections 3 and 4 of the *PM(NOC) Regulations*.

29. The Regulatory Impact Analysis Statements published following various amendments to the *PM(NOC) Regulations* also outline their policy purpose, including:

(a) "… the PM(NOC) Regulations are intended to provide effective patent protection by ensuring that a notice of compliance is not issued to the generic manufacturer until expiry of all relevant patents or such earlier time as the court or innovator is satisfied with the allegation by the generic manufacturer that no valid patent relating to the drug would be infringed. The linkage to relevant patents is assured through the maintenance of a patent register…" (SOR/2015-149, *C. Gaz.* 2015.II; p. 2205)

(b) "By stipulating that the application filing date of the patent precede the date of the corresponding drug submission, the timing requirement promotes a temporal connection between the invention sought to be protected and the product sought to be approved. This ensures that patents for inventions discovered after the existence of a product do not pre-empt generic competition on that product." (SOR/2006-242, *C. Gaz*. 2006.II; p. 1511-2)

G. The Patent Register

30. When a patent is listed on the Patent Register in respect of a drug marketed by a "first person", that first person is entitled to significant protections under the *PM(NOC) Regulations*:

(a) Any subsequent entrant (i.e., second person) seeking approval to market a generic or biosimilar version of the drug against which a patent is listed must either: (i) await the listed patent's expiry; or (ii) allege invalidity and/or non-infringement of the patent by serving a Notice of Allegation ("**NOA**") on the first person; and

(b) Where the first person receives an NOA, it may launch a patent infringement proceeding and avail of an up to 24-month statutory stay that prevents subsequent entrant market authorization while the patent proceeding is determined.

31. Sections 3 and 4 of the *PM(NOC) Regulations* address the Minister's maintenance of the Patent Register, the submission of patent lists filed by a first person, and the eligibility of patents for listing. The Applicant files drug submissions for STELARA in Canada and is a first person for the purposes of the *PM(NOC) Regulations*.

32. Pursuant to subsection 3(2) of the *PM(NOC) Regulations*, the Minister is required to maintain a register of patents submitted for addition to the Patent Register:

> 3(2) The Minister shall maintain a register of patents that have been submitted for addition to the register and certificates of supplementary protection in which any of those patents are set out [...]

33. Pursuant to subsections 3(2) to 3(8) of the *PM(NOC) Regulations*, the Minister has the discretion to maintain the Patent Register, including the ability to add or delete patents in a broad array of circumstances. Under subsection 3(2) of the *PM(NOC) Regulations,* the Minister is

expressly granted authority to: (i) add any patent on a patent list to the Patent Register; (ii) delete patents from the Patent Register in certain circumstances; and (iii) perform discretionary reviews of the Patent Register.

34. Subsections 4(1) to 4.1 of the *PM(NOC) Regulations* set out certain criteria for listing, including: (i) when patent lists for existing and newly issued patents can be submitted; (ii) the required content of patent lists; (iii) the eligible drug submissions for which patent lists may be filed; and (iv) the eligible patent claims for which patent lists may be filed.

35. First persons add patents to the Patent Register by submitting a patent list to OSIP. A patent list must identify: (i) a drug submission; (ii) a drug; (iii) a patent; (iv) the first person's right to list the patent; and (v) the address in Canada for service on the first person of any NOA by a second person alleging the patent is improperly listed, invalid, or not infringed.

36. Following service of an NOA, the first person and/or patent owner may, within 45 days, bring a court action pursuant to section 6 of the *PM(NOC) Regulations* against the second person seeking a declaration that making, constructing, using, or selling a drug in accordance with the second person's drug submission would infringe a listed patent.

37. When a first person commences a patent infringement proceeding in respect of a listed patent, the Minister is prohibited from approving the second person's drug submission during the statutory stay period which is triggered by the commencement of the action.

38. The Patent Register is the vehicle by which first persons and patentees access important rights under the *PM(NOC) Regulations*. A listed patent entitles the first person to receive early notice of generic entry in the form of an NOA and thereby elect to commence a patent infringement

proceeding prior to generic entry. Further this provides a first person with the benefit of a time limited statutory stay.

39. If no patents are listed on the Patent Register in respect of a drug product, then a first person cannot exercise these rights under the *PM(NOC) Regulations.*

40. The Patent Register is governed by the *PM(NOC) Regulations*, which are promulgated pursuant to the authority granted to the Governor General in Council by the *Patent Act*. They must therefore be consistent with the object and purpose of the *Patent Act*.

H. Requirements for Listing Patents on the Patent Register

41. This Application addresses both the product specificity and timing criteria for listing a newly issued patent on the Patent Register.

42. **Product specificity requirements**: Subsections 4(2), 4(2.1) and 4(3) of the *PM(NOC) Regulations* set out criteria regarding which patents can be added to the Patent Register.

43. Subsection 4(3) addresses eligibility criteria for a patent to be added to the Patent Register in relation to a SNDS:

> (3) A patent on a patent list in relation to a supplement to a new drug submission is eligible to be added to the register if the supplement is for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient, and
>
> (a) in the case of a change in formulation, the patent contains a claim for the changed formulation that has been approved through the issuance of a notice of compliance in respect of the supplement;
>
> (b) in the case of a change in dosage form, the patent contains a claim for the changed dosage form that has been approved through the issuance of a notice of compliance in respect of the supplement; or

> (c) in the case of a change in use of the medicinal ingredient, the patent contains a claim for the changed use of the medicinal ingredient that has been approved through the issuance of a notice of compliance in respect of the supplement.

44. **Timing requirement**: Subsections 4(6) of the *PM(NOC) Regulations* set out criteria regarding when a newly issued patent can be added to the Patent Register after the filing of an NDS or an SNDS:

> 4(6) A first person may, after the date of filing of a new drug submission or a supplement to a new drug submission, and within 30 days after the issuance of a patent that was issued on the basis of an application that has a filing date in Canada that precedes the date of filing of the submission or supplement, submit a patent list, including the information refenced to in subsection (4), in relation to the submission or supplement.

I. The Decision

45. On July 29, 2022, the Minister communicated a preliminary decision to the Applicant finding the ’837 Patent to be ineligible for listing on the Patent Register in respect of the drug STELARA (the “**Preliminary Decision**”). Although the ’837 Patent had been submitted for listing in respect of SNDS 244670, the Minister suggested that the ’837 Patent claims the new indication approved in a previous submission, SNDS 224739, and therefore raised the possibility that the ’837 Patent might be eligible for listing also as against SNDS 224739.

46. The Preliminary Decision found the ’837 Patent ineligible for listing on the Patent Register against either submission (SNDS 244670 or SNDS 224739) for failing to satisfy section 4 of the *PM(NOC) Regulations*, i.e. the product specificity and timing requirements.

47. On September 14, 2022, the Applicant sought reconsideration of the Preliminary Decision by the Minister (the “**Applicant’s Response**”). The Applicant submitted written representations, which maintained and provided further support for the Applicant’s listing request, (described

below in paragraphs 49 – 51 and 55 - 58) as well as a statement from an expert clinician and relevant literature.

48. By letter dated November 15, 2022, the Minister issued the Decision under review. The Decision rejected the Applicant's arguments and held that the '837 Patent was not eligible for inclusion on the Patent Register in respect of the drug STELARA.

(i) SNDS 244670

(i) The Applicant's Response

49. The Applicant asserted, *inter alia*, that the Minister's Decision failed to properly apply the listing requirements under section 4 of the *PM(NOC) Regulations.*

50. With respect to the product specificity requirements, the Applicant submitted that:

(a) The '837 Patent meets the product specificity requirements of subsection 4(3)(c) of the *PM(NOC) Regulations* in respect of SNDS 244670 because the '837 Patent claims to long term use of ustekinumab are a "change in use" approved through SNDS 244670, in the form of the additional safety data related to treatment of ulcerative colitis; and

(b) A clinician reviewing the new Product Monograph with this new information would change her prescribing practices, especially a clinician who may have been otherwise hesitant to prescribe STELARA beyond 44 weeks. The Applicant's Response included a clinician's statement supporting this position.

51. With respect to the timing requirements, there is no dispute that the '837 Patent meets the timing requirements of subsection 4(3)(c) of the *PM(NOC) Regulations* in respect of SNDS

244670. The '837 Patent was filed on September 24, 2019, prior to the filing date of SNDS 244670 (on October 1, 2020), and listing was sought within 30 days of patent issuance (the patent issued on July 12, 2022 and listing was sought on July 29, 2022).

(ii) The Decision Under Review

52. The Minister maintained that the '837 Patent was ineligible for listing on the Patent Register in respect of SNDS 244670.

53. With respect to the product specificity requirements, the Minister found, *inter alia*, that:

(a) SNDS 244670 was not approved for a change in use because the inclusion of safety information does not constitute a change in use of the medicinal ingredient for the purpose of subsection 4(3) of the *PM(NOC) Regulations*; and

(b) Even if SNDS 244670 was considered to have been approved for a change in use, the '837 Patent does not claim the "very change" that was approved in SNDS 244670, applying the test set out in Health Canada's Guidance Document.

(ii) SNDS 224739

(i) The Applicant's Response

54. The Applicant asserted, *inter alia*, that the Minister's Decision failed to properly apply the listing requirements under section 4 of the *PM(NOC) Regulations.*

55. With respect to the product specificity requirements, the Applicant submitted that the '837 Patent meets the product specificity requirements of subsection 4(3)(c) of the *PM(NOC) Regulations* in respect of SNDS 224739 because the '837 Patent claims to long term use of

ustekinumab are a "change in use" approved through SNDS 224739, in the form of a new indication for ulcerative colitis.

56. With respect to the timing requirements, the Applicant submitted that:

(a) The '837 Patent meets the timing requirements of subsection 4(6) of the *PM(NOC) Regulations* in respect of SNDS 224739 because the claim date is the rational date to consider under subsection 4(6) and the OPML ought to apply the intent of the *PM(NOC) Regulations* with respect to the timing of the patent and the submission under subsection 4(6) of the *PM(NOC) Regulations*, and determine that eligibility is met because the claim date of the patent precedes the filing date of the submission; and

(b) As a patent list was already submitted with respect to the '837 Patent within the requisite 30 days of its issuance in respect of SNDS 244670, the request to consider listing against SNDS 224739 was not out of time under subsection 4(6) of the *PM(NOC) Regulations*.

57. The Applicant also asserted, in respect of SNDS 224739, that the use of the filing date in subsection 4(6) of the *PM(NOC) Regulations* is *ultra vires* the scheme of the *Patent Act* and of the *PM(NOC) Regulations* themselves.

(ii) The Decision Under Review

58. The Minister maintained that the '837 Patent was ineligible for listing on the Patent Register in respect of SNDS 224739.

59. With respect to the product specificity requirements, the Minister made no explicit findings. The Minister's position appears to be that the product specificity requirements are met for SNDS 224739, based on the statement made in the Preliminary Decision and in the Decision under review.

60. With respect to the timing requirements, the Minister found, *inter alia,* that the '837 Patent is not eligible to be added to the Patent Register against SNDS 224739 because no patent list was filed, and because the filing date is the appropriate date to consider and the filing date for the '837 Patent is later than the filing date for SNDS 224739.

61. With respect to the Applicant's *ultra vires* argument, the Minister also found, *inter alia*, that the *PM(NOC) Regulations* cannot be considered in isolation from the *Patent Act*, and that the Governor in Council could have chosen for subsection 4(6) to refer to the "claim date" had it wished to do so.

J. The Decision is Unreasonable

62. The Minister's Decision that the '837 Patent is not eligible for listing against SNDS 244670 or SNDS 224739 is unreasonable.

63. Having regard to the facts and the law, the Minister made the Decision unreasonably in particular by:

(a) Misinterpreting the text, context, and purpose of the *PM(NOC) Regulations*, including sections 3 and 4 and misapplying these sections to arrive at a Decision that is unreasonable;

(b) Rejecting the amendment of the Applicant's original patent list to include SNDS 224739; requiring a separate patent list seeking listing of the '837 Patent against SNDS 224739; and requiring the filing of a Form IV rather than accepting the information required by subsection 4(4) of the *PM(NOC) Regulations,* which was provided in accordance therewith in the Applicant's letter dated September 14, 2022;

(c) Misinterpreting the scheme and purpose of Canadian patent law, including the *Patent Act*, the *PM(NOC) Regulations*, and the legislative intent of Parliament in enacting and amending the *PM(NOC) Regulations*;

(d) Refusing to list the '837 Patent on the Patent Register in respect of the drug STELARA;

(e) Fettering her discretion, including by applying Health Canada's Guidance Document on the *PM(NOC) Regulations* instead of the *PM(NOC) Regulations* and *Patent Act*;

(f) Failing to consider the prejudicial impact caused by the Decision on the Applicant; and

(g) Otherwise failing to interpret and apply the facts and law in an appropriate manner, including by refusing to exercise her discretion to find the '837 Patent eligible for listing on the Patent Register.

64. The '837 Patent was eligible for listing on the Patent Register against SNDS 244670 and SNDS 224739 as of the date that the patent was originally submitted for listing (July 29, 2022).

In the alternative, the ’837 Patent was eligible for listing as of the date the Applicant submitted its letter of representations (September 14, 2022). In the further alternative, the ’837 Patent is eligible for listing as of the date of the decision of this Court on this Application declaring the ’837 Patent eligible for listing.

K. Subsection 4(6) of the *PM(NOC) Regulations* is *Ultra Vires* the *Patent Act*

65. If the Court determines that the ’837 Patent is not listable against SNDS 244670, then in addition and/or in the alternative, subsection 4(6) is *ultra vires* because it refers to the filing date, and the 837 Patent is listable against SNDS 224739.

66. Section 4(6) of the *PM(NOC) Regulations* is inconsistent with the purpose and objects of the *Patent Act*, including s. 55.2 of the *Act*, to the extent that it connects the right to submit a patent list to the filing date of a patent as opposed to its claim date.

67. The designation of the “filing date” in section 4(6) bears no rational connection with the object of the *Patent Act.* The appropriate date is the claim date of the claims of a patent, as defined in sections 2 and 28.1 of the *Act*. The claim date is often, but not necessarily, the filing date; where a claim of priority has been made, it also includes the priority date (section 28.1 of the *Act*).

68. As one purpose of the *PM(NOC) Regulations* is to provide “effective patent protection” and as subsection 4(6) of the *PM(NOC) Regulations* seeks a “temporal connection between the invention … and the product”, the Canadian filing date in subsection 4(6) cannot be supported on any reasonable interpretation of the regulation-making power in the statute.

69. In the alternative, the Canadian filing date in subsection 4(6) is an illogical, irrational, and/or arbitrary date to employ in subsection 4(6) of the *PM(NOC) Regulations.*

70. The date that achieves the object and purpose of both the *Patent Act* and the *PM(NOC) Regulations* is the claim date. It underscores the temporal connection between the invention and the product.

71. Indeed, the temporal requirement that a patent be filed prior to the filing of the relevant submission undermines the purpose of the *Patent Act* by failing to recognize rights granted to patentees in the *Patent Act*. The *Patent Act* protects inventions through a "first to file" system in which claim dates serve as the relevant date for ascertaining the inventor's claim to priority to the invention. As such, the claim date is relevant to*, inter alia,* novelty and inventiveness (pursuant to sections 28.2 and 28.3 of the *Patent Act*) and to the prior use defence (pursuant to section 56 of the *Patent Act*).

72. By virtue of s. 4(6) of the *PM(NOC) Regulations*, first persons are prevented from benefitting from priority claims and are prevented from listing patents with claim dates before the filing of a regulatory submission but that are filed in Canada after the filing of the regulatory submission.

73. The use of filing date in the *PM(NOC) Regulations* is illogical, arbitrary, and *ultra vires* the scheme of the *Act* and of the *PM(NOC) Regulations* themselves.

L. Statutory Provisions

74. The Applicant relies on:

(a) *Patent Act*, R.S.C., 1985, c. P-4, including section 55.2;

(b) *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 as amended, including sections 3 and 4;

(c) *Federal Courts Act*, R.S.C., 1985, c. F-7 as amended, including sections 18 and 18.1;

(d) *Federal Courts Rules*, SOR/98-106 as amended;

(e) *Interpretation Act, RSC 1985, c I-21*, as amended, including s. 12; and

(f) Such further and other grounds as counsel may advise and this Honourable Court may permit.

THIS APPLICATION WILL BE SUPPORTED BY THE FOLLOWING MATERIAL:

(a) A certified copy of the ’837 Patent;

(b) Affidavit(s) to be sworn;

(c) The record before and the Decision of the Minister dated November 15, 2022; and

(d) Such further and other material as counsel may advise and this Honourable Court permit.

THE APPLICANT REQUESTS THE MINISTER OF HEALTH TO SEND A CERTIFIED COPY OF THE FOLLOWING MATERIAL THAT IS NOT IN THE POSSESSION OF THE APPLICANT BUT IS IN THE POSSESSION OF THE MINISTER OF HEALTH TO THE APPLICANT AND TO THE REGISTRY:

1. All materials considered or created by the Minister of Health, or by any person or entity acting on behalf of the Minister of Health, and including all documentation and communication, pertaining or relevant to the Decision herein.

December 14, 2022

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Solicitors for the Applicant

Exhibit “J23”

This is Exhibit “J23” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

Federal Court of Appeal | Cour d'appel fédérale

Date: 20231121

Docket: A-192-23

Citation: 2023 FCA 229

CORAM: **WEBB J.A.**
LASKIN J.A.
LOCKE J.A.

BETWEEN:

JANSSEN INC.

Appellant

and

THE MINISTER OF HEALTH and ATTORNEY GENERAL OF CANADA

Respondents

Heard at Ottawa, Ontario, on November 21, 2023.
Judgment delivered from the Bench at Ottawa, Ontario, on November 21, 2023.

REASONS FOR JUDGMENT OF THE COURT BY: LOCKE J.A.

Federal Court of Appeal | Cour d'appel fédérale

Date: 20231121

Docket: A-192-23

Citation: 2023 FCA 229

CORAM: **WEBB J.A.**
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BETWEEN:

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Appellant

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THE MINISTER OF HEALTH and ATTORNEY GENERAL OF CANADA

Respondents

REASONS FOR JUDGMENT OF THE COURT
(Delivered from the Bench at Ottawa, Ontario, on November 21, 2023).

LOCKE J.A.

[1] Janssen Inc. (Janssen) obtained notices of compliance in respect of supplemental new drug submissions (SNDSs) numbered 224739 and 244670 on January 23, 2020 and September 9, 2021, respectively. Canadian Patent No. 3,113,837 (the 837 Patent) issued on July 12, 2022, and on July 25, 2022, Janssen submitted a patent list (pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 (the *Regulations*)) in respect of SNDS 244670

identifying the 837 Patent. SNDS 224739 was not mentioned in this July 25, 2022 submission. It was only on September 14, 2022 that Janssen sought to include SNDS 224739 in the patent list.

[2] Health Canada's Office of Submissions and Intellectual Property (OSIP), on behalf of the Minister of Health, refused to accept the patent list in respect of SNDS 224739 citing several reasons. Janssen sought judicial review of OSIP's decision before the Federal Court, but this was dismissed (2023 FC 870, *per* Justice Mandy Aylen). For the purposes of the present appeal, it is sufficient to address only one of the reasons cited by OSIP: that the patent list submitted on July 25, 2022 did not relate to SNDS 224739, and the submission on September 14, 2022 that did mention SNDS 224739 was outside the 30-day period from the date of issuance of the 837 Patent, as contemplated in subsection 4(6) of the *Regulations*. Because of our conclusion on this issue, it is not necessary to address other questions raised in this appeal, such as (i) whether the September 14, 2022 submission satisfied the other requirements for a patent list, and (ii) whether part of subsection 4(6) of the *Regulations* (unrelated to the 30-day period referred to above) is *ultra vires*.

[3] The parties agree on the standard of review, and we concur. As discussed in *Agraira v. Canada (Public Safety and Emergency Preparedness)*, 2013 SCC 36, [2013] 2 S.C.R. 559 at para. 45, the question for this Court to decide is whether the Federal Court identified the appropriate standard of review and applied it correctly. We are to step into the shoes of the Federal Court and focus on OSIP's decision. The parties also agree, as do we, that the Federal Court identified the appropriate standard of review: reasonableness. The issue therefore is whether the Federal Court correctly applied the reasonableness standard of review.

[4] In respect of the one issue that we must address in this appeal, OSIP noted that subsection 4(4) of the *Regulations* enumerates requirements for a patent list, including paragraph 4(4)(a) concerning identification of the SNDS (or new drug submission) to which the list relates. OSIP noted correctly that the patent list submitted on July 25, 2022 did not identify SNDS 224739, and hence this requirement was not met. OSIP rejected Janssen's arguments that (i) the later September 14, 2022 submission could change the nature of the July 25, 2022 patent list, and (ii) OSIP's preliminary response to the July 25, 2022 patent list acknowledged that it also concerned SNDS 224739. OSIP also noted that the 30-day deadline contemplated in subsection 4(6) of the *Regulations* expired on August 11, 2022. Therefore, the September 14, 2022 submission was too late, even assuming (contrary to OSIP's view) that it met the requirements for a patent list.

[5] We are not convinced that there was anything unreasonable in OSIP's analysis in this regard. We also do not agree with Janssen's argument that subsection 4(7) of the *Regulations* should be read to permit it to update the patent list by adding reference to an additional SNDS. Subsection 4(7) provides that a first person "must keep the information on the list up to date"; this subsection does not permit adding a patent to the list. We see nothing in the patent list in this case that would have engaged this provision. The information on the patent list was up to date. Janssen cannot, under the guide of keeping the information on the patent list up to date, add a different SNDS to an existing patent list.

[6] It follows from the foregoing that we find no reviewable error in the Federal Court's conclusion that OSIP's refusal to add the patent list against SNDS 224739 was reasonable.

[7] We will dismiss this appeal with costs.

"George R. Locke"
J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-192-23
STYLE OF CAUSE:	JANSSEN INC. v. THE MINISTER OF HEALTH and ATTORNEY GENERAL OF CANADA
PLACE OF HEARING:	OTTAWA, ONTARIO
DATE OF HEARING:	NOVEMBER 21, 2023
REASONS FOR JUDGMENT OF THE COURT BY:	WEBB J.A. LASKIN J.A. LOCKE J.A.
DELIVERED FROM THE BENCH BY:	LOCKE J.A.

APPEARANCES:

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Elizabeth Koudys James Schneider Leah Bowes	FOR THE RESPONDENTS THE MINISTER OF HEALTH and ATTORNEY GENERAL OF CANADA

SOLICITORS OF RECORD:

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Shalene Curtis-Micallef Deputy Attorney General of Canada	FOR THE RESPONDENTS THE MINISTER OF HEALTH and ATTORNEY GENERAL OF CANADA

Exhibit “J24”

This is Exhibit “J24” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

Notice of Compliance Information

From Health Canada

New search

Notice of Compliance date :

2023-04-18

Manufacturer :

JANSSEN INC

Product type:

Biologic

NOC with conditions:

No

Submission type:

New Drug Submission (NDS)

Submission class:

Labelling Only

Reason for submission:

Administrative - Additional product name

Brand 1 of 2 :

FINLIUS

Product 1 of 2 :

Drug identification number: 02537257

Dosage form(s): Solution

Route(s) of administration: Subcutaneous

Medicinal ingredient(s):

Ingredient	Strength
USTEKINUMAB	90 MG/1ML

Product 2 of 2 :

Drug identification number: 02537303

Dosage form(s): Solution

Route(s) of administration: Subcutaneous

Medicinal ingredient(s):

Ingredient	Strength
USTEKINUMAB	45 MG/0.5ML

Brand 2 of 2 :

FINLIUS I.V.

Product 1 of 1 :

Drug identification number: 02537311

Dosage form(s): Solution

Route(s) of administration: Intravenous

Medicinal ingredient(s):

Ingredient	Strength
USTEKINUMAB	5 MG/ML

New search

Application information

- Search tips
- Notice of Compliance terminology
- Frequently asked questions

Related information

- Notice of Compliance listings
- MedEffect Canada
- Adverse Drug Reaction - veterinary drugs
- Drug Product Database

Contact us

- Content support
- Technical support

Date modified: 2022-11-25

Exhibit “J25”

This is Exhibit “J25” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

Court File No. T-873-23

FEDERAL COURT

B E T W E E N:

(Court Seal)

JANSSEN INC.

Applicant

- and -

THE MINISTER OF HEALTH
and ATTORNEY GENERAL OF CANADA

Respondents

APPLICATION UNDER sections 18 and 18.1 of the *Federal Courts Act*, R.S.C. 1985, c. F-7, as amended.

NOTICE OF APPLICATION

TO THE RESPONDENTS:

A PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the Applicant. The relief claimed by the Applicant appears below.

THIS APPLICATION will be heard by the Court at a time and place to be fixed by the Judicial Administrator. Unless the Court orders otherwise, the place of hearing will be as requested by the Applicant. The Applicant requests that this application be heard at Toronto, Ontario.

IF YOU WISH TO OPPOSE THIS APPLICATION, to receive notice of any step in the application or to be served with any documents in the application, you or a solicitor acting for you must file a notice of appearance in Form 305 prescribed by the *Federal Courts Rules* and serve it on the Applicant's solicitor or, if the Applicant is self-represented, on the Applicant, WITHIN 10 DAYS after being served with this notice of application.

Copies of the *Federal Courts Rules*, information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-992-4238) or at any local office.

IF YOU FAIL TO OPPOSE THIS APPLICATION, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

Date APR 2 6 2023 Issued by ALICE PRODAN GIL REGISTRY OFFICER AGENT DU GREFFE
(Registry Officer)

Address of local office: 180 Queen Street West, Suite 200
Toronto, Ontario
M5V 3L6

TO: **THE ADMINISTRATOR**
Federal Court

AND TO: **THE MINISTER OF HEALTH**
c/o Health Products and Food Branch
Resource Management and Operations Directorate
Office of Submissions and Intellectual Property
Finance Building
101 Tunney's Pasture Driveway
Postal Locator 0201A1
Ottawa ON
K1A 0K9

(service to be effected by filing duplicate copies in the Registry pursuant to s. 133 of the *Federal Courts Rules* and s. 48 of the *Federal Courts Act)*

ATTORNEY GENERAL OF CANADA
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Department of Justice Canada
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(service to be effected by filing duplicate copies in the Registry pursuant to s. 133 of the *Federal Courts Rules* and s. 48 of the *Federal Courts Act)*

APPLICATION

This is an Application for judicial review pursuant to sections 18 and 18.1 of the *Federal Courts Act*, R.S.C. 1985, c. F-7, as amended, in respect of a decision of the Office of Submissions and Intellectual Property ("**OSIP**"), on behalf of the Minister of Health (the "**Minister**"). By letter dated March 29, 2023, the Minister advised the Applicant that its patent list for new drug submission 267289 ("**NDS 267289**") for Canadian Patent No. 3,113,837 (the "'**837 Patent**") and the drug FINLIUS (including FINLIUS I.V.) ("**FINLIUS**") is not eligible for listing on the Patent Register because NDS 267289 is not the type of submission that can support the addition of a patent to the Patent Register pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended (the "***PM(NOC) Regulations***") (the "**Decision**").

THE APPLICANT MAKES APPLICATION FOR:

1. The Applicant seeks relief as follows:

   (a) An order quashing or setting aside the Minister's Decision refusing to list the '837 Patent on the Patent Register in respect of NDS 267289 FINLIUS;

   (b) A declaration that the '837 Patent is eligible for listing on the Patent Register in respect of FINLIUS as of:

      (i) The date on which the Notice of Compliance issues in respect of NDS 267289, which is the date on which FINLIUS can be

deemed eligible for listing, or the closest date thereto upon which it is eligible for listing;

(ii) In the alternative, the earliest date on which the patent list for FINLIUS can be deemed to meet the requirements for listing; or

(iii) In the further alternative, the date of the decision of this Court on this Application.

(c) A declaration pursuant to subsection 4.1(2) of the *PM(NOC) Regulations* that the patent list be carried forward and the '837 Patent be listed on the Patent Register in respect of any supplementary new drug submissions ("**SNDS**") filed for FINLIUS;

(d) An order directing the Minister to list the '837 Patent on the Patent Register in respect of FINLIUS, as of the date determined in (b);

(e) In the alternative to (b), (c) and (d), an order referring the matter back to the Minister for redetermination on proper principles as to whether the '837 Patent is eligible for listing on the Patent Register in respect of STELARA;

(f) In the further alternative to (b), (c), (d), and (e), a declaration that the '837 Patent be carried forward and the '837 Patent be listed on the Patent Register for FINLIUS in accordance with subsection 4.1(2) of the *PM(NOC) Regulations*, if the '837 Patent is added to the Patent Register in respect of STELARA (I.V.);

(g) Costs of this Application; and

(h) Such further and other relief as counsel may advise and this Honourable Court may permit.

THE GROUNDS FOR THE APPLICATION ARE:

A. Overview

2. This Application addresses whether a new drug submission is a "new drug submission" within the meaning of subsections 3(1) and 4(2) of the *PM(NOC) Regulations*. The Minister's decision that the '837 Patent is ineligible for listing on the Patent Register in respect of FINLIUS was unreasonable.

3. The '837 Patent is listable in respect of NDS 267289. NDS 267289 seeks approval of FINLIUS, which is identical to the approved drug STELARA I.V. ("STELARA") but is a distinct product and will have its own Drug Identification Number(s) ("DIN") from STELARA. NDS 267289 cross-references the regulatory dossier of STELARA and includes the required health and safety data for approval. FINLIUS will have different drug identification numbers than STELARA pursuant to the *Food and Drug Regulations*, CRC, c 870. NDS 267289 is a "new drug submission" within the meaning of subsections 3(1) and 4(2) of the *PM(NOC) Regulations* and therefore allows for the listing of the '837 Patent on the Patent Register.

4. NDS 267289 is a "new drug submission" within the meaning of subsections 3(1) and 4(2) of the *PM(NOC) Regulations* and therefore allows for the listing of the '837 Patent on the Patent Register. Accordingly, the '837 Patent is eligible for listing on the Patent Register in respect of FINLIUS.

5. The Minister erred in determining that NDS 267289 was not a submission that can support the addition of a new patent to the Patent Register within the meaning of subsections 3(1) and 4(2) of the *PM(NOC) Regulations*.

B. FINLIUS and NDS 267289

6. FINLIUS is a Schedule D biologic drug containing the medicinal ingredient ustekinumab.

7. NDS 267289 seeks approval of FINLIUS to treat *inter alia* moderately to severely active ulcerative colitis in adult subjects.

8. FINLIUS will contain the same medicinal ingredient and have the same manufacturer as STELARA. NDS 267289 seeks approval of FINLIUS and cross-references the regulatory dossier of STELARA. STELARA was first approved in Canada in December 2008 for the treatment of psoriasis. Since that time, STELARA has gained approvals for several other important indications including moderately to severely active ulcerative colitis.

9. NDS 267289 was filed through an administrative pathway created by Health Canada for submissions that do not require direct inclusion of new health and safety data. This pathway is described in *Guidance Document: Administrative Processing of Submissions and Applications Involving Human or Disinfectant Drugs* (the "*Guidance*").

10. The '837 Patent is sought to be listed in respect of NDS 267289. There are currently no patents listed on the Patent Register for FINLIUS pursuant to the *PM(NOC) Regulations*.

C. The '837 Patent

11. The '837 Patent is entitled "Safe and effective method of treating ulcerative colitis with anti-IL12/IL23 antibody". The '837 Patent application was filed on September 24, 2019 and issued on July 12, 2022. It will expire on September 24, 2039.

12. The '837 Patent is generally directed to the use of an anti-IL-12/IL-23p40 antibody, including ustekinumab, for the treatment of moderately to severely active ulcerative colitis in a subject in need thereof, where the subject failed to respond to or was intolerant of at least one enumerated therapy or the subject demonstrated corticosteroid dependence and compositions for use in such treatment.

D. The Governing Statute: The *Patent Act*

13. The object and purpose of the *Patent Act* is to promote innovation by granting patentees a time limited monopoly. The monopoly granted pursuant to the *Patent Act* provides a patentee with the exclusive right and liberty to make, use and sell the invention during the term of the patent in exchange for disclosure of new and useful innovations. Patents are granted for new, useful, and inventive subject matter, including incremental inventions. Once issued, patents are presumed to be valid.

14. The ability of patentees to benefit from their inventions is critical to the patent bargain and central to the *Patent Act*. It must therefore be maintained in any subordinate legislation like the *PM(NOC) Regulations*.

E. The Patent Register

15. When a patent is listed on the Patent Register in respect of a drug marketed by a "first person", that first person is entitled to significant protections under the *PM(NOC) Regulations*:

(a) Any subsequent entrant (i.e., second person) seeking approval to market a generic or biosimilar version of the drug against which a patent is listed must either: (i) await the listed patent's expiry; or (ii) allege invalidity and/or non-infringement of the patent by serving a Notice of Allegation ("**NOA**") on the first person; and

(b) Where the first person receives an NOA, it may launch a patent infringement proceeding and avail of an up to 24-month statutory stay that prevents subsequent entrant market authorization while the patent proceeding is determined.

16. Sections 3 and 4 of the *PM(NOC) Regulations* address the Minister's maintenance of the Patent Register, the submission of patent lists filed by a first person, and the eligibility of patents for listing. The Applicant files drug submissions for FINLIUS in Canada and is a first person for the purposes of the *PM(NOC) Regulations*.

17. Pursuant to subsection 3(2) of the *PM(NOC) Regulations*, the Minister is required to maintain a register of patents submitted for addition to the Patent Register:

> 3(2) The Minister shall maintain a register of patents that have been submitted for addition to the register and certificates of supplementary protection in which any of those patents are set out [...]

18. Pursuant to subsections 3(2) to 3(8) of the *PM(NOC) Regulations*, the Minister maintains the Patent Register, including by adding or deleting patents in a broad array of circumstances. Under subsection 3(2) of the *PM(NOC) Regulations,* the Minister is expressly granted authority to: (i) add any patent on a patent list to the Patent Register; (ii) delete patents from the Patent Register in certain circumstances; and (iii) perform discretionary reviews of the Patent Register.

19. Subsection 3(1) of the *PM(NOC) Regulations* sets out the definition of "new drug submission": "new drug submission means a new drug submission or an extraordinary use new drug submission as those terms are used in Division 8 of Part C of the *Food and Drug Regulations* but excludes such a submission that is based solely on the change of name of the manufacturer."

20. Subsection C.008.002 of the *Food and Drug Regulations* states:

> C.08.002 (1) No person shall sell or advertise a new drug unless (a) the manufacturer of the new drug has filed with the Minister a new drug submission, an extraordinary use new drug submission, an abbreviated new drug submission or an abbreviated extraordinary use new drug submission relating to the new drug that is satisfactory to the Minister; [...]
>
> (2) A new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following [list of information required for NDS].

21. Subsections 4(1) to 4.1 of the *PM(NOC) Regulations* set out certain criteria for listing, including: (i) when patent lists for existing and newly issued patents can be submitted; (ii) the required content of patent lists; (iii) the eligible drug submissions

for which patent lists may be filed; and (iv) the eligible patent claims for which patent lists may be filed.

22. Subsection 4(2) states:

> (2) A patent on a patent list in relation to a new drug submission is eligible to be added to the register if the patent contains
>
> (a) a claim for the medicinal ingredient and the medicinal ingredient has been approved through the issuance of a notice of compliance in respect of the submission;
>
> (b) a claim for the formulation that contains the medicinal ingredient and the formulation has been approved through the issuance of a notice of compliance in respect of the submission;
>
> (c) a claim for the dosage form and the dosage form has been approved through the issuance of a notice of compliance in respect of the submission; or
>
> (d) a claim for the use of the medicinal ingredient, and the use has been approved through the issuance of a notice of compliance in respect of the submission.

23. First persons add patents to the Patent Register by submitting a patent list to OSIP. A patent list must identify: (i) a drug submission; (ii) a drug; (iii) a patent; (iv) the first person's right to list the patent; and (v) the address in Canada for service on the first person of any NOA by a second person alleging the patent is improperly listed, invalid, or not infringed.

24. Following service of an NOA, the first person and/or patent owner may, within 45 days, bring a court action pursuant to section 6 of the *PM(NOC) Regulations* against the second person seeking a declaration that making, constructing, using, or selling a

drug in accordance with the second person's drug submission would infringe a listed patent.

25. When a first person commences a patent infringement proceeding in respect of a listed patent, the Minister is prohibited from approving the second person's drug submission during the statutory stay period which is triggered by the commencement of the action.

26. The Patent Register is the vehicle by which first persons and patentees access important rights under the *PM(NOC) Regulations*. A listed patent entitles the first person to receive early notice of generic entry in the form of an NOA and thereby elect to commence a patent infringement proceeding prior to generic entry. Further, listing a patent provides a first person with the benefit of a time limited statutory stay.

27. If no patents are listed on the Patent Register in respect of a drug product, then a first person cannot exercise these rights under the *PM(NOC) Regulations*.

F. Requirements for Listing Patents on the Patent Register

28. This Application addresses whether a new drug submission is a "new drug submission" within the meaning of subsections 3(1) and 4(2) of the *PM(NOC) Regulations*.

G. The Decision

29. On December 21, 2022, the Minister communicated a preliminary decision to the Applicant finding the '837 Patent to be ineligible for listing on the Patent Register in respect of the drug FINLIUS (the "**Preliminary Decision**"). The Minister advised

that it was of the preliminary view that the '837 Patent was ineligible for listing on the Patent Register against NDS 267289 because NDS 267289 is not a type of submission that can support the listing of a patent on the Patent Register within the meaning of subsections 3(1) and 4(2) of the *PM(NOC) Regulations*.

30. On January 18, 2023, the Applicant sought reconsideration of the Preliminary Decision by the Minister (the "**Applicant's Response**"). The Applicant submitted written representations, which maintained and provided further support for the Applicant's listing request.

31. By letter dated March 29, 2023, the Minister issued the Decision under review. The Decision rejected the Applicant's arguments and held that the '837 Patent was not eligible for inclusion on the Patent Register in respect of the drug FINLIUS.

H. The Applicant's Response

32. The Applicant asserted that the Minister's Preliminary Decision failed to properly interpret the definition of submission in subsection 3(1) of the *PM(NOC) Regulations* and failed to properly apply the listing requirements under subsection 4(2).

33. The Applicant submitted that:

(a) NDS 267289 satisfied the health and safety data requirements of the *Food and Drug Regulations* by cross-reference to approved STELARA health and safety data;

(b) NDS 267289 meets the definition of a new drug submission within the meaning of the *PM(NOC) Regulations* and the *Food and Drug Regulations*;

(c) It is not in dispute that the '837 Patent meets the requirements in subsections 4(3) and 4(6) (i.e., the product specificity and timing requirements) in the *PM(NOC) Regulations* in respect of NDS 267289; and

(d) The '837 Patent does not need to be "carried forward" to FINLIUS from a listing of the '837 Patent against STELARA under subsection 4.1(2) of the *PM(NOC) Regulations* to be listed.

I. The Decision Under Review

34. The Minister maintained that the '837 Patent was ineligible for listing on the Patent Register in respect of NDS 267289.

35. The Minister concluded that for the purpose of adding a new patent to the Patent Register, new drug submissions submitted under the administrative pathway in the *Guidance* are excluded from the definition of "new drug submission" in subsection 3(1) of the *PM(NOC) Regulations*.

J. The Decision is Unreasonable

36. The Minister's Decision that the '837 Patent is not eligible for listing against NDS 267289 is unreasonable.

37. Having regard to the facts and the law, the Minister made the Decision unreasonably by:

(a) Unreasonably interpreting the meaning of a "new drug submission" in the *PM(NOC) Regulations* including by:

(i) Disregarding the clear wording of the *PM(NOC) Regulations* and *Food and Drug Regulations*;

(ii) Failing to give effect to differences in the definitions of "new drug submission" and "supplement to a new drug submission" in the *PM(NOC) Regulations*;

(iii) Failing to properly consider the context and purpose of the *PM(NOC) Regulations*;

(iv) Failing to consider amendments to the *PM(NOC) Regulations*;

(v) Misapplying case law;

(vi) Adding to the plain meaning of the words "new drug submission" a policy gloss that has no support in the language of the *PM(NOC) Regulations* and is unnecessary to give effect to the text as it is worded;

(vii) Otherwise arriving at an unreasonable interpretation of the meaning of "new drug submission" in the *PM(NOC) Regulations*;

(b) Misapplying the *PM(NOC) Regulations* and the *Food and Drug Regulations* by, *inter alia*, failing to apply the proper meaning of "new drug submission" to the facts to arrive at an unreasonable Decision;

(c) Treating the interpretation of "new drug submission" to be a matter of discretion to be informed by the Minister's policy views;

(d) Refusing to list the '837 Patent on the Patent Register in respect of the drug FINLIUS;

(e) Fettering her discretion by taking the position that no new drug submissions submitted under the administrative pathway created by Health Canada and described in the *Guidance* can be submissions that can support listing of a patent on the Patent Register;

(f) Failing to consider the prejudicial impact caused by the Decision on the Applicant; and

(g) Otherwise failing to interpret and apply the facts and law in a reasonable manner, including by refusing to exercise her discretion to find the '837 Patent eligible for listing on the Patent Register.

38. In the alternative, if the Court finds that the '837 Patent cannot be listed in respect of NDS 267289, then the Minister's Decision is internally inconsistent and unreasonable for failing to determine that the '837 Patent will be eligible to be carried forward within the meaning of subsection 4.1(2) of the *PM(NOC) Regulations* and listed against FINLIUS if it is listed against STELARA. The '837 Patent is currently

the subject of another judicial review in Federal Court File No. T-2627-22, challenging the Minister's decision not to list it against STELARA.

39. The '837 Patent is eligible for listing on the Patent Register in respect of NDS 267289 as of the date that it is approved through issuance of a notice of compliance. In the alternative, the '837 Patent is eligible for listing as of such earliest date that NDS 26789 is eligible for listing. In the further alternative, the '837 Patent is eligible for listing as of the date of the decision of this Court on this Application declaring the '837 Patent eligible for listing.

K. Statutory Provisions

40. The Applicant relies on:

(a) *Patent Act*, R.S.C., 1985, c. P-4;

(b) *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 as amended, including sections 3 and 4;

(c) *Food and Drug Regulations*, CRC, c 870;

(d) *Federal Courts Act*, R.S.C., 1985, c. F-7 as amended, including sections 18 and 18.1;

(e) *Federal Courts Rules*, SOR/98-106 as amended;

(f) *Interpretation Act, RSC 1985, c I-21*, as amended, including s. 12; and

(g) Such further and other grounds as counsel may advise and this Honourable Court may permit.

THIS APPLICATION WILL BE SUPPORTED BY THE FOLLOWING MATERIAL:

(a) A certified copy of the '837 Patent;

(b) Affidavit(s) to be sworn;

(c) The record before and the Decision of the Minister dated March 29, 2023; and

(d) Such further and other material as counsel may advise and this Honourable Court permit.

THE APPLICANT REQUESTS THE MINISTER OF HEALTH TO SEND A CERTIFIED COPY OF THE FOLLOWING MATERIAL THAT IS NOT IN THE POSSESSION OF THE APPLICANT BUT IS IN THE POSSESSION OF THE MINISTER OF HEALTH TO THE APPLICANT AND TO THE REGISTRY:

41. All materials considered or created by the Minister of Health, or by any person or entity acting on behalf of the Minister of Health, and including all documentation and communication, pertaining or relevant to the Decision herein.

April 26, 2023

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Solicitors for the Applicant

Exhibit “J26”

This is Exhibit “J26” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.
Arash Rouhi

PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

Pr FINLIUS®
ustekinumab injection

Solution for Subcutaneous Injection

45 mg/0.5 mL
90 mg/1.0 mL

Pr FINLIUS® I.V.
ustekinumab for injection

Solution for Intravenous Infusion

130 mg/26 mL (5 mg/mL)

Selective Immunomodulating Agent

Janssen Inc.
19 Green Belt Drive
Toronto, Ontario
M3C 1L9

www.janssen.com/canada

Date of Initial Authorization:
December 12, 2008

Date of Revision:
July 7, 2023

Submission Control Number: 275432

RECENT MAJOR LABEL CHANGES

7 WARNINGS AND PRECAUTIONS, Immune, *Infant exposure* in utero	06/2023
7 WARNINGS AND PRECAUTIONS, 7.1.2 Breast-feeding	06/2023

TABLE OF CONTENTS

Sections or subsections that are not applicable at the time of authorization are not listed.

PART I: HEALTH PROFESSIONAL INFORMATION

Ustekinumab administered subcutaneously will be referred to throughout the Product Monograph as Finlius.
Ustekinumab administered through intravenous infusion will be referred to throughout the Product Monograph as Finlius I.V.

1 INDICATIONS

FINLIUS®/FINLIUS® I.V. (ustekinumab) should be used only by physicians who have sufficient knowledge of plaque psoriasis, psoriatic arthritis, Crohn's disease, and/or ulcerative colitis and who have fully familiarized themselves with the efficacy/safety profile of the drug.

Plaque Psoriasis

Finlius (ustekinumab) is indicated for:

- the treatment of chronic moderate to severe plaque psoriasis in adult patients who are candidates for phototherapy or systemic therapy
- the treatment of chronic moderate to severe plaque psoriasis in pediatric patients (6-17 years of age) who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies (see 1.1 Pediatrics).

Psoriatic Arthritis

Finlius (ustekinumab) is indicated for the treatment of adult patients with active psoriatic arthritis. Finlius can be used alone or in combination with methotrexate (MTX).

Crohn's Disease

Finlius/Finlius I.V. (ustekinumab) is indicated for the treatment of adult patients with moderately to severely active Crohn's disease, who have had an inadequate response, loss of response to, or were intolerant to either immunomodulators or one or more tumour necrosis factor-alpha (TNFα) antagonists, or have had an inadequate response, intolerance or demonstrated dependence on corticosteroids.

Ulcerative Colitis

Finlius/Finlius I.V. (ustekinumab) is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies.

1.1 Pediatrics

Pediatrics (6-17 years of age): Finlius (ustekinumab) is indicated for the treatment of chronic moderate to severe plaque psoriasis in pediatric patients (children and adolescents) from 6 to 17 years of age, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.

The safety and efficacy of Finlius has not been established in pediatric patients with plaque psoriasis <6 years of age. Pediatric studies of Finlius I.V. have not been conducted. The safety and efficacy of Finlius in pediatric patients with psoriatic arthritis, Crohn's disease, and ulcerative colitis have not been established (see 7.1.3 Pediatrics and 14.1 Clinical Trials by Indication, **Pediatric Plaque Psoriasis (6 to 17 years of age)**).

1.2 Geriatrics

Geriatrics (>65 years of age): No major age-related differences in clearance or volume of distribution were observed in clinical studies. Although no overall differences in safety and efficacy were observed between older and younger patients in clinical studies in approved indications, the number of patients aged 65 and over is not sufficient to determine whether they respond differently from younger patients (see 7.1.4 Geriatrics).

2 CONTRAINDICATIONS

- Finlius/Finlius I.V. is contraindicated in patients who are hypersensitive to ustekinumab or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container (see 7 WARNINGS AND PRECAUTIONS, **Sensitivity/Resistance, Hypersensitivity Reactions** and 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING).
- Finlius/Finlius I.V. is contraindicated in patients with severe infections such as sepsis, tuberculosis and opportunistic infections (see 7 WARNINGS AND PRECAUTIONS, **General, Infections**).

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

Finlius/Finlius I.V. (ustekinumab) is intended for use under the guidance and supervision of a physician.

The BioAdvance® Network has been established to facilitate the administration of Finlius/Finlius I.V. BioAdvance® clinics are staffed by qualified healthcare professionals specially trained in the administration of Finlius/Finlius I.V. and care of patients with Crohn's disease and ulcerative colitis. BioAdvance® clinics are available across Canada. Information about the BioAdvance® Network and location of the nearest BioAdvance® Network clinic can be obtained by calling Janssen Inc. Medical Information at: 1-800-567-3331.

4.2 Recommended Dose and Dosage Adjustment

Plaque Psoriasis

For the treatment of plaque psoriasis, Finlius is administered by subcutaneous injection.

Adults

The recommended dose of Finlius is 45 mg administered at Weeks 0 and 4, then every 12 weeks thereafter. Alternatively, 90 mg may be used in patients with a body weight greater than 100 kg. In patients weighing >100 kg, both 45 mg and 90 mg were shown to be efficacious. However, 90 mg was efficacious in a higher percentage of these patients than the 45 mg dose.

For patients who inadequately respond to dosing every 12 weeks, consideration may be given to treating as often as every 8 weeks.

Consideration should be given to discontinuing treatment in patients who have shown no response up to 12 weeks of treatment.

Re-treatment with a dosing regimen of Weeks 0 and 4 followed by 12-week dosing after interruption of therapy has been shown to be safe and effective (see 14.1 Clinical Trials by Indication, **Plaque Psoriasis – Adults, Efficacy of retreatment**).

Pediatrics (6 to 17 years of age)

The recommended dose of Finlius based on body weight is shown below (Table 1). Finlius should be administered at Weeks 0 and 4, then every 12 weeks thereafter.

Consideration should be given to discontinuing treatment in patients who have shown no response up to 12 weeks of treatment.

Table 1: Recommended dose of Finlius for pediatric psoriasis

Weight	Recommended Dose	Dosage Form
< 60 kg [a]	0.75 mg/kg*	vial
≥ 60 to ≤ 100 kg	45 mg	prefilled syringe, vial
> 100 kg [b]	90 mg	prefilled syringe

* To calculate the volume of injection (mL) for patients < 60 kg, use the following formula: *body weight* (kg) x *0.0083* (mL/kg). The calculated volume should be rounded to the nearest 0.01 mL and administered using a 1 mL graduated syringe. A 45 mg vial is available for pediatric patients who need to receive less than the full 45 mg dose.

[a] For patients with body weight < 60 kg, use the vial presentation only

[b] There were only 3 patients aged 12 to 17 years, with a body weight > 100 kg in the study

Table 2: Injection volumes of Finlius for pediatric psoriasis patients < 60 kg

Body weight at time of dosing (kg)	Dose (mg)	Volume of injection (mL)
15	11.3	0.12
16	12.0	0.13
17	12.8	0.14
18	13.5	0.15
19	14.3	0.16
20	15.0	0.17
21	15.8	0.17
22	16.5	0.18
23	17.3	0.19
24	18.0	0.20
25	18.8	0.21
26	19.5	0.22
27	20.3	0.22
28	21.0	0.23
29	21.8	0.24
30	22.5	0.25
31	23.3	0.26
32	24.0	0.27
33	24.8	0.27
34	25.5	0.28
35	26.3	0.29
36	27.0	0.30
37	27.8	0.31
38	28.5	0.32
39	29.3	0.32
40	30.0	0.33
41	30.8	0.34
42	31.5	0.35
43	32.3	0.36
44	33.0	0.37
45	33.8	0.37
46	34.5	0.38
47	35.3	0.39
48	36.0	0.40
49	36.8	0.41
50	37.5	0.42
51	38.3	0.42
52	39.0	0.43
53	39.8	0.44
54	40.5	0.45
55	41.3	0.46
56	42.0	0.46
57	42.8	0.47
58	43.5	0.48
59	44.3	0.49

Psoriatic Arthritis – Adults

For the treatment of psoriatic arthritis, Finlius is administered by subcutaneous injection. The recommended dose of Finlius is 45 mg administered at Weeks 0 and 4, then every 12 weeks thereafter. Alternatively, 90 mg may be used in patients with a body weight greater than 100 kg.

Crohn's Disease and Ulcerative Colitis – Adults

Intravenous induction dosing

In patients with Crohn's disease and ulcerative colitis, the recommended induction treatment regimen is a single intravenous (IV) tiered dose of Finlius I.V. based on body weight (Table 3) (see 4.4 Administration, **Intravenous Infusion (Crohn's Disease and Ulcerative Colitis)**).

Table 3: Initial dosing of Finlius I.V.

Body Weight of Patient at the time of dosing	Dose[a]	Number of 130 mg Finlius I.V. vials
≤ 55 kg	260 mg	2
> 55 kg to ≤ 85 kg	390 mg	3
> 85 kg	520 mg	4

[a] Recommended dose (approximately 6 mg/kg)

Subcutaneous maintenance dosing

The recommended maintenance dose of Finlius is 90 mg administered subcutaneously. The first subcutaneous dose should be given at week 8 following the intravenous induction dose. Subsequent doses should be given every 8 weeks thereafter.

In some patients, (e.g., those with low inflammatory burden) a single dose of Finlius I.V. followed by 90 mg subcutaneous dosing 8 weeks later, then every 12 weeks thereafter may be considered at the discretion of the treating physician. Patients should have their dose frequency adjusted to every 8 weeks if inadequate response occurs. Consideration should be given to discontinuing treatment in patients who show no evidence of therapeutic benefit 16 weeks after the IV induction dose (see 14 CLINICAL TRIALS).

Immunomodulators and/or corticosteroids may be continued during treatment with Finlius/Finlius I.V. In patients who have responded to treatment with Finlius/Finlius I.V. corticosteroids may be reduced or discontinued in accordance with standard of care.

If therapy is interrupted, resumption of treatment with subcutaneous dosing every 8 weeks is safe and effective.

Special Populations

Renal Insufficiency
Specific studies have not been conducted in patients with hepatic renal insufficiency.

Hepatic Insufficiency
Specific studies have not been conducted in patients with hepatic insufficiency.

4.4 Administration

Subcutaneous Administration

Finlius is supplied as 45 mg and 90 mg pre-filled syringes and 45 mg single-use vials. In pediatric patients, it is recommended that Finlius be administered by a health care provider. A patient may self-inject with Finlius if a physician determines that it is appropriate after proper training in subcutaneous injection technique and disposal (see PATIENT MEDICATION INFORMATION, **How to take Finlius**).

Prior to subcutaneous administration, visually inspect the solution for particulate matter and discoloration. The product is colourless to light yellow and may contain a few small translucent or white particles of protein. This appearance is not unusual for proteinaceous solutions. The product should not be used if solution is discolored or cloudy, or if other particulate matter is present. Finlius does not contain preservatives; therefore, any unused product remaining in the vial or syringe should not be used.

The needle cover on the pre-filled syringe contains dry natural rubber (a derivative of latex), which may cause allergic reactions in individuals sensitive to latex.

Patients should be instructed to inject the prescribed amount of Finlius according to the directions provided in the PATIENT MEDICATION INFORMATION Section.

Intravenous Infusion (Crohn's Disease and Ulcerative Colitis)

Finlius I.V. is supplied in a 130 mg vial. The solution is clear, colorless to light yellow with a pH of approximately 6.0. Intravenous infusion of Finlius I.V. should be administered by qualified health care professionals.

Instructions for dilution of Finlius I.V. (130 mg vial) Crohn's disease and ulcerative colitis
Finlius I.V. must be diluted and prepared for IV infusion by a healthcare professional using aseptic technique.

1. Calculate the dose and the number of Finlius I.V. vials needed based on patient's body weight (see Table 3). Each 26 ml vial of Finlius I.V. contains 130 mg of ustekinumab.
2. Withdraw, and then discard a volume of the 0.9% w/v sodium chloride solution from the 250 ml infusion bag equal to the volume of Finlius I.V. to be added. (26 mL for each vial of Finlius I.V. needed, for 2 vials - discard 52 mL, for 3 vials - discard 78 mL, for 4 vials - discard 104 mL). Alternatively, a 250 mL infusion bag containing 0.45% w/v sodium chloride solution may be used.
3. Withdraw 26 mL of Finlius I.V. from each vial needed and add it to the 250 ml infusion bag. The final volume in the infusion bag should be 250 ml. Gently mix.

4. Visually inspect the diluted solution before administration. Do not use if visibly opaque particles, discoloration or foreign particles are observed.
5. Infuse the diluted solution over a period of at least one hour. Once diluted, the infusion should be completed within eight hours of the dilution in the infusion bag.
6. Use only an infusion set with an in-line, sterile, non-pyrogenic, low protein-binding filter (pore size 0.2 micrometer).
7. Do not infuse Finlius I.V. concomitantly in the same intravenous line with other agents.
8. Finlius I.V. does not contain preservatives. Each vial is for single use only and any unused medicinal product should be disposed of in accordance with local requirements.

If necessary, the diluted infusion solution may be stored at room temperature. The infusion should be completed within 8 hours of the dilution in the infusion bag. Do not freeze. Discard any unused portion of the infusion solution.

4.5 Missed Dose

Patients who miss their scheduled dose of Finlius/Finlius I.V., should be advised to contact their healthcare provider for guidance.

5 OVERDOSAGE

Single doses up to 6 mg/kg intravenously have been administered in clinical studies without dose limiting toxicity. In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions or effects and appropriate symptomatic treatment be instituted immediately.

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

To help ensure the traceability of biologic products, including biosimilars, health professionals should recognise the importance of recording both the brand name and the non-proprietary (active ingredient) name as well as other product-specific identifiers such as the Drug Identification Number (DIN) and the batch/lot number of the product supplied.

Route of Administration	Dosage Form / Strength / Composition	Non-medicinal Ingredients
Subcutaneous Injection	Sterile solution in single-use pre-filled syringe: 45 mg / 0.5 mL, 90 mg / 1.0 mL or 45 mg / 0.5 mL vial	L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose, and water for injection.
Intravenous Infusion	Sterile solution in single-use vial 130 mg / 26 mL (5 mg/mL)	EDTA disodium salt dihydrate, L-histidine and L-histidine hydrochloride monohydrate, L-methionine, polysorbate 80, and sucrose.

Finlius/Finlius I.V. (ustekinumab) is approved in the following presentations:

Finlius

Pre-filled Syringe:
- 45 mg / 0.5 mL
- 90 mg / 1.0 mL

Single-use Vial:
- 45 mg / 0.5 mL

Finlius I.V.

Single-use Vial:
- 130 mg / 26 mL

Finlius: 45 mg Pre-filled Syringe/Vial or 90 mg Pre-filled Syringe

Finlius is supplied as a single-use, sterile solution for subcutaneous injection in a Type 1 glass syringe with a fixed 27G, half-inch needle and needle cover. The needle cover is manufactured using a dry natural rubber (a derivative of latex) (see 7 WARNINGS AND PRECAUTIONS, **Sensitivity/Resistance, Hypersensitivity Reactions**). The syringe is fitted with a passive safety guard. Finlius is also supplied as a sterile solution for subcutaneous injection in a single-use (Type 1) glass vial with a coated stopper. Only the needle cover on the pre-filled syringe contains latex. All other components of the vial and pre-filled syringe are latex free.

The solution is clear to slightly opalescent, colorless to light yellow with a pH of approximately 6.0. Each mL of Finlius contains 90 mg of ustekinumab. Finlius does not contain preservatives.

There are two strengths of Finlius available: 45 mg of ustekinumab in 0.5 mL and 90 mg of ustekinumab in 1.0 mL.

Finlius is available in single unit packaging presentations.

Finlius I.V.: 130 mg Vial

Finlius I.V., 130 mg vial, is supplied as a sterile solution for intravenous infusion in a single-use (Type 1) glass vial. The vial is stoppered with a latex-free coated stopper. The solution is clear, colorless to light yellow with a pH of approximately 6.0. Each mL of Finlius I.V. contains 5.0 mg of ustekinumab. Finlius I.V. does not contain preservatives. Finlius I.V. is available in one strength, 130 mg in 26 mL, and packaged as 1 single use vial.

7 WARNINGS AND PRECAUTIONS

General

Infections

Ustekinumab is a selective immunomodulator and may have the potential to increase the risk of infections and reactivate latent infections.

Finlius/Finlius I.V. should not be given to patients with any clinically important active infection. If a patient develops a serious infection they should be closely monitored and Finlius/Finlius I.V. should not be administered until the infection resolves or is adequately treated. Caution should be exercised when considering the use of Finlius/Finlius I.V. in patients with a chronic infection or a history of recurrent infection. Patients should be instructed to seek medical advice if signs or symptoms suggestive of an infection occur.

Prior to initiating treatment with Finlius/Finlius I.V., patients should be evaluated for tuberculosis infection. Finlius/Finlius I.V. should not be given to patients with active tuberculosis. Treatment of latent tuberculosis infection should be initiated prior to administering Finlius/Finlius I.V. Anti-tuberculosis therapy should also be considered prior to initiation of Finlius/Finlius I.V. in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed. In clinical studies, patients with latent tuberculosis who were concurrently treated with isoniazid did not develop tuberculosis. Patients receiving Finlius/Finlius I.V. should be monitored closely for signs and symptoms of active tuberculosis during and after treatment.

In clinical studies, serious bacterial, fungal, and viral infections were observed in subjects receiving Finlius/Finlius I.V. Serious infections requiring hospitalization occurred in the psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis development programs. In the psoriasis and psoriatic arthritis programs serious infections included diverticulitis, cellulitis, pneumonia, appendicitis, cholecystitis and sepsis. In the Crohn's disease program, serious infections included anal abscess, gastroenteritis, pneumonia and sepsis. Other clinically important infections included listeria meningitis and ophthalmic herpes which were reported in one patient each. In the ulcerative colitis program, serious infections included gastroenteritis and pneumonia (see 8 ADVERSE REACTIONS).

Carcinogenesis and Mutagenesis

Malignancies
Ustekinumab is a selective immunomodulator. Immunomodulating agents have the potential to increase the risk of malignancy. Some patients who received ustekinumab in clinical studies developed malignancies (see 8.2 Clinical Trial Adverse Reactions, **Malignancies**).

Finlius/Finlius I.V. has not been studied in patients with a history of malignancy. Caution should be exercised when considering the use of Finlius/Finlius I.V. in patients with a history of malignancy or when considering continuing treatment in patients who develop a malignancy.

All patients, in particular those greater than 60 years of age, those with a medical history of prolonged immunosuppressant therapy or those with a history of PUVA treatment, should be monitored for the appearance of skin cancer (see 8 ADVERSE REACTIONS).

Hepatic/Biliary/Pancreatic

Specific studies have not been conducted in patients with hepatic insufficiency.

Immune

Immunization
It is recommended that live viral or bacterial vaccines not be given concurrently with Finlius/Finlius I.V. (ustekinumab). No data are available on the secondary transmission of infection by live vaccines in patients receiving Finlius/Finlius I.V. Caution is advised when administering some live vaccines to household contacts of patients receiving Finlius/Finlius I.V. because of the potential risk for shedding from the household contact and transmission to the patient. Patients receiving Finlius/Finlius I.V. may receive concurrent inactivated or non-live vaccinations (see 9.4 Drug-Drug Interactions, **Live Vaccines**).

Prior to initiating therapy with Finlius/Finlius I.V., patients should receive all immunizations appropriate for age as recommended by current immunization guidelines. Long term treatment with Finlius does not appear to suppress the immune response to pneumococcal polysaccharide or tetanus vaccines polysaccharide or tetanus vaccines. During the long-term extension of a Phase 3 psoriasis study (PHOENIX 2), patients treated with Finlius for at least 3.5 years mounted similar antibody responses to both pneumococcal polysaccharide and tetanus vaccines as a non-systemically treated psoriasis control group. Similar proportions of patients developed protective levels of anti-pneumococcal and anti-tetanus antibodies and antibody titers were similar among Finlius-treated and control patients. However, non-live vaccinations received during a course of Finlius/Finlius I.V. may not elicit an immune response sufficient to prevent disease.

***Infant exposure* in utero**
For infants exposed *in utero* to ustekinumab, a six month waiting period following birth is recommended before the administration of live vaccines. Administration of a live vaccine prior to 6 months of age may be considered if ustekinumab serum levels are undetectable in the infant,

or the benefit of the vaccination clearly outweighs the risk of administration of live vaccines to the infant (see 7 WARNINGS AND PRECAUTIONS, **Immune, Immunization**).

Concomitant immunosuppressive therapy
In the Phase 3 psoriasis studies, the safety and efficacy of Finlius (ustekinumab) in combination with immunosuppressive agents or phototherapy have not been evaluated. In the Phase 3 psoriatic arthritis studies, concomitant methotrexate did not appear to influence the safety of Finlius. In Crohn's disease and ulcerative colitis studies, concomitant use of immunomodulators (6-mercaptopurine (6-MP), azathioprine (AZA), MTX) or corticosteroids did not appear to influence the overall safety of Finlius/Finlius I.V. Caution should be exercised when considering concomitant use of immunosuppressive agents and Finlius/Finlius I.V. or when transitioning from other biologic agents (see 9 DRUG INTERACTIONS, **Immunosuppressants**).

Immunotherapy
Finlius/Finlius I.V. (ustekinumab) has not been evaluated in patients who have undergone allergy immunotherapy. Finlius/Finlius I.V. may affect allergy immunotherapy. Caution should be exercised in patients receiving or who have received allergy immunotherapy particularly for anaphylaxis.

Neurologic

Reversible Posterior Leukoencephalopathy Syndrome
One case of reversible posterior leukoencephalopathy syndrome (RPLS) was observed during the clinical development programs which included 6709 ustekinumab-treated subjects. The subject, who had received 12 doses of Finlius over approximately two and a half years, presented with headache, seizures and confusion in the setting of alcohol abuse. No additional Finlius injections were administered and the subject fully recovered with appropriate treatment.

RPLS is a neurological disorder, which is not caused by demyelination or a known infectious agent. RPLS can present with headache, seizures, confusion and visual disturbances. Conditions with which it has been associated include preeclampsia, acute hypertension, cytotoxic agents, immunosuppressive therapy and alcohol abuse. Fatal outcomes have been reported.

If RPLS is suspected, administer appropriate treatment and discontinue Finlius/Finlius I.V.

Renal

Specific studies have not been conducted in patients with renal insufficiency.

Reproductive Health: Female and Male Potential

Women of Childbearing Potential: Women of childbearing potential initiating treatment with Finlius/Finlius I.V. should use effective methods of contraception and should receive preconception counselling before planning a pregnancy in accordance with disease specific clinical guidelines. Finlius/Finlius I.V. remains in the circulation for approximately 15 weeks after treatment. In clinical trials, women of childbearing potential were required to use effective

methods of contraception during treatment and for at least 15 weeks after treatment (see 7.1.1 Pregnant Women).

Sensitivity/Resistance

Hypersensitivity Reactions

Systemic
In post-marketing experience, serious allergic reactions, including anaphylaxis and angioedema, have been reported. If an anaphylactic or other serious allergic reaction occurs, institute appropriate therapy and discontinue administration of Finlius/Finlius I.V. (see 8 ADVERSE REACTIONS).

Respiratory
Cases of allergic alveolitis and eosinophilic pneumonia have been reported during post-approval use of ustekinumab. Clinical presentations included cough, dyspnoea, and interstitial infiltrates following one to three doses. Serious outcomes have included respiratory failure and prolonged hospitalisation. Improvement has been reported after discontinuation of ustekinumab and also, in some cases, administration of corticosteroids. If infection has been excluded and diagnosis is confirmed, discontinue ustekinumab and institute appropriate treatment.

Latex sensitivity
The needle cover on the pre-filled syringe contains dry natural rubber (a derivative of latex), which may cause allergic reactions in individuals sensitive to latex.

7.1 Special Populations

7.1.1 Pregnant Women

There is no evidence from animal studies of teratogenicity, birth defects or developmental delays at dose levels up to approximately 45-fold higher than the highest equivalent dose intended to be administered to patients with psoriasis and psoriatic arthritis (see 16 NON-CLINICAL TOXICOLOGY, **Reproductive and Developmental Toxicology**). However, animal reproductive and developmental studies are not always predictive of human response.

It is not known whether ustekinumab can cause fetal harm when administered to a pregnant woman or whether it can affect reproductive capacity. While it is known that human IgG antibodies, like ustekinumab, cross the placenta, no adequate and well-controlled studies have been conducted to evaluate if ustekinumab can cross the human placenta in pregnant women. In developmental toxicity studies in monkeys, ustekinumab was detected in fetal serum following repeated dosing of pregnant monkeys during the period of organogenesis. Although ustekinumab crossed the monkey placenta there was no evidence of teratogenicity in these studies. The decision to continue Finlius during pregnancy should be carefully evaluated taking into consideration clinical practice guidelines to ensure the safety of the pregnant woman and the fetus. Finlius/Finlius I.V. should be given to a pregnant woman only if the benefit clearly outweighs the risk.

7.1.2 Breast-feeding

Limited data from published literature suggests that ustekinumab is excreted in human breast milk in small amounts and it is not known if ustekinumab is absorbed systemically after ingestion. Because of the potential for adverse reactions in nursing infants from ustekinumab, a decision should be made whether to discontinue nursing or to discontinue the drug.

7.1.3 Pediatrics

Pediatrics (< 18 years of age): The efficacy of Finlius (ustekinumab) has been studied in 110 plaque psoriasis patients 12-17 years of age where the majority of patients (77/110) were 15-17 years of age. The efficacy of Finlius was studied in 44 plaque psoriasis patients 6-11 years of age where half of the patients (22/44) were 6-9 years of age. Studies of Finlius in pediatric plaque psoriasis patients below 6 years of age have not been conducted (see 14.1 Clinical Trials by Indication, **Pediatric Plaque Psoriasis (6 to 17 years of age)**).
Pediatric studies of Finlius I.V. have not been conducted. No studies have been conducted in pediatric patients with psoriatic arthritis, Crohn's disease or ulcerative colitis.

7.1.4 Geriatrics

Geriatrics (> 65 years of age): Of the 6709 patients exposed to Finlius/Finlius I.V. in clinical trials, a total of 353 were 65 years or older (183 patients with psoriasis, 69 patients with psoriatic arthritis, 58 patients with Crohn's disease and 43 patients with ulcerative colitis). No major age-related differences in clearance or volume of distribution were observed in clinical studies. Although no overall differences in safety and efficacy were observed between older and younger patients in clinical studies in approved indications, the number of patients aged 65 and over is not sufficient to determine whether they respond differently from younger patients. Patients over 60 years of age should be closely monitored for skin cancer (see 7 WARNINGS AND PRECAUTIONS, **Carcinogenesis and Mutagenesis**).

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

The most common adverse reactions (> 5%) in controlled periods of the clinical studies with Finlius/Finlius I.V. (ustekinumab) among all indications were nasopharyngitis, and headache. Most were considered to be mild and did not necessitate drug discontinuation. The overall safety profile of Finlius/Finlius I.V. was similar for patients among all indications. Serious infections and malignancies were also reported in clinical studies (see 8.2 Clinical Trial Adverse Reactions; **Infections** and **Malignancies**).

8.2 Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. The adverse reaction rates observed in the clinical trials; therefore, may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse reaction information from clinical trials may be useful in identifying and approximating rates of adverse drug reactions in real-world use.

Adults

The safety data described below reflect exposure to Finlius/Finlius I.V. in 14 Phase 2 and Phase 3 studies in 6709 patients (4135 with psoriasis and/or psoriatic arthritis, 1749 with Crohn's disease, and 825 with ulcerative colitis), including 4577 exposed for at least 6 months, 3253 exposed for at least 1 year, 1482 exposed for at least 4 years and 838 for at least 5 years.

Psoriasis and Psoriatic Arthritis

The safety data described below reflect exposure to Finlius in 7 phase 2 and phase 3 studies in 4135 adult patients with psoriasis and/or psoriatic arthritis, including 3256 exposed for at least 6 months, 1482 exposed for at least 4 years and 838 for at least 5 years.

Table 4 summarizes the adverse reactions that occurred at a rate of at least 1% in the Finlius group during the placebo-controlled period of the Phase 3 studies (PHOENIX 1, PHOENIX 2, PSUMMIT 1 and PSUMMIT 2).

Table 4: Adverse reactions reported by > 1% of patients during the placebo controlled period of PHOENIX 1 and 2 and PSUMMIT 1 and 2*

	Placebo	Finlius (ustekinumab)	
		45 mg	90 mg
Patients treated	974	972	974
Infections and infestations			
Nasopharyngitis	64 (6.6%)	72 (7.4%)	70 (7.2%)
Upper respiratory tract infection	44 (4.5%)	46 (4.7%)	40 (4.1%)
Dental Infection	2 (0.2%)	9 (0.9%)	10 (1.0%)
Nervous system disorders			
Headache	29 (3.0%)	48 (4.9%)	41 (4.2%)
Dizziness	9 (0.9%)	11 (1.1%)	13 (1.3%)
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain	9 (0.9%)	16 (1.6%)	15 (1.5%)
Gastrointestinal disorders			
Diarrhea	15 (1.5%)	22 (2.3%)	18 (1.8%)
Nausea	10 (1.0%)	18 (1.9%)	15 (1.5%)
Skin and subcutaneous tissue disorders			
Pruritus	9 (0.9%)	14 (1.4%)	12 (1.2%)
Musculoskeletal and connective tissue disorders			
Arthralgia	23 (2.4%)	30 (3.1%)	26 (2.7%)
Back pain	9 (0.9%)	12 (1.2%)	19 (2.0%)
Myalgia	5 (0.5%)	8 (0.8%)	11 (1.1%)
General disorders and administration site conditions			
Fatigue	16 (1.6%)	24 (2.5%)	24 (2.5%)
Injection site erythema	6 (0.6%)	8 (0.8%)	16 (1.6%)

*Placebo controlled periods are through Week 12 in PHOENIX 1 AND 2 and through Week 16 in PSUMMIT 1 and 2.

Table 5 present the rates at which the Finlius ADRs occurred in treatment groups in the ACCEPT trial.

Table 5: Adverse drug reactions reported by ≥ 1% of patients through Week 12 in ACCEPT

	ENBREL® (etanercept)	Finlius (ustekinumab)	
		45 mg	90 mg
Patients treated	347	209	347
Infections and infestations			
Nasopharyngitis	29 (8.4%)	21 (10.0%)	34 (9.8%)
Upper respiratory tract infection	20 (5.8%)	13 (6.2%)	22 (6.3%)
Nervous system disorders			
Headache	38 (11.0%)	31 (14.8%)	41 (11.8%)
Dizziness	8 (2.3%)	3 (1.4%)	6 (1.7%)
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain	14 (4.0%)	5 (2.4%)	14 (4.0%)
Gastrointestinal disorders			
Diarrhea	9 (2.6%)	8 (3.8%)	9 (2.6%)
Nausea	8 (2.3%)	8 (3.8%)	10 (2.9%)
Skin and subcutaneous tissue disorders			
Pruritus	14 (4.0%)	12 (5.7%)	16 (4.6%)
Musculoskeletal and connective tissue disorders			
Arthralgia	9 (2.6%)	11 (5.3%)	10 (2.9%)
Back pain	7 (2.0%)	14 (6.7%)	15 (4.3%)
Myalgia	7 (2.0%)	3 (1.4%)	7 (2.0%)
General disorders and administration site conditions			
Fatigue	13 (3.7%)	8 (3.8%)	19 (5.5%)
Injection site erythema	51 (14.7%)	2 (1.0%)	2 (0.6%)

Crohn's Disease

In the three Phase 3 studies and two Phase 2 studies, 1749 subjects with Crohn's disease were exposed to Finlius/Finlius I.V. with 849 exposed for 6 months and 464 exposed for at least 1 year with a total 1106 subject-years of follow-up.

The safety of Finlius/Finlius I.V. was assessed in three Phase 3 randomized, double-blind, placebo-controlled studies. Two 8-week IV induction studies (UNITI-1 and UNITI-2) were followed by a 44-week subcutaneous randomized withdrawal maintenance study (IM-UNITI) representing 52 weeks of therapy. The overall safety profile of Finlius/Finlius I.V. was consistent with the safety profile seen in the psoriasis and psoriatic arthritis clinical studies with the exception of new adverse drug reactions of acne, asthenia, vomiting and vulvovaginal mycotic infections.

The safety profile remained generally consistent throughout the Week 272 safety analysis.

Table 6: Adverse drug reactions reported by ≥ 1%[#] of Finlius I.V. (ustekinumab) treated patients UNITI-1 and UNITI-2 Induction Studies through Week 8

Patients Treated	Placebo (n=466)	Finlius I.V. ~6mg/kg[¥] (n=470)
Treatment Emergent Adverse Events (SOC/preferred term)		
Gastrointestinal disorders		
Nausea	22 (4.7%)	25 (5.3%)
Vomiting	12 (2.6%)	20 (4.3%)
Infections and infestations		
Nasopharyngitis	23 (4.9%)	25 (5.3%)
Musculoskeletal and connective tissue disorders		
Arthralgia	22 (4.7%)	24 (5.1%)
Back Pain	9 (1.9%)	10 (2.1%)
General disorders and administration site conditions		
Asthenia	2 (0.4%)	7 (1.5%)
Skin and subcutaneous tissue disorders		
Pruritus	2 (0.4%)	7 (1.5%)
Acne	2 (0.4%)	5 (1.1%)

[#] ≥ 1% and more frequently with ustekinumab than placebo

[¥] tiered weight-based dose approximating 6 mg/kg (see 4 DOSAGE AND ADMINISTRATION, Table 3)

Table 7: Adverse drug reactions reported by ≥ 1%¥ of patients in any Finlius (ustekinumab)-treated groups IM-UNITI study through Week 0 to Week 44 of maintenance

Patients Treated	Placebo (n=133)	Finlius 90 mg	
		Q12w (n=132)	Q8w (n=131)
Treatment Emergent Adverse Events (SOC/preferred term)			
Infections and Infestations			
Nasopharyngitis	10 (7.5%)	17 (12.9%)	14 (10.7%)
Vulvovaginal mycotic infection (including candidiasis)	1 (0.8%)	1 (0.8%)	6 (4.6%)
Gastrointestinal system disorders			
Diarrhea	7 (5.3%)	11 (8.3%)	5 (3.8%)
Nausea	9 (6.8%)	10 (7.6%)	4 (3.1%)
Musculoskeletal and connective tissue disorder			
Arthralgia	19 (14.3%)	22 (16.7%)	18 (13.7%)
Back pain	6 (4.5%)	5 (3.8%)	6 (4.6%)
Myalgia	1 (0.8%)	5 (3.8%)	1 (0.8%)
General disorders and administration site conditions			
Fatigue	6 (4.5%)	8 (6.1%)	6 (4.6%)
Injection site erythema	0	1 (0.8%)	7 (5.3%)
Injection site pain	1 (0.8%)	2 (1.5%)	0
Skin and subcutaneous tissue disorder			
Pruritus	3 (2.3%)	2 (1.5%)	5 (3.8%)
Acne	1 (0.8%)	1 (0.8%)	2 (1.5%)
Nervous system disorder			
Headache	15 (11.3%)	15 (11.4%)	16 (12.2%)
Psychiatric disorders			
Depression	2 (1.5%)	3 (2.3%)	2 (1.5%)

¥ ≥ 1% and more frequently with either Finlius 90 mg q12w or Finlius 90 mg q8w than placebo

Ulcerative Colitis

The safety of Finlius/Finlius I.V. was evaluated in two randomized, double-blind, placebo-controlled studies (UNIFI-I and UNIFI-M) in 960 adult patients with moderately to severely active ulcerative colitis. The overall safety profile was similar for patients with psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis.

The safety profile remained generally consistent throughout the Week 96 safety analysis.

Table 8: Adverse drug reactions reported by ≥ 1%[#] of Finlius I.V. (ustekinumab) treated patients in the ulcerative colitis induction study (UNIFI-I) through Week 8

Patients Treated	Placebo (n=319)	Finlius I.V. ~6mg/kg[¥] (n=320)
Treatment Emergent Adverse Events (SOC/preferred term)		
Gastrointestinal disorders		
Vomiting	1 (0.3%)	4 (1.3%)
Infections and infestations		
Nasopharyngitis	9 (2.8%)	18 (5.6%)
Musculoskeletal and connective tissue disorders		
Arthralgia	3 (0.9%)	6 (1.9%)
General disorders and administration site conditions		
Fatigue	5 (1.6%)	8 (2.5%)
Nervous system		
Dizziness	1 (0.3%)	4 (1.3%)
Respiratory, thoracic and mediastinal disorders		
Oropharyngeal pain	1 (0.3%)	8 (2.5%)

[#] ≥ 1% and more frequently with ustekinumab than placebo

[¥] tiered weight-based dose approximating 6 mg/kg (see 4 DOSAGE AND ADMINISTRATION, Table 3)

Table 9: Adverse drug reactions reported by ≥ 1%[¥] of patients in any Finlius (ustekinumab)-treated patients in the ulcerative colitis maintenance study (UNIFI-M) through Week 0 to Week 44 of maintenance

Patients Treated	Placebo (n=175)	Finlius 90 mg	
		Q12w (n=172)	Q8w (n=176)
Treatment Emergent Adverse Events (SOC/preferred term)			
Infections and Infestations			
Nasopharyngitis	28 (16.0%)	31 (18.0%)	26 (14.8%)
Upper respiratory tract infection	8 (4.6%)	5 (2.9%)	16 (9.1%)
Sinusitis	2 (1.1%)	2 (1.2%)	7 (4.0%)
Gastrointestinal system disorders			
Diarrhea	2 (1.1%)	5 (2.9%)	7 (4.0%)
Nausea	4 (2.3%)	4 (2.3%)	6 (3.4%)
Musculoskeletal and connective tissue disorder			
Arthralgia	15 (8.6%)	15 (8.7%)	8 (4.5%)
General disorders and administration site conditions			
Fatigue	4 (2.3%)	4 (2.3%)	7 (4.0%)
Injection site erythema	1 (0.6%)	1 (0.6%)	3 (1.7%)
Skin and subcutaneous tissue disorder			
Acne	0 (0%)	2 (1.2%)	3 (1.7%)
Nervous system disorder			
Dizziness	0 (0%)	0 (0%)	3 (1.7%)
Headache	7 (4.0%)	11 (6.4%)	18 (10.2%)
Respiratory, thoracic and mediastinal disorders			
Nasal congestion	0 (0%)	0 (0%)	3 (1.7%)
Oropharyngeal pain	5 (2.9%)	4 (2.3%)	7 (4.0%)
Psychiatric disorders			
Depression	1 (0.6%)	2 (1.2%)	1 (0.6%)

[¥] ≥ 1% and more frequently with either Finlius 90 mg q12w or Finlius 90 mg q8w than placebo

Infections:

In placebo-controlled studies of patients with psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis, the rates of infection or serious infection were similar between Finlius/Finlius I.V.-treated patients and those treated with placebo. In the placebo-controlled period of these clinical studies, the rate of infection was 1.36 per patient-year of follow-up in Finlius/Finlius I.V.-treated patients, and 1.34 per patient-year of follow-up in placebo-treated patients. Serious infections occurred at a rate of 0.03 per patient-year of follow-up in Finlius/Finlius I.V.-treated patients (30 serious infections in 930 patient-years of follow-up) and 0.03 per patient-year of follow-up in placebo-treated patients (15 serious infections in 434 patient-years of follow-up) (see 7 WARNINGS AND PRECAUTIONS).

In the controlled and non-controlled portions of placebo-controlled psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis clinical studies representing 11,581 patient-years of exposure in 6,709 patients, the median follow-up was 1.0 years; 1.1 years for psoriatic disease studies, 0.6 year for Crohn's disease studies and 1.0 years for ulcerative colitis studies. The rate of infection was 0.91 per patient-year of follow-up in Finlius/Finlius I.V.-treated patients. The rate of serious infections was 0.02 per patient-year of follow-up in Finlius/Finlius I.V.-treated patients (199 serious infections in 11581 patient-years of follow-up) and included pneumonia, anal abscess, sepsis, cellulitis, diverticulitis, gastroenteritis and viral infections.

Malignancies:

In the placebo-controlled period of the psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis clinical studies, the incidence of non-melanoma skin cancer was 0.43 per 100 patient-years of follow-up for Finlius/Finlius I.V.-treated patients (4 patients in 929 patient-years of follow-up) compared with 0.46 per 100 patient-years of follow-up for placebo-treated patients (2 patient in 433 patient-years of follow-up) during the placebo-controlled periods. In a Phase 3 clinical trial (ACCEPT) comparing ustekinumab and etanercept for the treatment of moderate to severe plaque psoriasis, 209 patients received ustekinumab 45 mg, 347 patients received ustekinumab 90 mg, and 347 patients received etanercept. Through Week 12, three (0.5%) subjects in the ustekinumab groups had a non-melanoma skin cancer detected in areas of psoriasis that had cleared with treatment. No skin cancers were observed in the etanercept group but due to the short treatment period, the possible pre-existing malignancies and the differences in efficacy (see 14 CLINICAL TRIALS), the clinical relevance has not been established.

The incidence of malignancies excluding non-melanoma skin cancer was 0.11 per 100 patient-years of follow-up for Finlius/Finlius I.V.-treated patients (1 patient in 929 patient-years of follow-up) compared with 0.23 per 100 patient-years of follow-up for placebo-treated patients (1 patient in 434 patient-years of follow-up) during the placebo-controlled periods. In the ACCEPT trial, through Week 12, one subject (0.2%) with a familial history of breast cancer was diagnosed with breast cancer versus no malignancies in the etanercept group.

In the controlled and non-controlled periods of psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis clinical studies representing 11,561 patient-years of exposure in 6709 patients, the median follow-up was 1.0 years; 1.1 years for psoriatic disease studies, 0.6 year for Crohn's

disease studies and 1.0 years for ulcerative colitis studies. Malignancies excluding non-melanoma skin cancers were reported in 62 patients in 11561 patient-years of follow-up. This represents an incidence of 0.54 per 100 patients-years of follow-up for Finlius/Finlius I.V.-treated patients. This rate of malignancies reported in Finlius/Finlius I.V.-treated patients was comparable to the rate expected in the general population (standardized incidence ratio = 0.93 [95% confidence interval: 0.71,1.20]). The most frequently observed malignancies, other than non-melanoma skin cancer, were prostate (16), colorectal (7), melanoma (6), and breast (5). The incidence of non-melanoma skin cancer was 0.49 per 100 patient-years of follow-up for Finlius/Finlius I.V.-treated patients (56 patients in 11545 patient-years of follow-up). The ratio of patients with basal versus squamous cell skin cancers (3:1) is comparable with the ratio expected in the general population.

Among 1569 patients exposed to Finlius for at least 3 years, 0.9% (n= 14) of patients reported NMSC and 1.4% (n=22) of patients reported malignancies excluding NMSC. This represents an incidence of 0.18 and 0.29 per 100 patient-years of follow-up for NMSC and malignancies excluding NMSC, respectively.

Hypersensitivity and Infusion Reactions:

Subcutaneous Administration
During the controlled periods of the psoriasis and psoriatic arthritis clinical studies of ustekinumab, rash and urticaria have each been observed in < 1% of patients.

In the maintenance Crohn's disease study, 1.7% of patients reported a placebo injection-site reaction and 3.0% reported a Finlius injection-site reaction.

Intravenous Administration
In Crohn's disease and ulcerative colitis induction studies, no events of anaphylaxis or other serious infusion reactions were reported. In these studies, 2.2% of 785 placebo treated patients and 1.9% of 790 patients treated with the recommended dose of Finlius I.V. reported adverse events occurring during or within an hour of the infusion.

Immunogenicity:

In psoriasis and psoriatic arthritis clinical studies, up to 12.4% of patients treated with ustekinumab developed antibodies to ustekinumab. In Crohn's disease and ulcerative colitis clinical studies, 2.9% and 4.6% of patients, respectively, developed antibodies to ustekinumab when treated with ustekinumab for approximately 1 year. No apparent association between the development of antibodies to ustekinumab and the development of injection site reactions was observed. 123 of 168 (73%) of psoriasis and psoriatic arthritis patients who were positive for antibodies to ustekinumab had neutralizing antibodies. Patients positive for antibodies to ustekinumab exhibited mean or median serum levels of ustekinumab that were consistently lower than those in patients negative or undetectable for antibodies to ustekinumab and tended to have lower efficacy; however, antibody positivity did not preclude a clinical response.

Immunogenicity tests are generally product-specific. Comparison of antibody rates to those from other products, or comparison of the incidence of antibodies between different tests without cross-validation is not appropriate.

8.2.1 Clinical Trial Adverse Reactions - Pediatrics

Pediatric Patients with Psoriasis

The safety of Finlius has been studied in two phase 3 studies of pediatric patients with moderate to severe plaque psoriasis. The first study was in 110 patients from 12 to 17 years of age treated for up to 60 weeks (CADMUS). The second study was in 44 patients from 6 to 11 years of age treated for up to 56 weeks (CADMUS Jr.). In general, the adverse events reported in these two studies were similar to those seen in previous studies in adults with plaque psoriasis.

Pediatrics (12 to 17 years of age)

Table 10: Adverse reactions reported by > 5% of patients during the placebo-controlled period of CADMUS

	Placebo	Finlius (ustekinumab)	
		Half Standard Dosage	Standard Dosage
Patients treated	37	37	36
Infections and infestations			
Upper respiratory tract infection	2 (5.4%)	1 (2.7%)	3 (8.3%)
Nervous system disorders			
Headache	2 (5.4%)	4 (10.8%)	3 (8.3%)
Gastrointestinal disorders			
Diarrhea	0	0	2 (5.6%)

Pediatrics (6 to 11 years of age)

No new safety issues were identified in pediatric patients 6 to 11 years of age and the observed safety profile in these pediatric patients was similar to the safety profile observed in Finlius-treated adolescent patients 12 to 17 years of age.

8.3 Less Common Clinical Trial Adverse Reactions

The following adverse reactions occurred at rates less than 1% during the controlled period of Finlius/Finlius I.V. clinical trials:

General disorders and administration site conditions: injection site reactions (including swelling, pruritus, induration, hemorrhage, hematoma), asthenia

Infections and infestations: cellulitis, herpes zoster, viral upper respiratory tract infections, vulvovaginal mycotic infections, dental infections

Psychiatric disorders: depression

Respiratory, thoracic and mediastinal disorders: nasal congestion

Skin and Subcutaneous tissue disorders: acne

8.4 Abnormal Laboratory Findings: Hematologic, Clinical Chemistry and Other Quantitative Data

During the placebo-controlled period of the Phase 2 and Phase 3 psoriasis studies (through week 12), an increase in non-fasting blood glucose levels was observed, as shown in Table 11. The clinical significance of these changes in glucose is unknown. No such increase in fasting blood glucose levels was observed in the same subjects.

Table 11: Proportion of patients with elevated non-fasting blood glucose levels in clinical trials

Increase in non-fasting blood glucose levels	Placebo n(%)	Combined ustekinumab group n(%)
Number of Patients	730	1580
Subjects with any abnormal value	49 (6.7%)	83 (5.3%)
Subjects with > 1 abnormal value	9 (1.2%)	35 (2.2 %)

8.5 Post-Market Adverse Reactions

Additional adverse events reported from worldwide post-marketing experience with ustekinumab are included in Table 12. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to ustekinumab exposure.

Table 12: Post-marketing Reports

Immune system disorders	Hypersensitivity reactions (including rash, urticaria) Serious allergic reactions (including anaphylaxis and angioedema)
Infections and infestations	Lower respiratory tract infection
Respiratory, thoracic and mediastinal disorders	Allergic alveolitis, eosinophilic pneumonia
Skin and subcutaneous tissue disorders	Pustular psoriasis Exfoliative dermatitis, erythrodermic psoriasis, hypersensitivity vasculitis

9 DRUG INTERACTIONS

9.2 Drug Interactions Overview

Specific drug interaction studies have not been conducted with Finlius/Finlius I.V. (ustekinumab).

In population pharmacokinetic analysis, the effect of the most frequently used concomitant medications in patients with psoriasis (including paracetamol/acetaminophen, ibuprofen, acetylsalicylic acid, metformin, atorvastatin, naproxen, levothyroxine, hydrochlorothiazide, and influenza vaccine) on pharmacokinetics of ustekinumab was explored and none of the concomitant medications exerted significant impact. In psoriatic arthritis studies, concomitant MTX use did not appear to influence the pharmacokinetics of ustekinumab. In Crohn's disease

and ulcerative colitis induction studies, immunomodulators (6-MP, AZA, MTX) were used concomitantly in approximately 30% of patients and corticosteroids were used concomitantly in approximately 40% and 50% of Crohn's disease and ulcerative colitis patients, respectively. Use of these concomitant therapies did not appear to influence the pharmacokinetics of ustekinumab.

9.3 Drug-Behavioural Interactions

The pharmacokinetics of ustekinumab were not impacted by the use of tobacco or alcohol.

9.4 Drug-Drug Interactions

Live Vaccines
Live vaccines should not be given concurrently with Finlius/Finlius I.V. (ustekinumab) (see 7 WARNINGS AND PRECAUTIONS, **Immune, Immunization**). Information regarding the administration of live vaccines in infants exposed to ustekinumab *in utero* is provided earlier in this product monograph (see 7 WARNINGS AND PRECAUTIONS, **Immune, *Infant exposure* in utero**).

Immunosuppressants
The safety and efficacy of Finlius/Finlius I.V. (ustekinumab) in combination with immunosuppressive agents or phototherapy have not been evaluated (see 7 WARNINGS AND PRECAUTIONS, **Immune**, **Concomitant immunosuppressive therapy**).

CYP450 Substrates
The effects of IL-12 or IL-23 on the regulation of CYP450 enzymes were evaluated in an *in vitro* study using human hepatocytes, which showed that IL-12 and/or IL-23 at levels of 10 ng/mL did not alter human CYP450 enzyme activities (CYP1A2, 2B6, 2C9, 2C19, 2D6, or 3A4). The clinical significance of this is not known, although these results do not suggest the need for dose adjustments in patients who are receiving concomitant CYP450 substrates.

9.5 Drug-Food Interactions

Interactions with food have not been established.

9.6 Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7 Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

Ustekinumab is a fully human IgG1κ monoclonal antibody, a first-in-class agent that binds with specificity to the shared p40 protein subunit of human cytokines interleukin IL-12 and IL-23.

Ustekinumab inhibits the bioactivity of human IL-12 and IL-23 by preventing p40 from binding to the IL-12Rβ1 receptor protein expressed on the surface of immune cells. Ustekinumab cannot bind to IL-12 or IL-23 that is already bound to IL-12Rβ1 cell surface receptors. Thus, ustekinumab is not likely to contribute to complement or antibody- mediated cytotoxicity of cells expressing IL-12 and/or IL-23 receptors.

IL-12 and IL-23 are heterodimeric cytokines secreted by activated antigen-presenting cells, such as macrophages and dendritic cells. IL-12 stimulates natural killer (NK) cells and drives the differentiation of CD4+ T cells toward the T helper 1(Th1) phenotype and stimulates interferon gamma (IFNγ) production. IL-23 induces the T helper 17 (Th17) pathway and promotes secretion of IL-17A, IL-21, and IL-22. Levels of IL-12 and IL-23 are elevated in the skin and blood of patients with psoriasis, and serum IL12/23p40 distinguishes patients with psoriatic arthritis from healthy individuals, implicating IL-12 and IL-23 in the pathophysiology of psoriatic inflammatory diseases. Genetic polymorphisms in IL23A, IL23R, and IL-12B genes confer susceptibility to these disorders. Additionally, IL-12 and IL-23 are highly expressed in lesional psoriatic skin, and IL-12-mediated induction of IFNγ correlates with psoriasis disease activity. IL-23 responsive T-cells have been found in the entheses in a mouse model of inflammatory arthritis, where IL-23 drives entheseal inflammation. In addition, there is pre-clinical evidence implicating IL-23 and downstream pathways in bone erosion and destruction through up-regulation of receptor activator of nuclear factor-κB ligand (RANKL), which activates osteoclasts.

In patients with Crohn's disease, IL-12 and IL-23 are elevated in the intestines and lymph nodes.

By binding the shared p40 subunit of IL-12 and IL-23, ustekinumab may exert its clinical effects in psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis through interruption of the Th1 and Th17 cytokine pathways, which have been implicated as contributors in the pathology of these diseases.

10.2 Pharmacodynamics

Treatment with ustekinumab resulted in significant improvement in histological measures of psoriasis including epidermal hyperplasia and cell proliferation. These results are consistent with the clinical efficacy observed. In patients with psoriasis and/or psoriatic arthritis Finlius (ustekinumab) had no apparent effect on the percentages of circulating immune cell populations including memory and naive T-cell subsets or circulating cytokine levels. Systemic markers of inflammation were measurable in the serum at baseline and 4 markers (MDC, VEGF, MCSF-1 and YKL-40) showed modest differences in concentration post-treatment in Finlius-treated patients as compared to placebo.

Treatment with ustekinumab resulted in a decrease in the gene expression of its molecular targets IL-12 and IL-23 as shown by analyses of mRNA obtained from lesional skin biopsies of psoriatic patients at baseline and up to two weeks post-treatment. In addition, ustekinumab down-regulated the gene expression of inflammatory cytokines and chemokines such as MCP-1, TNF-alpha, IP-10 and IL-8 in lesional skin biopsies. These results are consistent with the significant clinical benefit observed with ustekinumab treatment.

In psoriasis and psoriatic arthritis studies, clinical response (improvement in PASI or ACR measurements, respectively) appeared to be related to serum ustekinumab levels. Patients with psoriasis with higher PASI response had higher median serum concentrations of ustekinumab than those with lower clinical responses. In psoriasis studies, the proportion of patients with psoriasis who achieved PASI 75 response increased with increasing serum levels of ustekinumab. The proportion of patients who achieved PASI 75 response at Week 28 increased with increasing serum ustekinumab trough levels at Week 28. In psoriatic arthritis studies, patients achieving an ACR 20 response had higher median serum concentrations of ustekinumab than ACR 20 non-responders. The proportion of patients who achieved ACR 20 and ACR 50 response increased with increasing serum levels of ustekinumab.

In patients with Crohn's disease and ulcerative colitis, treatment with Finlius/Finlius I.V. resulted in a significant decrease in inflammatory markers including C-Reactive Protein (CRP) and fecal calprotectin. In patients with Crohn's disease, decrease in gene expression for IL-12Rβ1and IL-23 was observed in inflamed colon tissue in responders to Finlius I.V. treatment while no significant changes were observed in placebo treated patients at Week 6.

10.3 Pharmacokinetics

The median pharmacokinetic parameters of ustekinumab following a single SC administration in adult patients with psoriasis are shown in Table 11. The pharmacokinetic parameters of ustekinumab (CL/F, V_z/F, and $t_{1/2}$) were generally comparable between 45 mg and 90 mg subcutaneous doses.

Table 11: Summary of Pharmacokinetic Parameters of Ustekinumab Following a Single 45 or 90 mg Subcutaneous Administration in Adult Patients with Psoriasis

Dose	45 mg			90 mg		
PK parameter	N	Median (Range)	Mean (± SD)	N	Median (Range)	Mean (± SD)
C_{max} (mcg/mL)	22	2.4 (1.0, 5.4)	2.7 (± 1.2)	24	5.3 (1.2, 12.3)	6.1 (± 3.6)
t_{max} (day)	22	13.5 (1.9, 58.2)	15.3 (± 13.5)	24	7.0 (2.9, 27.1)	9.9 (± 7.4)
AUC (mcg·day/mL)	18	84.9 (31.2, 1261.9)	196.7 (± 298.2)	21	226.9 (57.1, 755.5)	274.9 (± 206.5)
$t_{1/2}$ (day)	18	19.8 (5.0, 353.6)	45.6 (± 80.2)	21	21.2 (13.6, 85.8)	26.7 (± 19.3)
CL/F (mL/day/kg)	18	5.3 (0.2, 12.9)	5.8 (± 3.5)	21	4.5 (1.5, 14.9)	5.7 (± 3.6)
V_z/F (mL/kg)	18	154.2 (32.6, 280.5)	160.5 (± 64.5)	21	160.5 (37.3, 354.1)	178.7 (± 85.2)

Source data: C0379T04 CSR

Dose Linearity: The systemic exposure of ustekinumab (C_{max} and AUC) increased in a linear manner following a single subcutaneous administration at doses ranging from approximately 24 mg to 240 mg in patients with psoriasis.

Single Dose vs. Multiple Doses: Serum concentration-time profiles of ustekinumab were generally predictable after single or multiple subcutaneous dose administrations on the basis of a one-compartment model. In patients with psoriasis, steady-state serum concentrations of ustekinumab were achieved by Week 28 after initial subcutaneous doses at Weeks 0 and 4 followed by doses every 12 weeks. The median steady-state trough concentration ranged from 0.21 mcg/mL to 0.26 mcg/mL (45 mg; n = 242 to 390) and from 0.47 mcg/mL to 0.49 mcg/mL (90 mg; n = 236 to 386) in patients with psoriasis. There was no apparent accumulation in serum ustekinumab concentration over time when given subcutaneously every 12 weeks.

Population Pharmacokinetic Analysis
Of the demographic factors (e.g., gender, race, age, body size), baseline patient physical or biochemical characteristics, medical or medication history, or concomitant medications evaluated in a population pharmacokinetic analysis, only body weight, diabetes comorbidity, and positive immune response to ustekinumab were found to be important covariates affecting the systemic exposure to ustekinumab in patients with moderate to severe psoriasis. Body weight and positive immune response to ustekinumab were also found to be important covariates affecting the systemic exposure to ustekinumab in subjects with psoriatic arthritis. Clinical relevance of the effects of these important covariates, however, needs to be evaluated concurrently with clinical efficacy and safety data.

Absorption:
The median time to reach the maximum serum concentration (t_{max}) was 8.5 days after a single 90 mg subcutaneous administration in healthy subjects (n = 30). The median t_{max} values of ustekinumab following a single subcutaneous administration of either 45 mg or 90 mg in patients with psoriasis were comparable to that observed in healthy subjects.

The absolute bioavailability (F) of ustekinumab following a single subcutaneous administration was estimated to be 57.2% in patients with psoriasis (n = 17).

Following the recommended IV induction dose, median peak serum ustekinumab concentration was 126.1 mcg/mL (IQ range 106.1 – 146.2 mcg/mL) in patients with Crohn's disease and 127.0 mcg/mL (IQ range 109.2 – 145.9 mcg/mL) in patient with ulcerative colitis. Starting at Week 8, subcutaneous maintenance dosing of 90 mg ustekinumab was administered every 8 or 12 weeks. Steady state ustekinumab concentration was achieved by the start of the second maintenance dose.

Following subcutaneous maintenance dosing of 90 mg ustekinumab every 8 weeks, median steady-state trough concentrations ranged from 1.97 mcg/mL to 2.24 mcg/mL in patients with Crohn's disease and 2.69 mcg/mL to 3.09 mcg/mL in patients with ulcerative colitis. Following subcutaneous maintenance dosing of 90 mg ustekinumab every 12 weeks, median steady state trough concentrations ranged from 0.61 mcg/mL to 0.76 mcg/mL in patients with Crohn's disease and 0.92 mcg/mL to 1.19 mcg/mL in patients with ulcerative colitis. The steady-state trough ustekinumab levels resulting from 90 mg ustekinumab every 8 weeks were associated

with higher clinical remission rates as compared to the steady-state trough levels following 90 mg every 12 weeks.

Distribution:
The median apparent volume of distribution during the terminal phase (V_z/F) following a single subcutaneous administration to patients with psoriasis ranged from 76 to 161 mL/kg (n = 4 to 21).

In a population pharmacokinetic analysis of ustekinumab in patients with Crohn's disease, the total volume of distribution at steady-state was 4.62 L and 4.44 L in patients with ulcerative colitis.

Metabolism:
The exact metabolic pathway for ustekinumab is unknown.

Elimination:
The median apparent clearance (CL/F) following a single subcutaneous administration to patients with psoriasis ranged from 2.7 to 5.3 mL/day/kg. The median half-life ($t_{1/2}$) of ustekinumab was approximately 3 weeks in patients with psoriasis and/or psoriatic arthritis, Crohn's disease and ulcerative colitis ranging from 15 to 32 days across all psoriasis and psoriatic arthritis studies (n = 4 to 55).

In a population pharmacokinetic analysis , the clearance of ustekinumab was 0.19 L/day (95% CI: 0.185, 0.197) in patients with Crohn's disease and 0.19 L/day (95% CI: 0.179, 0.192) in patients with ulcerative colitis with an estimated median terminal half-life of approximately 19 days in patients with Crohn's disease and ulcerative colitis.

Special Populations and Conditions

- **Pediatrics**
  Pediatrics (< 18 years of age): Studies of Finlius in pediatric patients with plaque psoriasis below 6 years of age have not been conducted. No pharmacokinetic data are available in pediatric patients with Crohn's disease or ulcerative colitis. Pediatric studies of Finlius I.V. have not been conducted.

  Serum ustekinumab concentrations in plaque psoriasis patients 6 to 17 years of age, treated with the recommended weight-based dose were generally comparable to those in the adult psoriasis population treated with the adult dose.

- **Geriatrics**
  Geriatrics (> 65 years of age): No specific studies have been conducted in elderly patients. A population pharmacokinetic analysis indicated there were no apparent changes in CL/F and V/F estimates in patients ≥ 65 years.

- **Sex, Ethnic Origin and Genetic Polymorphism:** The apparent clearance of ustekinumab was not impacted by sex, age, or race.

- **Hepatic Insufficiency:** No pharmacokinetic data are available in patients with impaired hepatic function.

- **Renal Insufficiency:** No pharmacokinetic data are available in patients with renal insufficiency.

- **Obesity:**
  Impact of Weight on Pharmacokinetics:
  Serum ustekinumab concentrations were affected by weight in patients with psoriasis and/or psoriatic arthritis. When given the same dose, patients of higher weight (> 100 kg) had lower median serum ustekinumab concentrations compared with those in patients of lower weight (≤ 100 kg). However, across doses, the median trough serum concentrations of ustekinumab in patients with higher weight (> 100 kg) in the 90 mg group were comparable to those in patients with lower weight (≤ 100 kg) in the 45 mg group.

11 STORAGE, STABILITY AND DISPOSAL

Finlius/Finlius I.V. must be refrigerated at 2 to 8ºC and protected from light. Keep the product in the original carton to protect from light until the time of use. Do not freeze. Do not shake.

If needed, individual Finlius pre-filled syringes may be stored at room temperature up to 30°C for a maximum single period of up to 30 days in the original carton with protection from light. Record the date when the pre-filled syringe is first removed from the refrigerator and the new expiry date on the carton in the spaces provided. The new expiry date must not exceed the original expiry date printed on the carton. Once a syringe has been stored at room temperature, it should not be returned to the refrigerator. Discard the syringe if not used within 30 days at room temperature storage.

If necessary, the diluted Finlius I.V. infusion solution may be stored for up to eight hours at room temperature. Do not freeze. Discard any unused portion of the infusion solution.

12 SPECIAL HANDLING INSTRUCTIONS

Following administration of Finlius/Finlius I.V., discard any unused portion. The syringe should be disposed of in a puncture-resistant container for syringes and needles. Patients or caregivers should be instructed in the technique as well as proper syringe and needle disposal, and not to reuse these items.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: ustekinumab

Chemical name: ustekinumab

Molecular formula and molecular mass: Ustekinumab is a fully human IgG1κ mAb, with an approximate molecular weight of 148,600 daltons.

Physicochemical properties: FINLIUS® (ustekinumab) is clear to slightly opalescent, colourless to light yellow with a pH of approximately 6.0. Finlius I.V. is clear, colorless to light yellow with a pH of approximately 6.0.

Product Characteristics:

Finlius

Finlius (ustekinumab) is supplied as a single-use, sterile solution for subcutaneous injection in a Type 1 glass syringe with a fixed 27G, half-inch needle and needle cover. The needle cover is manufactured using a dry natural rubber (a derivative of latex) (see 7 WARNINGS AND PRECAUTIONS, **Sensitivity/Resistance, Hypersensitivity Reactions**). The syringe is fitted with a passive safety guard. Finlius is also supplied as a sterile solution for subcutaneous injection in a single-use (Type 1) glass vial for SC administration‡.

Finlius is supplied as 2 dosage presentations at 45 mg in 0.5 mL volume as a pre-filled syringe or a single-use vial or at 90 mg in a 1 mL volume as a pre-filled syringe. Each 1 mL of Finlius solution contains 90 mg ustekinumab. No preservatives are present.

Finlius I.V.

Finlius I.V., 130 mg vial, is supplied as a sterile solution for intravenous infusion in a single-use (Type 1) glass vial. The vial is stoppered with a coated stopper.

Viral Inactivation

Ustekinumab is produced by a recombinant cell line cultured by continuous perfusion and is purified by a series of steps that includes measures to inactivate and remove viruses.

14 CLINICAL TRIALS

14.1 Clinical Trials by Indication

Plaque Psoriasis - Adults

The safety and efficacy of Finlius were assessed in two multicentre, randomized, double-blind, placebo-controlled studies (PHOENIX 1 and PHOENIX 2) in patients 18 years of age and older with chronic (> 6 months) plaque psoriasis who had a minimum body surface area (BSA) involvement of 10%, and Psoriasis Area and Severity Index (PASI) score ≥ 12 and who were candidates for phototherapy or systemic therapy. Patients with guttate, erythrodermic, or pustular psoriasis were excluded from the studies. No concomitant anti-psoriatic therapies were allowed during the study with the exception of low-potency topical corticosteroids on the face and groin after Week 12. A total of 1996 patients were enrolled in the two studies. The safety and efficacy of Finlius beyond 5 years have not been established.

In addition, a multicenter, randomized, active-controlled study (ACCEPT) compared the safety and efficacy of Finlius and etanercept in patients 18 years of age and older with chronic (> 6 months) plaque psoriasis who had a minimum BSA involvement of 10%, PASI score ≥ 12, Physician Global Assessment (PGA) score ≥ 3, who were candidates for phototherapy or systemic therapy, and who had had an inadequate response to, intolerance to, or contraindication to cyclosporine, methotrexate, or PUVA therapy. A total of 903 patients were enrolled in the study.

Baseline disease characteristics across PHOENIX 1 and 2 were similar (Table 12 and Table 13). In both studies, patients in all treatment groups had a median baseline PASI score ranging from 17 to 18. Approximately two-thirds of all patients had received prior phototherapy, 69% had received either prior conventional systemic or biologic therapy for the treatment of psoriasis, with 56% receiving prior conventional systemic therapy and 43% receiving prior biologic therapy. A total of 28% of study patients had a history of psoriatic arthritis. Similar disease characteristics were also seen in the ACCEPT trial (Table 12 and Table 13).

Table 12: Summary of patient demographics for PHOENIX 1, PHOENIX 2 and ACCEPT

Study #	Study design	Dosage, route of administration and duration	Study subjects (n)	Mean age (Range)	Sex
C0743T08 (PHOENIX 1)	Double-Blind Placebo-Controlled	Fixed doses: Placebo (N = 255) Placebo → 45 mg SC regimen[a] (N = 123) Placebo → 90 mg SC regimen[a] (N = 120) 45 mg SC Weeks 0, 4 then q12w (N = 255) 90 mg SC Weeks 0, 4 then q12w (N = 256)	N=766	45.3 (19,76)	M=531 F=235
C0743T09 (PHOENIX 2)	Double-Blind Placebo-Controlled	Fixed doses: Placebo (N = 410)-Placebo → 45 mg SC regimen[a] (N = 197) Placebo → 90 mg SC regimen[a] (N = 195) 45 mg SC Weeks 0, 4 then q12w (N = 409) 90 mg SC Weeks 0, 4 then q12w (N = 411)	N=1230	46.2 (18, 86)	M=840 F=390
C0743T12 (ACCEPT)	Assessor-Blind Active-Comparator Controlled	Fixed doses: Etanercept 50 mg (N=347) twice weekly through Week 12 Finlius 45 mg (N=209) at Week 0 and 4 Finlius 90 mg (N=347) at Week 0 and 4	N= 903	45.0 (18, 81)	M=613 F=290

[a] The placebo groups crossed over to receive Finlius (45 mg or 90 mg) at Weeks 12 and 16 then q12w

Table 13: Baseline Disease Characteristics in PHOENIX 1, PHOENIX 2 and ACCEPT

	PHOENIX 1		PHOENIX 2		ACCEPT	
	Placebo	Finlius	Placebo	Finlius	Etanercept	Finlius
Patients randomized at Week 0	N=255	N=511	N=410	N=820	N=347	N=556
Median BSA	22.0	21.0	20.0	21.0	19.0	20.0
BSA ≥ 20%	145 (57%)	276 (54%)	217 (53%)	445 (54%)	169 (49%)	289 (52%)
Median PASI	17.80	17.4	16.90	17.60	16.8	17.1
PASI ≥ 20	91 (36%)	169 (33%)	133 (32%)	300 (37%)	102 (29%)	205 (37%)
PGA of marked or severe	112 (44%)	223 (44%)	160 (39%)	328 (40%)	148 (43%)	242 (44%)
History of psoriatic arthritis	90 (35%)	168 (33%)	105 (26%)	200 (24%)	95 (27%)	157 (28%)
Prior phototherapy	150 (59%)	342 (67%)	276 (67%)	553 (67%)	224 (65%)	368 (66%)
Prior conventional systemic therapy excluding biologics[a]	142 (56%)	282 (55%)	241 (59%)	447 (55%)	199(57%)	311 (56%)
Prior conventional systemic or biologic therapy[a]	189 (74%)	364 (71%)	287 (70%)	536 (65%)	218(63%)	337 (61%)
Failed to respond to, had contraindication for, or intolerant to ≥ 1 conventional therapy[a]	139 (55%)	270 (53%)	254 (62%)	490 (60%)	347 (100%)	555 (100%)
Failed to respond to, had contraindication for, or intolerant to ≥ 3 conventional therapies[a]	30 (12%)	54 (11%)	66 (16%)	134 (16%)	52 (15%)	78 (14%)

[a] In PHOENIX 1 and 2, conventional systemic agents include acitretin, PUVA, methotrexate, and cyclosporine. In ACCEPT, conventional systemic agents included PUVA, methotrexate, and cyclosporine. All patients were required to be etanercept naïve at baseline in ACCEPT, but in PHOENIX 1 and 2 patients may have previously received etanercept.

PHOENIX 1 evaluated the safety and efficacy of Finlius versus placebo in 766 patients with plaque psoriasis. Patients were randomized in equal proportion to placebo, 45 mg or 90 mg of Finlius. Patients randomized to Finlius received 45 mg or 90 mg doses at Weeks 0 and 4 followed by the same dose every 12 weeks. Patients randomized to receive placebo at Weeks 0 and 4 crossed over to receive Finlius (either 45 mg or 90 mg) at Weeks 12 and 16 followed by the same dose every 12 weeks. To evaluate the efficacy of every 12-week dosing, patients who were PASI 75 responders at both Weeks 28 and 40 were re-randomized to either continue dosing of Finlius every 12 weeks or to placebo (i.e., withdrawal of therapy). Patients withdrawn from Finlius at Week 40 reinitiated Finlius at their original dosing regimen when they experienced at least a 50% loss of their PASI improvement obtained at Week 40. Patients were followed for at least 76 weeks.

PHOENIX 2 evaluated the safety and efficacy of Finlius versus placebo in 1230 patients with plaque psoriasis. This study design was identical to PHOENIX 1 through Week 28.

Dose Adjustment (every 8 weeks)
At Week 28, PHOENIX 1 patients who were nonresponders (< PASI 50 response) discontinued treatment and patients who were partial responders (≥ PASI 50 response and < PASI 75 response) were adjusted to every-8-week dosing. PASI 75 responders at Week 28 who became partial responders or nonresponders at Week 40 were adjusted to every-8-week dosing.

In PHOENIX 2, patients who were partial responders at Week 28 were re-randomized to either continue every 12 weeks dosing of Finlius or to switch to every 8 weeks dosing.

All patients were followed for up to 76 weeks in PHOENIX 1 and up to 52 weeks in PHOENIX 2 following first administration of study treatment.

In both studies, the primary endpoint was the proportion of patients who achieved a reduction in score of at least 75% from baseline at Week 12 by the PASI (PASI 75). Patients achieving ≥ 90% improvement in PASI from baseline (PASI 90) were considered PASI 90 responders and patients with ≥ 50% improvement in PASI from baseline (PASI 50) were considered PASI 50 responders. Another key efficacy assessment was the Physician's Global Assessment (PGA), a 6-category scale ranging from 0 (cleared) to 5 (severe) that indicates the physician's overall assessment of psoriasis focusing on plaque thickness/induration, erythema, and scaling.

The Dermatology Life Quality Index (DLQI), a dermatology-specific quality of life instrument designed to assess the impact of the disease on a patient's quality of life, was assessed in both PHOENIX 1 and PHOENIX 2. Other efficacy assessments included the Nail Psoriasis Severity Index (NAPSI), a physician-assessed score that measures the severity of nail involvement (PHOENIX 1); the Itch Visual Analog Scale (VAS), used to assess the severity of itch at the time of the assessment (PHOENIX 1); the Hospital Anxiety and Depression Scale (HADS), a self-rating tool developed to evaluate psychological measures in patients with physical ailments (PHOENIX 2); and the Work Limitations Questionnaire (WLQ), a 25-item, self-administered questionnaire that was used to measure the impact of chronic health conditions on job performance and work productivity among employed populations (PHOENIX 2).

The ACCEPT trial compared the efficacy of Finlius to etanercept and evaluated the safety of Finlius and etanercept in moderate to severe psoriasis patients. The active-controlled portion of the study was from Week 0 to Week 12, during which the efficacy and safety of etanercept and 2 dose levels of Finlius were evaluated. This trial was powered to test the superiority of each dose level to etanercept and the primary endpoint was the proportion of patients who achieved a PASI 75 at week 12.

Study results

The results of PHOENIX 1 and PHOENIX 2 for key psoriasis clinical outcomes are presented in Table 14.

Efficacy at the Primary Endpoint, PHOENIX 1 and PHOENIX 2

The onset of action with Finlius was rapid and improvement was seen within 2 weeks of the first dose. In both the PHOENIX 1 and PHOENIX 2 studies, a significantly greater proportion of patients randomized to treatment with Finlius were PASI 75 responders compared with placebo at Week 12 (Table 14). In the PHOENIX 1 study, 67% and 66% of patients receiving Finlius 45 mg and 90 mg, respectively, achieved a PASI 75 response at Week 12 compared with 3% of patients receiving placebo. In the PHOENIX 2 study, 67% and 76% of patients receiving Finlius 45 mg and 90 mg, respectively, achieved a PASI 75 response at Week 12 compared with 4% of patients receiving placebo.

All 3 components of the PASI (plaque thickness/induration, erythema, and scaling) contributed comparably to the improvement in PASI.

The efficacy of Finlius was significantly superior (p<0.001) to placebo across all subgroups defined by baseline demographics, clinical disease characteristics (including patients with a history of psoriatic arthritis) and prior medication usage. While pharmacokinetic modelling suggested a trend towards higher CL/F in patients with diabetes, a consistent effect on efficacy was not observed.

Table 14: Clinical Outcomes - PHOENIX 1 and PHOENIX 2

	PHOENIX 1			**PHOENIX 2**		
		Finlius			**Finlius**	
	Placebo	**45 mg**	**90 mg**	**Placebo**	**45 mg**	**90 mg**
Week 12						
Patients randomized	255	255	256	410	409	411
PASI response						
PASI 50 response[a]	26 (10%)	213 (84%)	220 (86%)	41 (10%)	342 (84%)	367 (89%)
PASI 75 response[a]	8 (3%)	171 (67%)	170 (66%)	15 (4%)	273 (67%)	311 (76%)
PASI 90 response[a]	5 (2%)	106 (42%)	94 (37%)	3 (1%)	173 (42%)	209 (51%)
PASI 100 response[a]	0 (0%)	33 (13%)	28 (11%)	0 (0%)	74 (18%)	75 (18%)
PGA of Cleared or Minimal[a]	10 (4%)	151 (59%)	156 (61%)	18 (4%)	277 (68%)	300 (73%)
Week 28						
Patients evaluated	--	250	243	--	397	400
PASI response						
PASI 50 response	--	228 (91%)	234 (96%)	--	369 (93%)	380 (95%)
PASI 75 response	--	178 (71%)	191 (79%)	--	276 (70%)	314 (79%)
PASI 90 response	--	123 (49%)	135 (56%)	--	178 (45%)	217 (54%)
PASI 100 response	--	52 (21%)	71(29 %)	--	74(19%)	118 (30%)
PGA of Cleared or Minimal	--	146 (58%)	160 (66%)	--	241(61%)	279 (70%)

[a] p < 0.001 for 45 mg or 90 mg comparison with placebo.

Other efficacy measures at Week 12

In both PHOENIX 1 and PHOENIX 2, compared with placebo, significantly greater proportions of patients randomized to 45 mg or 90 mg Finlius achieved a cleared or minimal PGA score, and significantly greater proportions of patients randomized to 45 mg or 90 mg Finlius were PASI 50, PASI 90 and PASI 100 responders at Week 12 (Table 14). In the PHOENIX 1 study, 60% and 62% of the patients treated with 45 mg and 90 mg Finlius, respectively, achieved PGA scores of cleared or minimal compared with 4% of placebo-treated patients. In PHOENIX 2, 68% and 73% of patients receiving 45 mg or 90 mg Finlius, respectively, had cleared or minimal PGA scores compared with 5% of the placebo patients. In PHOENIX 1, PASI 90 was achieved by 42% and 37% of the patients treated with 45 mg and 90 mg Finlius, respectively, compared with 2% of placebo-treated patients. In addition, a significantly higher proportion of subjects treated with either 45 mg (13%) or 90 mg (11%) achieved a PASI of 0 (i.e., PASI 100 response) compared with the placebo group (0.0%; $p<0.001$). In PHOENIX 2, the percentage of patients achieving PASI 100 and PASI 90 was 18% and 42%, respectively, in the 45 mg Finlius group, and 18% and 51%, respectively, in the 90 mg Finlius group versus 1% in the placebo group. The percentage of patients achieving PASI 50 in PHOENIX 1 was 84% and 86% in the 45 mg and 90 mg Finlius groups, respectively, compared with 10% in the placebo group. Similarly, 84% of patients treated with 45 mg Finlius, 89% of patients treated with 90 mg Finlius and 10% of patients treated with placebo reached PASI 50 in PHOENIX 2 (Table 14).

Response over time

In PHOENIX 1, significantly greater proportions of Finlius-treated patients had PASI 50 responses (9% and 10% for the 45 mg and 90 mg groups, respectively) compared with placebo (2%) by Week 2 ($p<0.001$). Significantly greater proportions of patients treated with Finlius achieved PASI 75 responses (9% and 12% for the 45 mg and 90 mg Finlius groups, respectively) compared with placebo (0.4%) by Week 4 ($p<0.001$). Maximum response was generally achieved by Week 24 in the 45 mg and 90 mg Finlius treatment groups, and response rates were generally sustained through Week 36 (Figure 1). In PHOENIX 1, PASI 75 rates at Week 24 were 76% for the 45 mg group, and 85% for the 90 mg group. Higher response rates were observed in patients receiving Finlius 90 mg than in those receiving Finlius 45 mg by Week 16 and these higher response rates were sustained through Week 36 (Figure 1). Similar results were observed in the PHOENIX 2 study through Week 28.

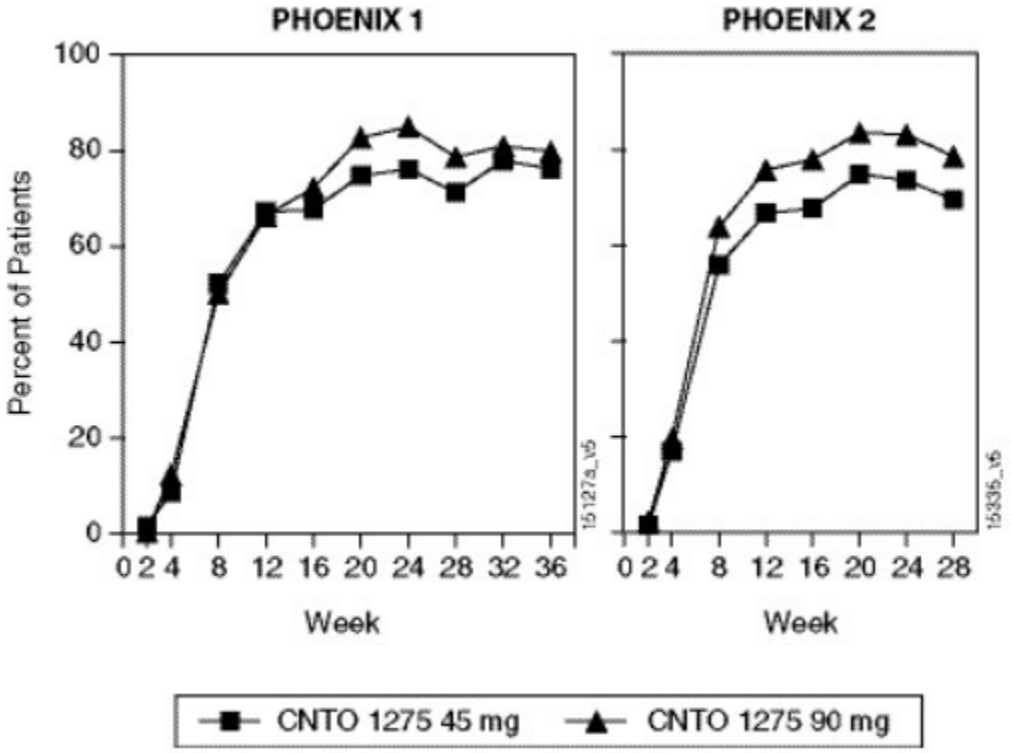


Figure 1: PASI 75 response over time in PHOENIX 1 and 2

In prespecified analyses of efficacy by body weight in PHOENIX 1 and PHOENIX 2, no consistent pattern of dose response was seen in patients ≤ 100 kg. In patients who weighed > 100 kg, higher PASI 75 response rates were seen with 90 mg dosing compared with 45 mg dosing, and a higher proportion of patients receiving 90 mg dosing had PGA scores of cleared or minimal compared with patients receiving 45 mg dosing (Table 15).

Table 15: Clinical Outcomes by Weight – PHOENIX 1 and PHOENIX 2

Week 12						
	PHOENIX 1			**PHOENIX 2**		
		Finlius			**Finlius**	
	Placebo	**45 mg**	**90 mg**	**Placebo**	**45 mg**	**90 mg**
Patients randomized at Week 0	255	255	256	410	409	411
PASI 75 response by weight						
≤ 100 kg						
N	166	168	164	290	297	289
PASI 75 response	6 (4%)	124 (74%)	107 (65%)	12 (4%)	218 (73%)	225 (78%)
>100 kg						
N	89	87	92	120	112	121
PASI 75 response	2 (2%)	47 (54%)	63 (68%)	3 (3%)	55 (49%)	86 (71%)
PGA of Cleared or Minimal by weight						
≤ 100 kg						
N	166	168	164	290	297	289
PGA response	7 (4%)	110 (65%)	104 (63%)	16 (6%)	219 (74%)	217 (75%)
> 100 kg						
N	89	87	92	120	112	121
PGA response	3 (3%)	44 (51%)	54 (59%)	4 (3%)	59 (53%)	85 (70%)

Week 28				
	PHOENIX 1		**PHOENIX 2**	
	Finlius		**Finlius**	
	45 mg	**90 mg**	**45 mg**	**90 mg**
N	250	243	397	400
PASI 75 response by weight				
≤ 100 kg				
N	164	153	287	280
PASI 75 response	130 (79%)	124 (81%)	217 (76%)	226 (81%)
> 100 kg				
N	86	90	110	119
PASI 75 response	48 (56%)	67 (74%)	59 (54%)	88 (74%)
PGA of Cleared or Minimal by weight				
≤ 100 kg				
N	164	153	287	280
PGA response	107 (65%)	107 (70%)	194 (68%)	208 (74%)
> 100 kg				
N	86	90	110	119
PGA response	40 (47%)	54 (60%)	49 (45%)	71 (60%)

Therapeutic benefit of long-term continuous use

At Week 40 in PHOENIX 1, among patients who were PASI 75 responders at both weeks 28 and 40, 162 patients were re-randomized to receive Finlius at 45 mg and 90 mg given every 12 weeks (maintenance treatment) and 160 were re-randomized to receive placebo (treatment withdrawal). Maintenance of PASI 75 was significantly superior with continuous maintenance treatment compared with treatment withdrawal ($p<0.001$) through at least 1.5 years of follow-up. Similar results were seen with each dose of Finlius.

At 1 year (Week 52), 89% of patients re-randomized to maintenance treatment were PASI 75 responders compared with 63% of patients re-randomized to placebo (treatment withdrawal) ($p<0.001$) (Table 16). At Week 76, 84% of patients re-randomized to maintenance treatment were PASI 75 responders compared with 19% of patients re-randomized to placebo (treatment withdrawal) ($p<0.001$). Through 18 months (Week 76), the proportion of subjects in the combined maintenance treatment group who were PASI 50 responders remained consistently at greater than 95%. By contrast, the proportion of PASI 50 responders in the combined withdrawal group progressively decreased over time such that by Weeks 52 and 76, only 50% and 31% remained as PASI 50 responders respectively. Among patients withdrawn from treatment, the rates of loss of the various PASI responses (PASI 50, 75, 90) were generally comparable in all groups regardless of dose. No rebound of psoriasis occurred in patients who were randomized to treatment withdrawal. Among the patients who reached PASI 75 response at weeks 28 and 40 and were re-randomized to maintenance treatment, 82% were PASI 75 responders at 3 years (Week 148). At 5 years (Week 244), 80% of patients (112/140) re-randomized to maintenance treatment were PASI 75 responders.

Table 16: Summary of PASI response from Week 40 through Week 76 in subjects randomized at Week 40 in PHOENIX 1

	Finlius		**Finlius**		**Finlius**	
	45 mg		**90 mg**		**Combined**	
	Placebo	**q12 wks**	**Placebo**	**q12 wks**	**Placebo**	**q12 wks**
Patients randomized at Week 40	73	77	87	85	160	162
Week 52 N	73	77	86	85	159	162
≥ 90% improvement	27 (37.0%)	45 (58.4%)	33 (38.4%)	60 (70.6%)	60 (37.7%)	105 (64.8%)
≥ 75% improvement	47 (64%)	67 (87.0%)	53 (61.6%)	77 (90.6%)	100 (62.9%)	144 (88.9%)
≥ 50% improvement	63 (86%)	75 (97.4%)	71 (82.6%)	83 (97.6%)	134 (84.3%)	158 (97.5%)
Week 76 N	71	77	85	82	156	159
≥ 90% improvement	5 (7.0%)	38 (49.4%)	4 (4.7%)	52 (63.4%)	9 (5.8%)	90 (56.6%)
≥ 75% improvement	14 (19.7%)	63 (81.8%)	15 (17.6%)	71 (86.6%)	29 (18.6%)	134 (84.3%)
≥ 50% improvement	22 (31.0%)	74 (96.1%)	27 (31.8%)	79 (96.3%)	49 (31.4%)	153 (96.2%)

Efficacy of retreatment

In PHOENIX 1, after randomized withdrawal from therapy at week 40, patients reinitiated their original Finlius treatment regimen after a loss of ≥ 50% of PASI improvement. Retreatment with Finlius resulted in 71% of evaluated patients regaining PASI 75 response within 8 weeks after

reinitiating therapy and 85% of evaluated patients regaining PASI 75 response within 12 weeks after reinitiating therapy.

Dosing interval adjustment
In PHOENIX 1, Week 28 and Week 40 partial responders and Week 40 nonresponders were adjusted from every-12-week to every-8-week dosing. Approximately 40%-50% of Week 28 partial responders to every-12-week dosing achieved PASI 75 response after adjustment to every-8-week dosing and this proportion of PASI 75 responders was maintained through Week 52. A similar proportion of patients who were PASI 75 responders at Week 28 and subsequently became partial responders or nonresponders at Week 40 achieved PASI 75 response following a dosing interval adjustment to every 8 weeks.

In PHOENIX 2, among patients initially randomized to 90 mg dosing who were partial responders at Week 28, dosing adjustment to every 8 weeks resulted in consistently superior efficacy as compared with continued every 12 weeks dosing: Partial responders randomized to 90 mg every 8 weeks achieved PASI 75 response at more visits between Weeks 40 and 52 than partial responders randomized to continue 90 mg every 12 weeks ($p = 0.014$), and a higher proportion of subjects achieved a PASI 75 response at Week 52 (68.8% with every 8 weeks dosing versus 33.3% with every 12 weeks dosing; $p = 0.004$). Among patients initially randomized to 45 mg dosing who were partial responders at Week 28, response rates were not higher among patients in whom dosing was adjusted to every 8 weeks compared with patients who continued every 12 weeks dosing.

Quality of life
In PHOENIX 1 and 2, the mean baseline DLQI scores ranged from 11 to 12. In PHOENIX 1, the mean baseline SF-36 Physical Component ranged from 47-49 and the mean baseline SF-36 Mental Component was approximately 50. Quality of life improved significantly in patients randomized to 45 mg or 90 mg Finlius compared with patients randomized to placebo as evaluated by DLQI in PHOENIX 1 and 2 and SF-36 in PHOENIX 1. Quality of life improvements were significant as early as 2 weeks in patients treated with Finlius ($p<0.001$) and these improvements were maintained over time with continued dosing.

In PHOENIX 1, 65% and 71% of patients treated with 45 mg and 90 mg of Finlius, respectively, showed a clinically meaningful reduction (5 or more points) in DLQI from baseline at week 12 compared to 18% in placebo group ($p<0.001$ for both groups compared with placebo). Furthermore, 33% and 34% of patients treated with 45 mg and 90 mg of Finlius, respectively, showed a DLQI score of 0 compared to 1% in the placebo group ($p<0.001$ for both groups compared with placebo), indicating no impairment in QOL from disease or treatment in these patients. In PHOENIX 2, 72% and 77% of patients treated with 45 mg and 90 mg of Finlius, respectively, showed a clinically meaningful reduction (5 or more points) in DLQI from baseline at Week 12 compared to 21% in placebo group ($p<0.001$ for both groups compared with placebo). In addition, 37% and 39% of patients treated with 45 mg and 90 mg of Finlius, respectively, showed a DLQI score of 0 compared to 1% in the placebo group ($p<0.001$ for both groups compared with placebo).

In PHOENIX 1, the median baseline NAPSI score for nail psoriasis was 4.0 and the median number of fingernails involved with psoriasis was 8.0. Nail psoriasis improved significantly in

patients randomized to 45 mg or 90 mg Finlius compared with patients randomized to placebo when measured by the NAPSI score (p≤0.001). Improvements in physical and mental component summary scores of the SF-36 and in the Itch Visual Analogue Scale (VAS) were also significant in each Finlius treatment group compared with placebo (p<0.001). In PHOENIX 2, the Hospital Anxiety and Depression Scale (HADS) and Work Limitations Questionnaire (WLQ) were also significantly improved in each Finlius treatment group compared with placebo (p<0.001).

ACCEPT

Significantly greater proportions of subjects treated with Finlius 45 mg (67%; p = 0.012) or 90 mg (74%; p < 0.001) were PASI 75 responders at Week 12 compared with the etanercept group (56.8%). PASI 90 response was observed in 36% and 45 % of patients in the Finlius 45 mg and 90 mg groups, respectively, compared with 23% of patients receiving etanercept (p<0.001 for each comparison versus etanercept). PASI 100 response was observed in 12% and 21% of patients in the Finlius 45 mg and 90 mg groups, respectively, compared to 6% of patients receiving etanercept (Table 17). In addition, a greater proportion of patients in the Finlius 45 mg and 90 mg treatment groups achieved a PGA score of “cleared” or “minimal” (65 % and 71 %, respectively) compared with patients in the etanercept treatment group (49 %) (p<0.001 for each comparison versus etanercept).

Table 17: Clinical outcomes at Week 12: ACCEPT

	ACCEPT		
	Etanercept (50mg twice a week)	**Finlius (at week 0 and week 4)**	
		45 mg	**90 mg**
Patients randomized	347	209	347
PASI response			
PASI 50 response	286 (82%)	181 (87%)	320 (92%)[a]
PASI 75 response	197 (57%)	141 (67%)[b]	256 (74%)[a]
PASI 90 response	80 (23%)	76 (36%)[a]	155 (45%)[a]
PASI 100 response	22 (6%)	25 (12%)[c]	74 (21%)[a]
PGA of Cleared or Minimal[a]	170 (49%)	136 (65%)[a]	245 (71%)[a]
PASI 75 RESPONSE BY WEIGHT			
≤ 100 kg			
N	251	151	244
PASI 75 response	154 (61%)	109 (72%)	189 (77%)
> 100 kg			
N	96	58	103
PASI 75 response	43 (45%)	32 (55%)	67 (65%)
PGA of Cleared or Minimal by weight			
≤ 100 kg			
N	251	151	244
PGA response	131 (52%)	110 (73%)	185 (76%)
> 100 kg			

	ACCEPT		
	Etanercept (50mg twice a week)	Finlius (at week 0 and week 4)	
		45 mg	90 mg
N	96	58	103
PGA response	39 (41%)	26 (45%)	60 (58%)

[a] p <0.001 for Finlius 45 mg or 90 mg comparison with etanercept.
[b] p =0.012 for Finlius 45 mg comparison with etanercept.
[c] p =0.020 for Finlius 45 mg comparison with etanercept.

Greater proportions of subjects in the Finlius 45 mg and 90 mg groups achieved PASI 75 responses when compared with subjects in the etanercept group regardless of a subject's previous psoriasis medication history.

Pediatric Plaque Psoriasis (6 to 17 years of age)

The safety and efficacy of Finlius in pediatric patients with plaque psoriasis was assessed in two multicenter phase 3 studies, CADMUS and CADMUS Jr.

Plaque Psoriasis – Pediatrics (12 to 17 years of age): CADMUS

The efficacy of Finlius was studied in 110 pediatric patients 12 to 17 years of age, in a multicenter, Phase 3, randomized, double blind, placebo-controlled study (CADMUS). Two distinct, subcutaneous weight based dosages of Finlius were studied. Randomization was stratified by investigational site and baseline weight (≤ 60 kg or > 60 kg).

Patients were randomized to one of four treatment groups (Groups 1, 2, 3a and 3b) at week 0 as follows:
Group 1: Finlius half-standard dosage at Weeks 0 and 4 followed by doses every 12 weeks, with the last dose at Week 40.
Group 2: Finlius standard dosage at Weeks 0 and 4 followed doses every 12 weeks, with the last dose at Week 40.
Group 3: Placebo at Weeks 0 and 4. At Weeks 12 and 16, subjects crossed over to receive either Finlius half-standard dosage (Group 3a) or standard dosage (Group 3b) followed by doses every 12 weeks, with the last dose at Week 40. The dosage assignment (Group 3a or 3b) following crossover was randomly assigned at week 0, ensuring that the assignment remained double blinded throughout the duration of the study.
All subjects were followed for efficacy through Week 52 and for safety through Week 60.

Adolescent patients with a diagnosis of plaque-type psoriasis for at least 6 months prior to first study agent administration, who had moderate to severe disease, and with PASI ≥ 12, PGA ≥ 3 and BSA involvement of at least 10%, and who were candidates for systemic or phototherapy, were eligible for the study. 43% and 11% of subjects had prior exposure to conventional systemic or biologic therapies respectively.

The primary endpoint was the proportion of patients who achieve a PGA score of cleared (0) or minimal (1) at Week 12. Secondary endpoints included PASI 75 at Week12. Subjects who discontinued study treatment due to lack of efficacy, an adverse event (AE) of psoriasis, or who

started a protocol-prohibited medication/therapy prior to Week 12 were considered as non-responders. Subject with missing PGA or PASI scores at Week 12 were considered non-responders. For the Week 12 analysis, any subject receiving moderate to high potency topical steroid preparations were considered as non-responders.

The study population were predominantly Caucasian (89%) and 51% were female. Median body weight was 61.6 kg, 56% had a body weight of between 50 and 70 kg and the median body mass index was 22.15 kg/m^2. Median psoriasis duration was 5.29 years with median age at onset of 10 years. The majority of subjects (70.0%) were 15 to 17 years of age, with a median age of 15.5 years. 57% of subjects had ≥ 20% body surface area affected with psoriasis and median PASI score was 18.8 (range 12-51), and 62% and 38% of subjects had PGA scores of moderate and marked/severe respectively.

Table 18: Summary of patient demographics for CADMUS

Study #	Study design	Dosage, route of administration and duration	Study subjects (n)	Mean age (Range)	Sex
CNTO1275 PSO3006 (CADMUS)	Double-Blind Placebo-Controlled	Fixed doses (weight based): Placebo (N=37) Placebo → Half-standard dosage (N=19) Placebo → Standard dosage (N=18) Half-standard dosage Weeks 0, 4 then q12w (N=37) Standard dosage Weeks 0, 4 then q12w (N=36)	N=110	15,2 (12,17)	M=54 (49%) F=56 (51%)

Study Results

At Week 12, subjects treated with Finlius showed significantly greater improvement in their psoriasis compared with placebo (Table 19).

Table 19: Summary of Primary and Secondary End-points at Week 12

	Placebo	Finlius Half Standard Dose	Finlius Standard Dose
	n (%)	n (%)	n (%)
Patients randomized at Week 0	37	37	36
Number of patients who achieved a PGA score of cleared (0) or minimal (1)	2 (5.4%)	25 (67.6%)[a]	25 (69.4%)[a]
PASI 75 responders	4 (10.8%)	29 (78.4%)[a]	29 (80.6%)[a]

[a] p<0.001

P-values are based on the Cochran-Mantel-Haenszel chi-square test stratified by baseline weight (≤ 60kg, > 60kg).

Multiplicity was controlled by sequential testing of endpoints.

All patients were followed for efficacy for up to 52 weeks following first administration of study agent. The PGA scores of cleared (0) or minimal (1) and PASI 75 responders at Week 52 are summarized in Table 20.

Table 20: Summary of Secondary Endpoints at Week 52

	Finlius Half- Standard Dose	Finlius Standard Dose
Number of evaluable subjects at Week 52	n=34	n=35
Number of patients who achieved a PGA score of cleared (0) or minimal (1)	20 (58.8%)	20 (57.1%)
PASI 75 responders	23 (67.6%)	28 (80%)

Plaque Psoriasis – Pediatrics (6 to 11 years of age): CADMUS Jr

The efficacy of Finlius was studied in 44 pediatric patients 6 to 11 years of age with moderate to severe plaque psoriasis in an open label, single-arm, multicenter, Phase 3 study. Patients were treated with the recommended dose of Finlius (n=44) based on body weight measured at each visit (see 4.2 Recommended Dose and Dosage Adjustment) by subcutaneous injection at Weeks 0 and 4 followed by every 12 week (q12w) dosing.

The primary endpoint was the proportion of patients who achieved a PGA score of cleared (0) or minimal (1) at Week 12. Secondary endpoints included PASI 75 at Week 12.

Patients with moderate to severe plaque-type psoriasis with or without psoriatic arthritis (PsA) for at least 6 months prior to first administration of study drug, with widespread lesions defined by PASI ≥ 12, PGA ≥ 3, and involved BSA ≥ 10% and who were candidates for phototherapy or systemic treatment or had psoriasis poorly controlled with topical therapy after an adequate dose and duration of therapy were eligible for the study. Approximately 18% and 5% of patients had prior exposure to conventional systemic or biologic therapies respectively. The study population was predominantly Caucasian (91%) and 61% were female. The median body weight was 33.3 kg, with 91% of patients having a body weight less than 60 kg. The median body mass index was 18.0 kg/m^2. The median psoriasis duration was 2.9 years and the median age of onset of disease was 6.0 years. The median percent of BSA affected with psoriasis was 18.0%. The median PASI score was 16.1. The median age was 9.5 years, with 50.0% of subjects < 10 years of age. All ages across the age range (≥ 6 to < 12 year of age) were represented in the study population. The majority of subjects (65.9%) had PGA scores of moderate and 34.1% had a PGA score of marked or severe. The median PASI score was 16.1 and the median Children's Dermatology Life Quality Index (CDLQI) score was 7.0 (representing a moderate impact of psoriasis on quality of life).

Table 21: Summary of patient demographics for CADMUS Jr

Study #	Study design	Dosage, route of administration and duration	Study subjects (n)	Mean age (Range)	Sex
CNTO1275 PSO3013 (CADMUS Jr)	Open-label single arm, multicentre	Fixed doses (weight based): Standard dosage (0.75 mg/kg for patients < 60 kg, 45 mg for patients ≥ 60 kg to ≤ 100 kg and 90 mg for patients > 100 kg) Weeks 0, 4 then q12w (N=36)	N=44	8.9 (6,11)	M=17 (39%) F=27 (61%)

Study Results

At Week 12, patients treated with Finlius showed clinically meaningful improvements in their psoriasis. All patients were followed for efficacy for up to 52 weeks following first administration Finlius. The PGA scores and PASI 75 responders at Week 12 and 52 are summarized in Table 22. Efficacy measured by PGA score of 0 or 1 was observed as early as the first post-baseline visit at Week 4 and increased through Week 16 and then remained relatively stable through Week 52. Improvements in PGA and PASI were maintained through Week 52.

Table 22: Summary of Primary and Secondary End-points at Week 12 and 52: CADMUS Jr. (Age 6-11)

	Finlius Week 12	**Finlius Week 52**
	N (%)	N (%)
Patients enrolled at Week 0	44	41
Number of patients who achieved a PGA score of cleared (0) or minimal (1)	34 (77.3%)	31 (75.6%)
PGA of cleared (0)	17 (38.6%)	23 (56.1%)
PASI 75 responders	37 (84.1%)	36 (87.8%)

Psoriatic Arthritis

The safety and efficacy of Finlius was assessed in two multicenter, randomized, double-blind, placebo-controlled, phase 3 studies, PSUMMIT I and PSUMMIT II, in patients with active psoriatic arthritis. Patients were randomized to receive treatment with either Finlius 45 mg, 90 mg, or placebo subcutaneous injections at Weeks 0 and 4 followed by every 12 week (q12w) dosing. The primary endpoint in these studies was the reduction in the signs and symptoms of psoriatic arthritis (PsA) as measured by the percentage of ACR 20 responders at Week 24. Secondary endpoints included change from baseline in Disability Index of the Health Assessment Questionnaire (HAQ-DI), PASI 75, ACR 50, ACR 70 and change from baseline in total radiographic scores of the hands and feet at Week 24. Efficacy data were collected and analyzed through Week 52.

These studies included 927 adult patients (≥18 years) who had active psoriatic arthritis (≥5 swollen joints and ≥5 tender joints, despite disease modifying antirheumatic (DMARD) and/or nonsteroidal anti-inflammatory (NSAID) therapy. Methotrexate (MTX) use was allowed during the studies but was not mandatory. Approximately 50% of patients continued on stable doses of MTX (≤25 mg/week). In PSUMMIT I and PSUMMIT II, 80% and 86% of the patients, respectively, had been previously treated with DMARDs.

In PSUMMIT I patients, who had been previously treated with anti-TNFα therapy, prior to the first study dose, were excluded. In PSUMMIT II, the majority of patients (58%, n=180) had been previously treated with one or more an anti-TNFα agent(s) for at least 8 weeks (14 weeks with infliximab) or had discontinued anti-TNFα for intolerance at any time. Among the patients who had been previously treated with an anti-TNFα agent, over 70% had discontinued their anti-TNFα treatment for lack of efficacy or intolerance.

Patients with each subtype of psoriatic arthritis were enrolled, including polyarticular arthritis with no evidence of rheumatoid nodules (39%, N=362), spondylitis with peripheral arthritis (28%, N=255), asymmetric peripheral arthritis (21%, N=193), distal interphalangeal (DIP) arthritis (12%, N=112) and arthritis mutilans (0.5%, N=5). Over 70% and 40% of the patients in both studies had enthesitis and dactylitis at baseline, respectively.

Table 23: Summary of patient demographics in PSUMMIT I and PSUMMIT II

Study #	Study design	Dosage, route of administration and duration	Study subjects (n)	Mean age (Range)	Sex
CNTO1275 PSA3001 (PSUMMIT I)	Double-Blind Placebo-Controlled	Placebo SC (n=206): Placebo SC at Weeks 0, 4,16, and 20 Placebo→45 mg SC at Weeks 24 and 28 followed by q12w dosing through Week 88 45 mg SC (n=205): 45 mg SC at Weeks 0 and 4 followed by q12w dosing through Week 88 90 mg SC (n=204): 90 mg SC at Weeks 0 and 4 followed by q12w dosing through Week 88	615	47.1 (18, 81)	M=330 F=285
CNTO1275 PSA3002 (PSUMMIT II)	Double-Blind Placebo-Controlled	Placebo SC (n=104): Placebo SC at Weeks 0, 4, 16, and 20 45 mg SC at Weeks 24 and 28 followed by q12w dosing through Week 40 45 mg SC (n=103): 45 mg SC at Weeks 0 and 4 followed by q12w dosing through Week 40 90 mg SC (n=105): 90 mg SC at Weeks 0 and 4 followed by q12w dosing through Week 40	312	48.0 (19, 75)	M=148 F=164

Study Results

Reduction in Signs and Symptoms

In both studies, a significantly greater proportion of patients achieved ACR 20 and ACR 50 responses at Week 24 in the Finlius 45 mg and 90 mg groups compared to placebo (Table 24). In PSUMMIT I, a significantly greater proportion of patients and in PSUMMIT II, a numerically

greater proportion of patients (p=NS) achieved ACR 70 responses in the Finlius 45 mg and 90 mg groups compared to placebo (Table 24).

Table 24: Number of patients who achieved ACR 20, ACR 50 and ACR 70 at Week 24

	PSUMMIT I			PSUMMIT II		
		Finlius			Finlius	
	Placebo (N=206)	45 mg (N= 205)	90 mg (N= 204)	Placebo (N= 104)	45 mg (N= 103)	90 mg (N= 105)
ACR 20	47 (23%)	87 (42%) [a]	101 (50%) [a]	21 (20%)	45 (44%)[a]	46 (44%) [a]
ACR 50	18 (9%)	51 (25%) [a]	57 (28%) [a]	7 (7%)	18 (17%) [b]	24 (23%) [a]
ACR 70	5 (2%)	25 (12%) [a]	29 (14%) [a]	3 (3%)	7 (7%) [c]	9 (9%) [c]

[a] p<0.001, [b] p<0.05, [c] p= NS

An ACR 20 response (Felson et al, 1995) was defined as:

1. ≥ 20% improvement in swollen joint count (66 joints) and tender joint count (68 joints); and
2. ≥ 20 % improvement in ≥3 of the following 5 assessments:

- Patient's assessment of pain [Visual Analog Scale (VAS)]
- Patient's global assessment of disease activity (VAS)
- Physician's global assessment of disease activity (VAS)
- Patient's assessment of physical function as measured by the HAQ-DI
- CRP

ACR 50 or ACR 70 are similarly defined.

The time course for ACR 20 response rates during the first 24 weeks in both studies for patients receiving Finlius or placebo are summarized in Figure 2. During the controlled phase of the studies, ACR 20 responses showed improvement at the first assessment (Week 4) and maximum responses were achieved at Week 20 or 24. ACR 20, 50 and 70 responses continued to improve or were maintained through Week 52.

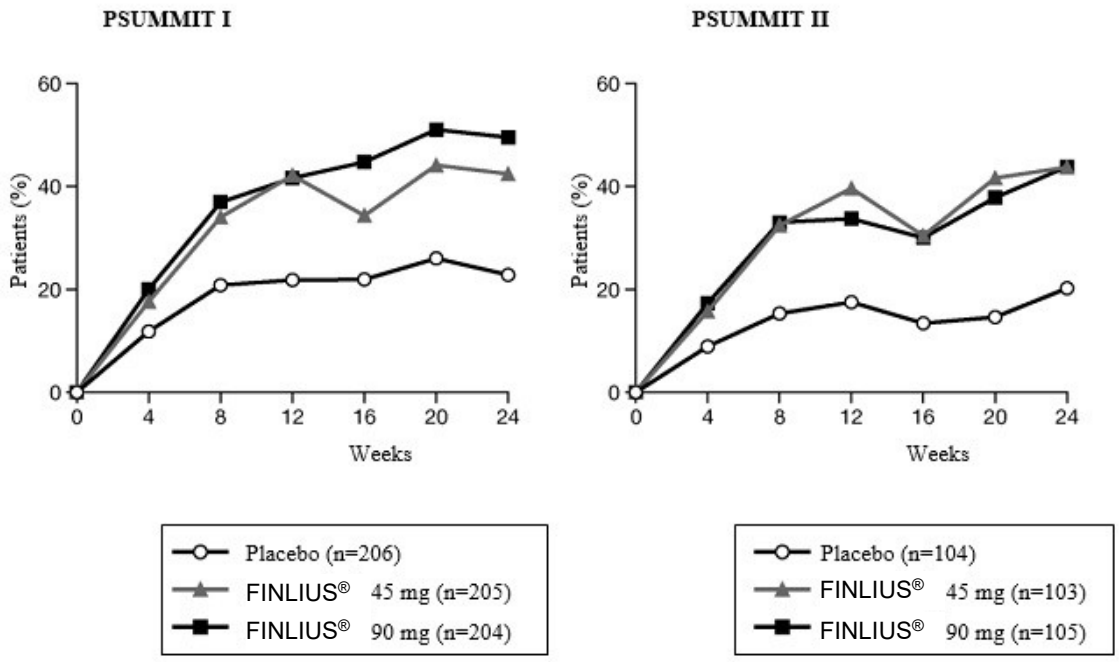


Figure 2: Percent of patients achieving ACR 20 response through Week 24

In PSUMMIT I, of 205 subjects randomized to Finlius 45 mg, 153 continued the same dose and were available for evaluation at Week 52. Among those, ACR 20, 50 and 70 responses were achieved by 99 (64.7%), 57 (37.3%) and 34 (22.2%) subjects respectively. Of 204 subjects randomized to Finlius 90 mg, 185 were available for evaluation at Week 52. Among those, ACR 20, 50 and 70 responses were achieved by 120 (64.9%), 74 (40%) and 41 (22.2%) subjects respectively.

In PSUMMIT II, of 103 subjects randomized to Finlius 45 mg, 68 continued the same dose and were available for evaluation at Week 52. Among those, ACR 20, 50, and 70 responses were achieved by 41 (60.3%), 23 (33.8%) and 11 (16.2%) subjects respectively. Of 105 subjects randomized to Finlius 90 mg, 83 were available for evaluation at Week 52. Among those, ACR 20, 50 and 70 responses were achieved by 49 (59%), 26 (31.3%) and 17 (20.5%) subjects respectively.

Additionally, within each weight group (≤100 kg and >100 kg), ACR 20, ACR 50 and ACR 70 responses were consistently higher in the Finlius 45 mg and 90 mg groups than in the placebo group (Table 25).

Table 25: Number of patients who achieved ACR 20, ACR 50 and ACR 70 responses by weight at Week 24

	PSUMMIT I			**PSUMMIT II**		
		Finlius			**Finlius**	
	Placebo (N=206)	**45 mg (N=205)**	**90 mg (N=204)**	**Placebo (N=104)**	**45 mg (N=103)**	**90 mg (N=105)**

Patients randomized with weight ≤100 kg at baseline	154	153	154	74	74	73
ACR 20	39 (25%)	67 (44%)	78 (51%)	17 (23%)	32 (43%)	34 (47%)
ACR 50	14 (9%)	38 (25%)	48 (31%)	6 (8%)	15 (20%)	21 (29%)
ACR 70	5 (3%)	20 (13%)	26 (17%)	3 (4%)	6 (8%)	8 (11%)
Patients randomized with weight >100 kg at baseline	52	52	50	30	29	31
ACR 20	8 (15%)	20 (38%)	23 (46%)	4 (13%)	13 (45%)	12 (39%)
ACR 50	4 (8%)	13 (25%)	9 (18%)	1 (3%)	3 (10%)	3 (10%)
ACR 70	0	5 (10%)	3 (6%)	0	1 (3%)	1 (3%)

Finlius treatment resulted in significantly greater improvement compared with placebo for each ACR component at week 24 (Table 26).

Table 26: Median percent improvement from baseline in ACR components at Week 24

	PSUMMIT I			**PSUMMIT II**		
		Finlius			**Finlius**	
	Placebo (N=206)	**45 mg (N=205)**	**90 mg (N=204)**	**Placebo (N=104)**	**45 mg (N=103)**	**90 mg (N=105)**
Number of swollen joints [d]	21.54	58.82 [a]	60.00 [a]	0.00	52.94 [b]	50.00 [c]
Number of tender joints [e]	13.61	45.45 [a]	51.51 [a]	0.00	33.33 [a]	35.00 [c]
Patient's assessment of pain [f]	0.00	31.33 [a]	42.58 [a]	0.00	24.19 [a]	24.29 [a]
Patient global assessment [f]	4.11	32.84 [a]	42.44 [a]	0.00	21.25 [a]	22.54 [a]
Physician global assessment [f]	17.64	48.39 [a]	55.91 [a]	0.83	36.67 [a]	36.11 [a]
Disability index (HAQ-DI)[g]	0.00	22.22 [a]	32.46 [a]	0.00	12.50 [a]	14.29 [a]
CRP (mg/dL) [h]	0.00	38.56 [a]	48.30 [a]	0.00	25.61 [c]	33.69 [a]

[a] p<0.001
[b] p<0.05
[c] p<0.01
[d] Number of swollen joints counted (0-66)
[e] Number of tender joints counted (0-68)
[f] Visual analogue scale; 0=best, 10=worst.
[g] Disability Index of the Health Assessment Questionnaire; 0=best, 3=worst, measures the patient's ability to perform the following: dress/groom, arise, eat, walk, reach, grip, maintain hygiene, and maintain daily activity.
[h] CRP: (Normal Range 0.0-1.0 mg/dL)

In PSUMMIT I and PSUMMIT II, the proportion of subjects with good or moderate Disease Activity Index Score 28 using C-reactive protein (DAS28-CRP) responses and the proportion of subjects in DAS28 remission were greater in both Finlius-treated groups compared to placebo at Week 24. DAS28-CRP responses were maintained through Week 52.

Methotrexate Use

The proportion of patients achieving ACR responses were consistently greater in patients treated with Finlius than those treated with placebo regardless of concomitant MTX use. Responses observed in the Finlius groups were similar in patients receiving or not receiving concomitant MTX. ACR responses were maintained through Week 52 (Table 27).

Table 27: Summary of patients achieving ACR 20, ACR 50 and ACR 70 responses through Week 24 by methotrexate usage

PSUMMIT I						
	Receiving MTX at baseline			*Not receiving MTX at baseline*		
		Finlius			**Finlius**	
	Placebo (N=206)	**45 mg (N=205)**	**90 mg (N=204)**	**Placebo (N=206)**	**45 mg (N=205)**	**90 mg (N=204)**
Patients randomized	96	99	101	110	106	103
ACR 20	25 (26%)	43 (43%)	46 (46%)	22 (20%)	44 (42%)	55 (53%)
ACR 50	8 (8%)	23 (23%)	27 (27%)	10 (9%)	28 (26%)	30 (29%)
ACR 70	2 (2%)	11 (11%)	13 (13%)	3 (3%)	14 (13%)	16 (16%)
PSUMMIT II						
	Receiving MTX at baseline			*Not receiving MTX at baseline*		
		Finlius			**Finlius**	
	Placebo (N=104)	**45 mg (N=103)**	**90 mg (N=105)**	**Placebo (N=104)**	**45 mg (N=103)**	**90 mg (N=105)**
Patients randomized	49	54	52	55	49	53
ACR 20	14 (29%)	27 (50%)	21 (40%)	7 (13%)	18 (37%)	25 (47%)
ACR 50	4 (8%)	10 (19%)	12 (23%)	3 (5%)	8 (16%)	12 (23%)
ACR 70	2 (4%)	4 (7%)	3 (6%)	1 (2%)	3 (6%)	6 (11%)

Prior Anti-TNFα therapy

PSUMMIT II evaluated 180 patients who were previously treated with one or more anti-TNFα agents for at least 8 weeks (14 weeks with infliximab), or had documented intolerance of anti-TNFα therapy at any time in the past.

Among patients previously treated with anti-TNFα agents, a greater proportion of Finlius-treated patients in both the 45 mg and 90 mg groups achieved an ACR 20 response at Week 24 compared to placebo (37% and 34% vs 15%). ACR 20 response was generally maintained through Week 52.

Enthesitis and Dactylitis

For patients with enthesitis and/or dactylitis at baseline, in PSUMMIT I, greater improvement in enthesitis and dactylitis score was observed in the Finlius 45 mg and 90 mg groups compared to placebo. For enthesitis, the median improvement was 43% and 50% for each dose group respectively, compared to 0% for placebo. For dactylitis, the median improvement was 75% and

71% for each dose group respectively, compared to 0% for placebo. In PSUMMIT II, a greater improvement was observed in enthesitis score in both doses and in dactylitis score in the 90 mg group compared with the placebo group. In both studies, improvement in enthesitis score and dactylitis score were maintained at Week 52.

Psoriasis Skin Response

In PSUMMIT I and PSUMMIT II, the proportion of patients with psoriasis involvement of ≥3% BSA at baseline who achieved a ≥75% improvement in the PASI assessment at Week 24 was significantly greater in the Finlius 45 mg and 90 mg groups compared with the placebo group (Table 28). In both studies the proportion of patients achieving the PASI 75 response was maintained through Week 52.

Table 28: Number of patients who achieved PASI 75, PASI 90 and PASI 100 responses at Week 24

	PSUMMIT I			PSUMMIT II		
		Finlius [a]			Finlius [a]	
	Placebo (N=206)	45 mg (N=205)	90 mg (N=204)	Placebo (N= 104)	45 mg (N=103)	90 mg (N=105)
Patients with ≥ 3% BSA psoriasis skin involvement at baseline	146	145	149	80	80	81
PASI 75	16 (11%)	83 (57%)	93 (62%)	4 (5%)	41 (51%)	45 (56%)
PASI 90	4 (3%)	60 (41%)	65 (44%)	3 (4%)	24 (30%)	36 (44%)
PASI 100	2 (1%)	29 (20%)	41 (28%)	1 (1%)	13 (16%)	17 (21%)

[a] p<0.001 for 45 mg or 90 mg comparison with placebo.

Additionally, within each weight group (≤ 100 kg and > 100 kg), PASI 75, 90 and 100 responses were consistently higher in the Finlius 45 mg and 90 mg groups than in the placebo group. In both studies, the proportion of patients who achieved a PASI 75 response at Week 24 was consistently higher in Finlius 45 mg and 90 mg groups compared with placebo regardless of concomitant MTX use. PASI 75 responses were maintained through Week 52.

Radiographic Response

Structural damage in both hands and feet was assessed by readers unaware of treatment group and order of visits, and expressed as change in total van der Heijde-Sharp score (vdH-S score), modified for PsA by addition of hand distal interphalangeal (DIP) joints, compared to baseline. A pre-specified major secondary endpoint based on the integrated analysis combining data from 927 subjects in both PSUMMIT I and PSUMMIT II was performed. At Week 24, based on this integrated analysis, patients treated with either Finlius 45 mg (n=308, mean change in total vdH-S score=0.40) or 90 mg (n=309, mean change=0.39) demonstrated significantly less progression of structural damage compared to placebo (n=310, mean change=0.97), p<0.05 and p<0.001 for the 45 mg and 90 mg groups, respectively. This effect was demonstrated irrespective of concomitant MTX use, and was maintained through Week 52.

Similar results were seen in PSUMMIT I for patients treated with either Finlius 45 mg (n=205, mean change=0.28) or 90 mg (n=204, mean change=0.17) compared to placebo (n=206, mean

change=1.20). In PSUMMIT II, the mean change was 0.66 for 45 mg (n=103), 0.81 for 90 mg (n=105) and 0.51 for placebo (n=104).

Physical Function and Health-Related Quality of Life

In PSUMMIT I and PSUMMIT II, physical function and health-related quality of life were assessed using the Disability Index of the Health Assessment Questionnaire (HAQ-DI) and the SF-36 health survey.

Patients treated with Finlius 45 mg and 90 mg showed significant improvement in physical function as assessed by the HAQ-DI at Week 24 as compared to placebo in both PSUMMIT I and PSUMMIT II. The proportion of patients achieving a clinically meaningful ≥ 0.3 improvement in HAQ-DI score from baseline at Week 24 was also significantly greater in the Finlius groups when compared with placebo. Improvement was observed at the first assessment (Week 4), reached maximum at Week 12 and was maintained through Week 24. In both studies the improvement in HAQ-DI at Week 24 was consistently greater in the Finlius 45 mg and 90 mg groups compared with placebo regardless of concomitant MTX use. Improvement in HAQ-DI score from baseline was maintained at Week 52 (Table 29).

Table 29: Improvement in physical function as measured by HAQ-DI at Week 24

	PSUMMIT I			**PSUMMIT II**		
		Finlius			**Finlius**	
	Placebo (N=206)	**45 mg (N=205)**	**90 mg (N=204)**	**Placebo (N=104)**	**45 mg (N=103)**	**90 mg (N=105)**
HAQ-DI Baseline Score						
N	204	205	204	104	103	104
Mean (SD)	1.24 (0.647)	1.22 (0.610)	1.22 (0.634)	1.25 (0.723)	1.34 (0.704)	1.29 (0.666)
Median	1.25	1.25	1.25	1.25	1.38	1.25
Improvement in HAQ-DI						
N[c]	206	205	204	104	103	105
Mean (SD)	0.10 (0.390)	0.31 (0.521)	0.40 (0.514)	0.03 (0.380)	0.21 (0.461)	0.22 (0.436)
Median	0.00	0.25 [a]	0.25 [a]	0.00	0.13 [b]	0.25 [a]
HAQ-DI Responders*	58 (28%)	98 (48%) [a]	97 (48%) [a]	17 (16%)	35 (34%) [b]	40 (38%) [a]

[a] p<0.001

[b] p<0.01

[c] Includes all randomized subjects

* achieving a ≥ 0.3 improvement from baseline

In PSUMMIT I, of 205 subjects randomized to Finlius 45 mg, 153 continued the same dose and were available for evaluation at Week 52. Among those, the HAQ-DI response was achieved by 83 (54.2%) subjects. Of 204 subjects randomized to Finlius 90 mg, 185 were available for evaluation at Week 52. Among those, HAQ-DI response was achieved by 102 (55.1%) subjects.

In PSUMMIT II, of 103 subjects randomized to Finlius 45 mg, 68 continued the same dose and were available for evaluation at Week 52. Among those, the HAQ-DI response was achieved by

29 (42.6%) subjects. Of 105 subjects randomized to Finlius 90 mg, 83 were available for evaluation at Week 52. Among those, HAQ-DI response was achieved by 44 (53%) subjects.

In both PSUMMIT I and PSUMMIT II, at Week 24, the change from baseline in the SF-36 physical component summary (PCS) scores was significantly greater in the Finlius 45 mg and 90 mg groups compared with the placebo group. In both studies, the change from baseline in the SF-36 mental component summary (MCS) scores at Week 24 was greater in both Finlius groups compared with the placebo group. In both studies, the change from baseline in the SF-36 PCS and MCS scores was maintained at Week 52.

The DLQI was assessed by comparing the change in DLQI scores from baseline for those patients with ≥3% BSA at baseline. In both studies at Week 24, there was a greater improvement from baseline in DLQI scores in both the Finlius 45 mg and 90 mg groups as compared with placebo and the improvement was maintained at Week 52.

In PSUMMIT II, the improvement from baseline in Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) scores at Week 24 was greater in the Finlius 45 mg and 90 mg groups compared with the placebo group. Similarly, the percentage of patients with clinically meaningful improvement in fatigue from baseline (4 points in FACIT-F) was greater in both dose groups compared with the placebo group. The change from baseline in the FACIT-F scores was maintained at Week 52.

Crohn's Disease

The safety and efficacy of Finlius/Finlius I.V. were evaluated in three randomized, double-blind, placebo-controlled clinical trials in adult patients with moderately to severely active Crohn's disease (Crohn's Disease Activity Index [CDAI] score of 220 to 450). The clinical development program consisted of two 8-week IV induction studies (UNITI-1 and UNITI-2) followed by a 44-week subcutaneous randomized withdrawal maintenance study (IM-UNITI) representing 52 weeks of therapy (Table 30).

Table 30: Summary of controlled clinical trials supporting safety and efficacy in patients with CD

Study #	Study Design	Dosage: Route of Administration and Duration	Study Subjects (n)	Median Age (Range)	Sex
UNITI-1 (Induction)	Multicentre, double-blinded, randomized, placebo-controlled	IV administration at Week 0	741	36 (18, 71)	M: 317, 43 F: 424, 57
		Placebo	247		
		Finlius I.V. 130 mg	245		
		Finlius I.V. ~6 mg/kg[a]	249		
UNITI-2 (Induction)	Multicentre, double-blinded, randomized, placebo-controlled	IV administration at Week 0	628	37.0 (18, 77)	M:293, 47 F:335, 53
		Placebo	210		
		Finlius I.V. 130 mg	209		
		Finlius I.V. ~6 mg/kg[a]	209		
IM-UNITI (Maintenance)	Multicentre, double-blinded, placebo-controlled randomized-withdrawal,	SC administration at Week 0 [b], and then q8w or q12w for 44 weeks	397	36.0 (18, 75)	M:173, 44 F: 224, 56
		placebo	133		
		Finlius 90 mg q8w	132		
		Finlius 90 mg q12 w	132		

[a] tiered weight-based dose approximating 6 mg/kg (see 4 DOSAGE AND ADMINISTRATION)
[b] 8 weeks following the intravenous dose of Finlius I.V.

Induction Studies: UNITI-1 and UNITI-2

UNITI-1 and UNITI-2 studies included 1409 (UNITI-1, n=769; UNITI-2 n=640) patients. Of these subjects, 1368 (UNITI-1, n=741; UNITI-2, n=627) patients are included in the final efficacy analysis. In both studies, patients were permitted to concomitantly receive oral 5-ASA compounds, immunomodulators, corticosteroids, and/or antibiotics. Patients were randomized to receive a single IV administration of either 130 mg Finlius I.V., or approximately 6 mg/kg Finlius I.V. designed as a tiered dose based on patient body weight (Table 3) or placebo at Week 0.

The primary endpoint for UNITI-1 and UNITI-2 was clinical response defined as a reduction in CDAI score of ≥ 100 points or CDAI score < 150 (for subjects with a baseline CDAI score of ≥ 220 to ≤ 248) at Week 6. Secondary endpoints included clinical remission (CDAI score of < 150 points) at Week 8, clinical response at Week 8, 70-point response at Week 3, and 70-point response at Week 6. Efficacy data were collected and analyzed through Week 8 for both studies.

In UNITI-1, patients had failed or were intolerant to prior anti-TNFα therapy. At baseline, patients had a median (min, max) baseline CDAI score of 317 (198, 515), and approximately 46% (n=340) patients were receiving corticosteroids (including budesonide) and 31.4% of patients were receiving immunomodulators. Approximately 48% had failed 1 prior anti-TNFα therapy and 52% had failed 2 or 3 prior anti-TNFα therapies (40.8% and 10.4%, respectively). In this study, 29.1% patients had an inadequate initial response (primary non-responders), 69.4%

responded but subsequently lost response (secondary non-responders), and 36.4% were intolerant to anti-TNFα therapies.

Patients in UNITI-2 had failed at least one conventional therapy (corticosteroids or immunomodulators) and were either anti-TNFα naïve (68.6%) or had previously received but not failed anti-TNFα therapy (31.4%). At baseline, patients had a median (min, max) baseline CDAI score of 292.5 (198, 608), and approximately 40% patients were receiving corticosteroids (including budesonide) and 35% patients were receiving immunomodulators.

Maintenance: IM-UNITI

The maintenance study (IM-UNITI) evaluated 388 patients who achieved clinical response (≥ 100 point reduction in CDAI score or CDAI score < 150 [patients with a baseline CDAI score of ≥ 220 to ≤ 248]) at Week 8 of induction with Finlius I.V. in UNITI-1 or UNITI-2 out of 397 patients who were randomized into the study. Of those, approximately 60% of the patients entered the maintenance study in remission. Patients were randomized to receive a subcutaneous maintenance regimen of either 90 mg Finlius every 8 weeks, 90 mg Finlius every 12 weeks or placebo for an additional 44 weeks. Patients who completed the maintenance study through Week 44 were eligible to continue treatment through Week 272. An efficacy analysis was performed at Week 92 of the extension study.

Concomitant doses of oral 5-ASA compounds, immunomodulators, corticosteroids and antibiotics were permitted. At baseline, 45.6% of patients were receiving corticosteroids and 35% of patients were receiving immunomodulators. Corticosteroids were tapered at the start of the maintenance trial and during the trial in patients in clinical response. The primary endpoint was clinical remission (CDAI < 150) at Week 44 of maintenance. Secondary endpoints assessed at Week 44 of maintenance included clinical response, clinical remission among Finlius treated patients in clinical remission after induction, corticosteroid-free remission, and clinical remission in the subset of patients who were refractory or intolerant to anti-TNFα treatment. Other endpoints and planned analyses included evaluations for inflammatory markers, such as C-reactive protein and fecal calprotectin, fistula response, and patient reported outcomes.

Study Results

Induction of Response and Remission

In these induction studies, efficacy was higher and better sustained in the tiered dose group compared to the 130 mg dose group, and tiered dosing is therefore the recommended IV induction dose. In both UNITI-1 and UNITI-2, a significantly greater proportion of patients were in clinical response at Week 6 and remission at Week 8 in the group treated with Finlius I.V. compared to placebo (Table 31, Figure 3). Clinical response and remission were observed as early as Week 3 in Finlius I.V. treated patients and continued to improve through Week 8 (Figure 3)

Table 31: Induction of Clinical Response and Remission in UNITI-1* and UNITI 2**

	UNITI-1			UNITI-2		
	Placebo N=247	**Finlius I.V. N=249**	**Treatment difference, 95% CI and p-value**	**Placebo N=209**	**Finlius I.V. N=209**	**Treatment difference, 95% CI and p-value**
Clinical Response Week 6[c]	53 (21.5%)	84 (33.7%)	12% (4%, 20%) p = 0.003[ab]	60 (28.7%)	116 (55.5%)	27% (18%, 36%) p < 0.001[ab]
Clinical Remission, Week 8[c]	18 (7.3%)	52 (20.9%)	14% (8%, 20%) p < 0.001[ab]	41 (19.6%)	84 (40.2%)	21% (12%, 29%) p < 0.001[ab]
Clinical Response Week 8[c]	50 (20.2%)	94 (37.8%)	18% (10%, 25%) p < 0.001[ab]	67 (32.1%)	121 (57.9%)	26% (17%, 35%) p < 0.001[ab]
70 Point Response, Week 6[c]	75 (30.4%)	109 (43.8%)	13% (5%, 22%) p = 0.002[ab]	81 (38.8%)	135 (64.6%)	19% (10%, 28%) p < 0.001[ab]
70 Point Response, Week 3[c]	67 (27.1%)	101 (40.6%)	13% (5%, 22%) p < 0.001[ab]	66 (31.6%)	106 (50.7%)	26% (17%, 35%) p < 0.001[ab]

Clinical remission is defined as CDAI score < 150; Clinical response is defined as reduction in CDAI score by at least 100 points or being in clinical remission (for subjects with a baseline CDAI score of ≥ 220 to ≤ 248).

70 point response is defined as reduction in CDAI score by at least 70 points

* Patients who failed or were intolerant to anti-TNF α agents

** Patients who failed or were intolerant to corticosteroids or immunomodulators. Patients may have previously received but not failed an anti- TNF α agent or were never treated with an anti-TNF α agent

[a] Based on a Cochran-Mantel-Haenszel chi-square test, stratified by study region (Asia, Eastern Europe, or Rest of World), CDAI score (≤ 300 or > 300), and initial response to TNF antagonist therapy (yes or no; CRD3001 only)

[b] To control the overall Type I error rate at the 0.05 significance level, the endpoints were tested in the hierarchical order presented in this table

[c] Subjects who had a prohibited Crohn's disease-related surgery, had prohibited concomitant medication changes, or had insufficient data to determine response and remission status were considered to not be in response or remission.

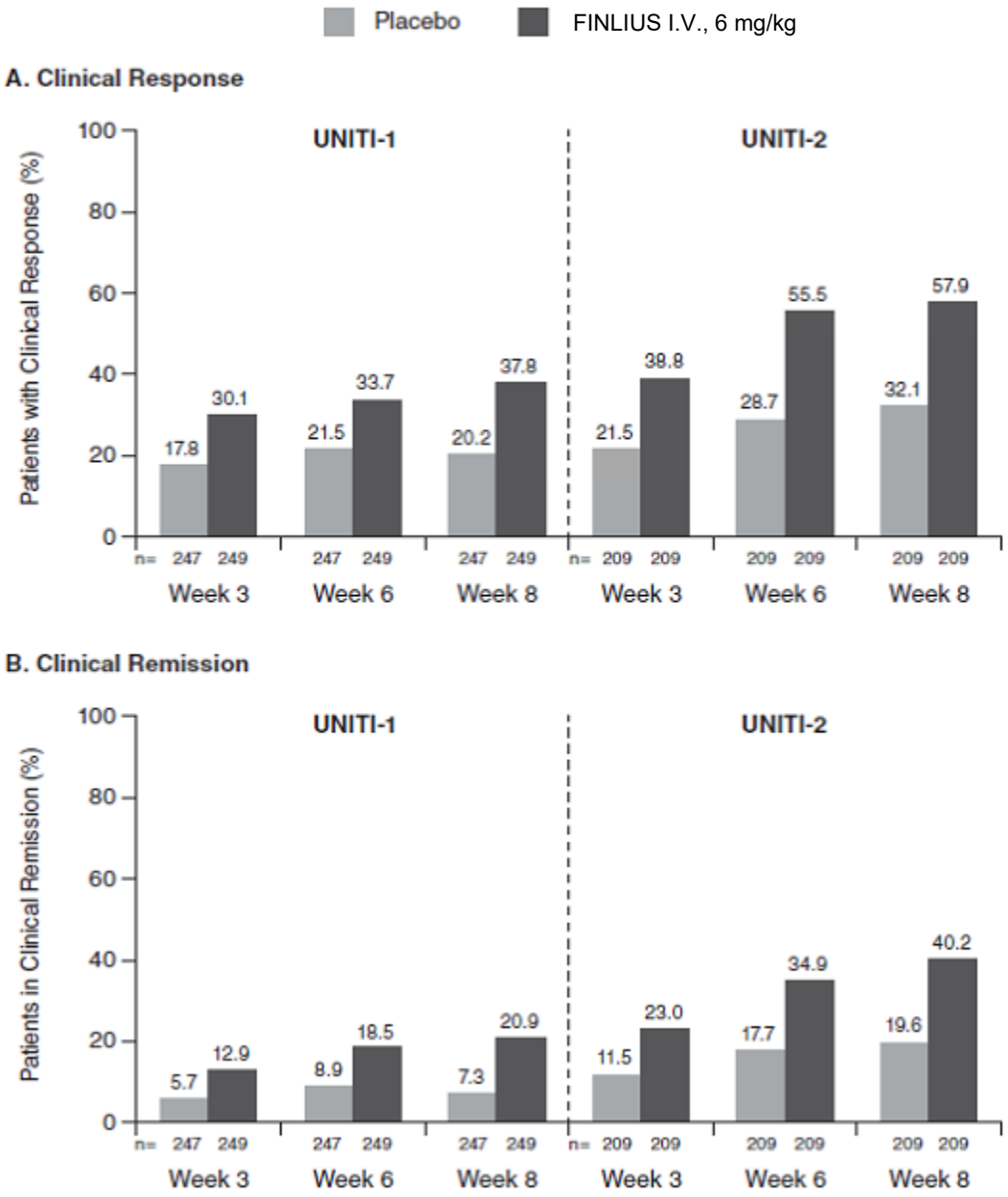


Figure 3: Proportion of Finlius I.V. treated patients in clinical response (A) and remission (B) through Week 8 in UNITI-1 and UNITI-2 studies

Anti-TNFα Naïve group

UNITI-2 evaluated 246 patients (69% of the UNITI-2 population) who have had an inadequate response, loss of response or were intolerant to conventional therapy but have never been exposed to anti-TNF α agents. Among this subgroup of patients, 56.3% of Finlius I.V.-treated patients and 32.6% of patients treated with placebo achieved a clinical response at Week 6.

Maintenance of Response and Remission

In IM-UNITI, significantly higher proportions of patients maintained clinical remission and response in the Finlius treated groups as compared to placebo at Week 44 of maintenance (Table 32).

Table 32: Maintenance of Clinical Response and Remission in IM-UNITI (Week 44; 52 weeks from initiation of the induction dose)

	Placebo* N=131†	90 mg Finlius every 12 weeks N=129†	Treatment difference, 95% CI and p-value	90 mg Finlius every 8 weeks N=128†	Treatment difference, 95% CI and p-value
Clinical Remission [c] n (%)	47 (35.9%)	63 (48.8%)	13% (1%, 25%) p = 0.040 [ab]	68 (53.1%)	17% (5%, 29%) p = 0.005 [ab]
Clinical Response [c] n (%)	58 (44.4%)	75 (58.1%)	14% (2%, 26%) p = 0.033 [ab]	76 (59.4%)	15% (3%, 27%) p = 0.018 [ab]
Clinical Remission in patients in remission at the start of maintenance therapy [c] n/N (%)	36/79 (45.6%)	44/7[illegible] (56.4[illegible]	10.8% (-5%, 26%) p = 0.189 [abd]	52/78 (66.7%)	21% (6%, 36%) p = 0.007 [ab]

Clinical remission is defined as CDAI score < 150; Clinical response is defined as reduction in CDAI of at least 100 points or being in clinical remission (for subjects with a baseline CDAI score of ≥ 220 to ≤ 248)

* The placebo group consisted of patients who were in response to Finlius and were randomized to receive placebo at the start of maintenance therapy.

† Patients who achieved a clinical response to Finlius I.V. at start of maintenance therapy

[a] Based on a Cochran-Mantel-Haenszel chi-square test, stratified by clinical remission status at Week 0 (yes or no), Finlius I.V. induction dose (130 mg or tiered doses approximating ustekinumab 6 mg/kg), and induction study (UNITI-1 or UNITI-2)

[b] To control the overall Type I error rate at the 0.05 significance level, the endpoints were tested in the hierarchical order presented in this table for the q8w dosing regimen and then in the same hierarchical order for the q12w regimen.

[c] Subjects who had a prohibited Crohn's disease-related surgery, had a loss of response, had prohibited concomitant medication changes, discontinued study agent due to lack of efficacy or due to an adverse event indicated to be of worsening Crohn's disease, or had insufficient data to determine the response and remission status were considered to not be in response or remission.

[d] p-value is not significant at the 0.05 level of significance.

Patients who were not in clinical response 8 weeks after Finlius I.V. induction were not included in the primary efficacy analysis for IM-UNITI; however, these patients were eligible to receive a 90 mg subcutaneous injection of Finlius upon entry in IM-UNITI. Of these patients, 236/467 (50.5%) achieved clinical response eight weeks later and were followed for the duration of the study.

In IM-UNITI, patients who did not maintain response to Finlius when treated every 12 weeks were allowed to increase the frequency of dosing and receive Finlius every 8 weeks. In these patients (n=29), 55% and 41% achieved clinical response and clinical remission respectively 16 weeks after dosing frequency adjustment.

Of the randomized patients in clinical remission at Week 44 who entered the long-term extension, 57/69 (83%) and 52/65 (80%) of patients who received Finlius q8w and q12w respectively were in clinical remission at Week 92. Of the randomized patients in clinical response at Week 44 who entered the long-term extension, 64/78 (82%) and 69/82 (84%) of patients who received Finlius q8w and q12w respectively were in clinical response at Week 92.

Corticosteroid Use in Maintenance
At Week 44, 47% and 43% of patients who received Finlius q8w and q12w respectively were corticosteroid-free and in clinical remission compared to 30% of patients in the placebo group. In the subgroup of patients who were on corticosteroids at baseline, 30% of subjects in the Finlius treated groups were corticosteroid free and in clinical remission at Week 44, compared to 15% in the placebo group.

Endoscopic Assessment of Bowel Mucosa
Mucosal disease of the bowel (ileum and colon) was evaluated in 252 patients with baseline endoscopic disease activity in a substudy. At Week 8, after a single IV induction dose, the reduction in Simplified Endoscopic Activity Score for Crohn's Disease (SES-CD) was -3.0 in patients treated with Finlius I.V. (n=83), compared -0.7 in patients treated with placebo (n=97).

Other Health Related Outcomes
Health-related quality of life was assessed by the disease specific instrument, Inflammatory Bowel Disease Questionnaire (IBDQ). In UNITI-1, the median change from baseline in the IBDQ score at Week 8 was 20 in the group treated with Finlius I.V. compared with 7 in the placebo group. The corresponding changes in UNITI-2 are 29 in the group treated with Finlius I.V. compared with 9 in the placebo group. At Week 44, the median change in IBDQ scores from Week 0 of the maintenance study was -2.5 in the Finlius q12w dose group and -2.0 in the Finlius q8w dose group, compared with -14.5 in the placebo group.

Ulcerative Colitis

The safety and efficacy of Finlius/Finlius I.V. was assessed in two randomized, double-blind, placebo-controlled, clinical trials in adult patients with moderately to severely active ulcerative colitis who had an inadequate response to or failed to tolerate a biologic (i.e., anti-TNFα agent and/or vedolizumab) or conventional therapy. An 8-week IV induction study (UNIFI-I) was followed by a 44-week subcutaneous randomized withdrawal maintenance study (UNIFI-M) representing a total 52 weeks of therapy (Table 33).

Disease assessment was based on the Mayo score, which ranged from 0 to 12 and has four subscores that were each scored from 0 (normal) to 3 (most severe): stool frequency, rectal bleeding, findings of endoscopy, and physician global assessment. Moderately to severely active ulcerative colitis was defined at baseline (Week 0) as Mayo score of 6 to 12, including a Mayo endoscopy subscore ≥ 2. The endoscopy subscore was assessed by the investigator (ie,

local endoscopist) during the endoscopy procedure and by a central reader who reviewed a video of the endoscopy. Patients were permitted to receive concomitant aminosalicylates, immunomodulators, and/or corticosteroids and 90% of patients continued to receive at least one of these medications.

Table 33: Summary of controlled clinical trials supporting safety and efficacy in patients with UC

Study #	Study Design	Dosage: Route of Administration and Duration	Study Subjects (n)	Median Age (Range)	Sex
UNIFI-I (Induction)	Multicentre, double-blinded, randomized, placebo-controlled	IV administration at Week 0	961	41 (18-84)	M: 582, 61 F: 379, 39
		Placebo	319		
		Finlius I.V. 130 mg	320		
		Finlius I.V. ~6 mg/kg [a]	322		
UNIFI-M (Maintenance)	Multicentre, double-blinded, placebo-controlled randomized-withdrawal	SC administration at Week 0 [b], and then q8w or q12w for 44 weeks	523	40 (18-84)	M: 297, 57 F: 226, 43
		Placebo	175		
		Finlius 90 mg q8w	176		
		Finlius 90 mg q12w	172		

[a] tiered weight-based dose approximating 6 mg/kg (see 4 DOSAGE AND ADMINISTRATION)
[b] 8 weeks following the intravenous dose of Finlius I.V.

Induction Study: UNIFI-I

In the induction study (UNIFI-I), 961 patients were randomized to receive a single intravenous administration of 130 mg Finlius I.V., or approximately 6 mg/kg Finlius I.V. designed as a tiered dose based on patient body weight (Table 3) or placebo at Week 0. Randomization was stratified by biologic failure status (yes/no) and region (Eastern Europe, Asia, or rest of world).

The primary endpoint was clinical remission (defined as a Mayo score ≤ 2 points, with no individual sub-score > 1) at Week 8. The secondary endpoints included: clinical response (≥ 3 points and 30% decrease in Mayo score with either a decrease from baseline in the rectal bleeding subscore ≥ 1 or a rectal bleeding subscore of 0 or 1), improvement of endoscopic appearance of the mucosa (Mayo endoscopy subscore of 0 or 1), and histo-endoscopic mucosal healing (defined as combined improvement of endoscopic appearance of the mucosa and histologic healing of the colon tissue [neutrophil infiltration in < 5% of crypts, no crypt destruction, and no erosions, ulcerations, or granulation tissue]).

Patients enrolled in UNIFI-I had to have failed conventional therapy (corticosteroids or immunomodulators) or at least one biologic (an anti-TNFα agent and/or integrin antagonist). Of the total population, 49% of patients had failed conventional therapy but not a biologic (of which 94% were biologic-naïve) and 51% of patients had failed or were intolerant to a biologic. Approximately 50% of patients had failed at least 1 prior anti-TNFα agent (of which 48% were primary non-responders) and 17% had failed both an anti-TNFα agent and an integrin antagonist. At induction baseline and throughout the study, approximately 52% of patients were

receiving oral corticosteroid, 28% of patients were receiving immunomodulators (AZA, 6-MP, or MTX) and 69% of patients were receiving aminosalicylates.

In UNIFI-I, a significantly greater proportion of patients were in clinical remission and response and achieved improvement of endoscopic appearance of the mucosa and histo-endoscopic mucosal healing in the Finlius I.V. treated group (at the recommended dose of approximately 6 mg/kg) compared to placebo at Week 8 (Table 34).

Table 34: Results for Efficacy Endpoints at Week 8 in UNIFI-I*

	Placebo N = 319	**Finlius I.V. ~6 mg/kg N = 322**	**Treatment difference, 97.5% CI**
Clinical Remission**	17 (5.3%)	50 (15.5%)	10.2 (5.0, 15.5)[a]
Biologic-naïve[ɾ]	15/151 (9.9%)	27/147 (18.4%)	
With prior biologic failure	2/161 (1.2%)	21/166 (12.7%)	
Improvement of endoscopic appearance of the mucosa‡	44 (13.8%)	87 (27.0%)	13.3 (6.4, 20.1)[a]
Biologic-naïve[ɾ]	32/151 (21.2%)	49/147 (33.3%)	
With prior biologic failure	11/161 (6.8%)	35/166 (21.1%)	
Clinical Response§	100 (31.3%)	199 (61.8%)	30.5 (22.2, 38.8)[a]
Biologic-naïve[ɾ]	54/151 (35.8%)	98/147 (66.7%)	
With prior biologic failure	44/161 (27.3%)	95/166 (57.2%)	
Histo-Endoscopic Mucosal Healing†	28 (8.8%)	58 (18.0%)	9.3 (3.4, 15.2)[a]
Biologic-naïve[ɾ]	21/151 (13.9%)	33/147 (22.4%)	
With prior biologic failure	6/161 (3.7%)	22/166 (13.3%)	

* Subjects who had insufficient data or had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to the Week 8 visit were considered not to have achieved the respective endpoints

[ɾ] An additional 7 patients on placebo and 9 patients on Finlius (~6 mg/kg) had been exposed to, but had not failed, biologics.

** Clinical remission is defined as Mayo score ≤2 points, with no individual subscore > 1

‡ Improvement of endoscopic appearance of the mucosa is defined as a Mayo endoscopic sub-score of 0 or 1 determined by central review of the endoscopy

§ Clinical response was defined as a decrease from baseline in the Mayo score by ≥ 30% and ≥ 3 points, with either a decrease from baseline in the rectal bleeding subscore ≥ 1 or a rectal bleeding subscore of 0 or 1

† Histo-endoscopic mucosal healing is defined as combined improvement of endoscopic appearance of the mucosa (Mayo endoscopy sub-score of 0 or 1) and histologic healing of the colon tissue (neutrophil infiltration in < 5% of crypts, no crypt destruction, and no erosions, ulcerations, or granulation tissue)

[a] $p < 0.001$; p-value is based on a Cochran-Mantel-Haenszel (CMH) chi-square test stratified by biologic failure status and region. Type I error rate is controlled at the 0.025 significance level based on a pre-defined hierarchical testing procedure

Maintenance Study: UNIFI-M

The maintenance study (UNIFI-M), evaluated 523 patients who achieved clinical response at Week 8 following the administration of Finlius I.V. in UNIFI-I. These patients were randomized to

receive a subcutaneous maintenance regimen of either 90 mg Finlius every 8 weeks, 90 mg Finlius every 12 weeks or placebo for 44 weeks. Randomization was stratified by clinical remission status at maintenance baseline (yes/no), oral corticosteroid use at maintenance baseline (yes/no), and induction treatment.

The primary endpoint was the proportion of patients in clinical remission at Week 44. Secondary endpoints included the proportion of patients maintaining clinical response through Week 44, the proportion of patients with improvement of endoscopic appearance of the mucosa at Week 44, the proportion of patients with corticosteroid-free clinical remission at Week 44, and the proportion of patients maintaining clinical remission through Week 44 in patients who achieved clinical remission 8 weeks after induction. Patients who completed the maintenance study through Week 44 were eligible to continue treatment through Week 96.

Results of the primary and secondary endpoints at Week 44 in patients treated with Finlius at the recommended dosage (90 mg every 8 weeks) compared to the placebo are shown in Table 35.

Table 35: Results for Efficacy Endpoints at Week 44 in UNIFI-M (52 weeks from initiation of the induction dose)*

	Placebo¥ N = 175	Finlius 90 mg every 8 Weeks N = 176	Treatment difference, 95% CI
Clinical Remission**	42 (24.0%)	77 (43.8%)	19.7 (10.3, 29.0)[ab]
Biologic-naïve[+]	27/84 (32.1%)	40/79 (50.6%)	
With prior biologic failure	15/88 (17.0%)	36/91 (39.6%)	
Maintenance of Clinical Response through Week 44[§]	78 (44.6%)	125 (71.0%)	26.4 (16.6, 36.1)[ab]
Biologic-naïve[+]	44/84 (52.4%)	61/79 (77.2%)	
With prior biologic failure	34/88 (38.6%)	59/91 (64.8%)	
Improvement of Endoscopic Appearance of the Mucosa[†]	50 (28.6%)	90 (51.1%)	22.5 (12.8, 32.2)[ab]
Biologic-naïve[+]	30/84 (35.7%)	46/79 (58.2%)	
With prior biologic failure	20/88 (22.7%)	41/91 (45.1%)	
Corticosteroid free clinical remission	41 (23.4%)	74 (42.0%)	18.5 (9.3, 27.8)[ab]
Biologic-naïve[+]	27/84 (32.1%)	39/79 (49.4%)	
With prior biologic failure	14/88 (15.9%)	34/91 (37.4%)	
Maintenance of clinical remission through Week 44 in patients who achieved clinical remission 8 weeks after induction	17/45 (37.8%)	22/38 (57.9%)	
Biologic-naïve[+]	9/25 (36.0%)	12/16 (75.0%)	
With prior biologic failure	8/20 (40.0%)	10/20 (50.0%)	

* Subjects who had insufficient data or had a prohibited change in UC medication, an ostomy or colectomy, or used a rescue medication after clinical flare, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC prior to the Week 44 visit were considered not to have achieved the respective endpoints

¥ The placebo group consisted of patients who were in response to Finlius I.V. and were randomized to receive placebo at the start of maintenance therapy

[+] An additional 3 patients on placebo and 6 patients on q8w Finlius had been exposed to, but had not failed, biologics

** Clinical remission is defined as Mayo score ≤2 points, with no individual subscore > 1

[§] Clinical response was defined as a decrease from baseline in the Mayo score by ≥ 30% and ≥ 3 points, with either a decrease from baseline in the rectal bleeding subscore ≥ 1 or a rectal bleeding subscore of 0 or 1

[†] Improvement of endoscopic appearance of the mucosa is defined as a Mayo endoscopic sub-score of ≤ 1 point

[a] $p < 0.001$

[b] p value is based on a Cochran-Mantel-Haenszel (CMH) chi-square test stratified by clinical remission status at maintenance baseline (not applicable to the last endpoint) and induction treatment. Type I error rate is controlled based on a pre-defined hierarchical testing procedure

Week 16 Responders to Finlius I.V Induction

Patients who were not in clinical response 8 weeks after Finlius I.V. induction were not included in the primary efficacy analysis for UNIFI-M; however, these patients were eligible to receive a 90 mg subcutaneous injection of Finlius at Week 8. Of the 101 patients who received the

recommended induction dose of 6 mg/kg who were not in clinical response at Week 8, 59/101 (58.4%) achieved clinical response at Week 16 of UNIFI-I and received Finlius every 8 weeks during UNIFI-M. Patients who did not achieve clinical response at Week 16 were discontinued from the study.

Histo-Endoscopic Mucosal Healing
The proportion of patients achieving histo-endoscopic mucosal healing at Week 44 was 79/176 (44.9%) in patients receiving Finlius every 8 weeks compared to 41/175 (23.4%) in patients treated with placebo. The relationship of histo-endoscopic mucosal healing at Week 44 to progression of disease or long-term outcomes was not evaluated.

15 MICROBIOLOGY

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

The toxicity of ustekinumab was specifically evaluated in a number of nonclinical studies. An overview of these toxicity studies is provided in Table 36.

General Toxicology: In repeated-dose toxicity studies in cynomolgus monkeys, ustekinumab was well tolerated following IV doses up to 45 mg/kg/week for up to 1 month and following twice-weekly SC doses up to 45 mg/kg for 6 months. There were no ustekinumab-related findings in the immunotoxicity and cardiovascular safety pharmacology evaluations. In histopathology evaluations there were no preneoplastic changes observed. No evidence of ustekinumab-related local intolerance was observed in examinations of subcutaneous injection sites in a local tolerance study and in the chronic subcutaneous toxicity study.

The 45 mg/kg dose is approximately 45-fold higher than the highest equivalent dose intended to be administered to patients with psoriasis (based on administration of a 90 mg SC dose to a 90 kg patient) and the average C_{max} value observed following the last SC 45 mg/kg dose in the 6-month chronic toxicity study in cynomolgus monkeys was approximately 118-fold higher than the median C_{max} value of ustekinumab observed following 4 weekly 90 mg SC doses in psoriasis patients.

Carcinogenicity
The carcinogenic potential has not been evaluated.

Genotoxicity
The genotoxic potential has not been evaluated.

Reproductive and Developmental Toxicology: Three developmental toxicity studies were conducted in cynomolgus monkeys. No ustekinumab-related maternal toxicity, abortions, still-births, embryotoxicity, developmental delays, malformations or birth defects were observed at doses up to 45 mg/kg following weekly or twice weekly administration of ustekinumab via the IV

or SC routes, respectively. In neonates born from pregnant monkeys treated with ustekinumab, no adverse effects on growth or functional development were observed and no deficits were observed in immunotoxicity evaluations. In a male fertility study in cynomolgus monkeys, no ustekinumab-related effects on mating behaviour, sperm parameters, or serum concentrations of male hormones were observed following twice weekly subcutaneous administration of ustekinumab at doses up to 45 mg/kg.

A female fertility toxicity study was conducted in mice using an analogous antibody that binds to and inhibits IL-12 and IL-23 activity in mice. Twice weekly subcutaneous administration of the anti-mouse IL-12/23 antibody was well tolerated at doses up to 50 mg/kg and no adverse effects on female fertility parameters were observed.

Table 36: Non-Clinical Toxicology Studies with ustekinumab

Study	Species/ Strain	Route	Duration of Dosing	Doses (mg/kg)	Results
Repeat-Dose Toxicity					
Subchronic toxicity	Monkey/ Cynomolgus	IV	1 month	9, 45 weekly	No treatment-related signs of toxicity.
Subchronic toxicity	Monkey/ Cynomolgus	IV	1 month	9, 45 weekly	No treatment-related signs of toxicity.
Chronic toxicity	Monkey/ Cynomolgus	SC	6 months	22.5, 45 twice weekly	No treatment-related signs of toxicity. No preneoplastic changes observed on histopathology.
Reproductive and Developmental Toxicity					
Embryofetal Development	Monkey/ Cynomolgus	IV	Pregnant females: gestation day 20 to gestation day 50	9, 45 weekly	No maternal or fetal abnormalities were observed.
Embryofetal Development	Monkey/ Cynomolgus	SC	Pregnant females: gestation day 20 – gestation day 51	22.5, 45 twice weekly	A statistically significant increase in maternal 17ß-estradiol levels relative to the control group was observed on days 80 and 100 of gestation in the 22.5 and 45 mg/kg groups. However, foetal 17ß-estradiol levels were not affected, and there were no other treatment-related maternal or foetal

Study	Species/ Strain	Route	Duration of Dosing	Doses (mg/kg)	Results
					abnormalities observed at either dose level.
Male fertility	Monkey/ Cynomolgus	SC	Males: 13 weeks	22.5, 45 twice weekly	No changes in fertility parameters observed.
Female fertility	Mouse/Crl CD-1	SC	Beginning 15 days before cohabitation and continuing through day 7 of presumed gestation	25, 50 twice weekly	No maternal or fetal abnormalities were observed.
Embryofetal and pre- and postnatal development	Monkey/ Cynomolgus	SC	Pregnant females: gestation day 20 – postpartum day 30	22.5, 45 twice weekly	No effects on pregnancy or delivery; or morphological, functional and immunological developmental parameters of offspring. Ustekinumab was detected in the milk of lactating monkeys.
Local Tolerance					
Pharmacokinetics and injection site irritation	Monkey/ Cynomolgus	SC	18 days	45 twice weekly	Minimal signs of local irritation at injection sites were observed, with no associated histopathologic findings.
Other Toxicity Studies					
Tissue cross-reactivity	Human Tissues	In vitro		1.13,11.3, 113, 225 mg/mL	No binding to nontarget normal human tissues.
Tissue cross-reactivity	Human Tissues	In vitro		1.13,11.3, 113, 225 mg/mL	No binding to nontarget normal human tissues
Asthma model	Monkey/ Cynomolgus	IV	Single dose	9, 45	No exacerbation of pulmonary function or cellular responses.

Study	Species/ Strain	Route	Duration of Dosing	Doses (mg/kg)	Results
Asthma model	Monkey/ Cynomolgus	IV	1 week	45	No exacerbation of pulmonary function or cellular responses.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **FINLIUS®**
fin li' us'
ustekinumab injection
Solution for Subcutaneous Injection

Read this carefully before you start taking **Finlius** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Finlius**.

What is Finlius used for?

- **Adults with Plaque Psoriasis**

Finlius is a prescription medicine that is approved for adults with moderate to severe plaque psoriasis that is chronic (doesn't go away).

- **Children 6 to 17 years of age with Plaque Psoriasis**

Finlius is a prescription medicine that is approved for children and adolescent patients 6 to 17 years of age with moderate to severe plaque psoriasis that is chronic (doesn't go away) and who have had an inadequate response to other treatments.

- **Adults with Psoriatic Arthritis**

Finlius is a prescription medicine that is approved for adults with active psoriatic arthritis.

Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis. If you have active psoriatic arthritis, you will be given Finlius by injection under the skin, alone or in combination with methotrexate, to reduce signs and symptoms of your arthritis, help improve your ability to perform daily activities (such as dressing, walking and climbing stairs) and improve your psoriasis.

- **Adults with Crohn's disease or ulcerative colitis**

Finlius/Finlius I.V. is a prescription medicine that is approved for adults with moderately to severely active Crohn's disease and for adults with moderately to severely active ulcerative colitis. For patients with Crohn's disease or ulcerative colitis, the first dose, Finlius I.V., is given by an intravenous infusion, through a needle placed in a vein. Subsequent doses of Finlius are given by injection under the skin.

Crohn's disease (CD) is a chronic inflammatory bowel disorder. Ulcerative colitis is an inflammatory disease of the colon. If you have moderately to severely active Crohn's disease or ulcerative colitis that has not responded to other medications and you are an adult, you may be given Finlius/Finlius I.V. to help relieve your symptoms and keep the disease under control. Finlius/Finlius I.V. may help reduce or stop the use of your corticosteroid medication.

How does Finlius work?

Finlius blocks the action of two proteins in your body called interleukin 12 (IL-12) and interleukin 23 (IL-23). In people with psoriasis, psoriatic arthritis, Crohn's disease or ulcerative colitis, their immune system may attack parts of their body and that attack uses IL-12 and IL-23. Ustekinumab can block the IL-12 and IL-23 from causing the immune system to attack the skin, nails, joints or the digestive tract.

What are the ingredients in Finlius?

Medicinal ingredients: ustekinumab

Non-medicinal ingredients: L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose and water for injection. No preservatives are present.

Finlius comes in the following dosage forms:

Pre-filled Syringe:
- 45 mg / 0.5 mL
- 90 mg / 1.0 mL

Single-use Vial:
- 45 mg / 0.5 mL

Do not use Finlius if:

- you have a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- you have had an allergic reaction to Finlius, Finlius I.V., or any of the other ingredients in Finlius. See below for a complete list of ingredients in Finlius.
- after the expiration date on the label.
- the seal is broken.
- the liquid is discoloured, cloudy or you can see other particulate matter floating in it.
- you know or think that it may have been exposed to extreme temperatures (such as accidentally frozen or heated).

You should not receive a live vaccine while taking Finlius.

If you used Finlius while pregnant, tell your baby's healthcare professional about your Finlius use before the baby receives any vaccine, including live vaccines, such as the BCG vaccine (used to prevent tuberculosis), rotavirus vaccine, or any other live vaccines.

Always keep medicine out of the reach of children.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Finlius. Talk about any health conditions or problems you may have, including if you:

- ever had an allergic reaction to Finlius or Finlius I.V. Ask your healthcare professional if you are not sure.
- have any kind of infection even if it is very minor.
- have an infection that won't go away or a history of infection that keeps coming back.
- have burning when you urinate.
- have diarrhea or abdominal pain.
- have had TB (tuberculosis), notice blood in your phlegm or if you have recently been near anyone who might have TB.
- have or have had any type of cancer.
- have any new or changing skin lesions.
- have recently received or are scheduled to receive a vaccine. Tell your healthcare professional if anyone in your house needs a vaccine. The viruses in some vaccines can spread to people with a weakened immune system and can cause serious problems.
- are receiving or have received “allergy shots”, especially for serious allergic reactions.
- are pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding. Finlius may pass into your breast milk in small amounts.

Contact your healthcare professional immediately:

- if you develop signs of a serious allergic reaction such as skin rash, swollen face, lips, mouth, throat, wheezing, dizziness, trouble swallowing or breathing.
- if you develop headache, vision problems, seizures or change in mental status (for example, confusion).

The needle cover on the pre-filled syringe contains dry natural rubber (a form of latex). This may cause allergic reactions in people who are sensitive to latex. Tell your healthcare professional if you have ever had an allergic reaction to latex and developed any allergic reaction to Finlius injection.

There is limited experience with Finlius in pregnant and breastfeeding women. If you are a woman of childbearing potential, you should use effective contraception when starting Finlius and talk to your healthcare professional before planning to conceive a child. If you are pregnant or breastfeeding, your healthcare professional will help you decide whether or not to use Finlius.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Know the medicines you take. Keep a list of your medicines and show them to your healthcare professionals when you get a new medicine.

The following may interact with Finlius:

- Finlius may change the way the body responds to live vaccines.
- Finlius may interact with other medications that decrease the activity of the immune system.

Your healthcare professional will assess your health before each treatment.

If you have questions, ask your health care provider.

How to take Finlius:

<u>Instructions for injecting Finlius under the skin yourself</u>:

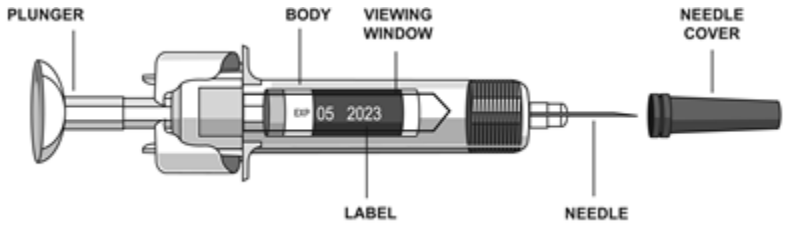
Finlius may be injected by your healthcare provider. In children 6 to 17 years of age, it is recommended that all doses of Finlius be administered by a health care provider. However, your healthcare professional may decide that it is right for you or your caregiver to learn how to inject Finlius under the skin (subcutaneously) yourself. Before you self-inject Finlius, you must be trained by a healthcare professional. If you or your caregiver have not been trained, please contact your healthcare provider to schedule a training session. Call your healthcare provider if you have any questions about giving yourself an injection. Finlius is not to be mixed with other liquids for injection.

INSTRUCTIONS FOR INJECTING FINLIUS USING A PRE-FILLED SYRINGE

To reduce the risk of accidental needle sticks to users, each pre-filled syringe is equipped with a needle guard that is automatically activated to cover the needle after complete delivery of the syringe content.

Do not shake Finlius at any time. Prolonged vigorous shaking may damage the product. If the product has been shaken vigorously, don't use it.

1: PREPARING FOR PRE-FILLED SYRINGE USE



Take the Syringe out of the Refrigerator
If your dose amount is 90 mg and you receive two 45 mg packages, you need to give a second injection right after the first. Choose a different site for the second injection. Children who weigh 60 kg or more may use the prefilled syringe.

Check Expiration Date
Open the box and remove the pre-filled syringe. Check the expiration date on the pre-filled syringe and the label of the box. If the expiration date has passed, or if the pre-filled syringe has been kept at room temperature up to 30°C for longer than 30 days or if the pre-filled syringe has been stored above 30°C, DO NOT use the pre-filled syringe.

Assemble Additional Supplies
Assemble the additional supplies you will need for your injection. These include an antiseptic wipe, a cotton ball or gauze, and a sharps container for syringe disposal.

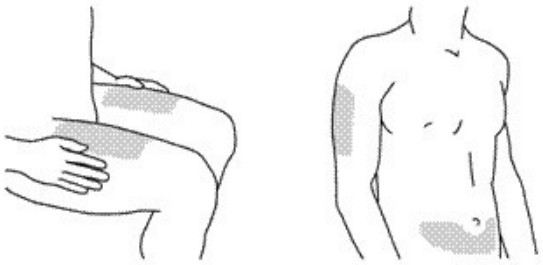
Check Solution in Syringe
Hold the pre-filled syringe with the covered needle pointing upward. Make sure the syringe is not damaged. Look at the solution or liquid in the syringe to make sure that it is clear to slightly opalescent and colorless to slightly yellow. DO NOT use if it is frozen, discolored, cloudy or contains particles and contact your healthcare provider for assistance.

DO NOT remove the needle cover from the pre-filled syringe.

DO NOT pull back on the plunger head at any time.

2: CHOOSING AND PREPARING THE INJECTION SITE

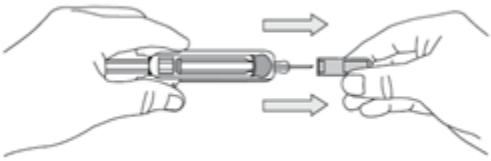
Choose the Injection Site*
Good sites are the top of the thigh and around the tummy (abdomen) but about 2 inches away from the belly button (navel). Avoid, if possible, skin involved with psoriasis. If your caregiver is giving you the injection, they may use the upper arms or buttocks as well.



*Areas in gray are recommended injection sites.

Prepare the Injection Site
Thoroughly wash your hands with soap and warm water. Wipe the injection site with an antiseptic wipe. DO NOT touch this area again before giving the injection.

3: INJECTING THE MEDICATION



Remove the Needle Cover
When you are ready to inject, pick up the pre-filled syringe, hold the body of the syringe with one hand and pull the needle cover straight off. Throw the needle cover into the trash. You may notice a small air bubble in the pre-filled syringe. You do not need to remove the air bubble. You may also see a drop of liquid at the end of the needle – this is normal. Do not touch the needle or allow it to touch any surface.

Note: The needle cover should NOT be removed until you are ready to inject the dose. Do not use syringe if it is dropped without the needle cover in place. If you drop the syringe without the needle cover in place, please contact your healthcare provider for assistance.

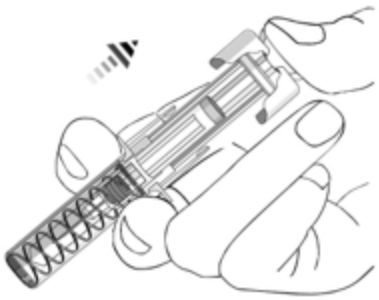
Inject the Medication
Gently pinch the cleaned skin between your thumb and index finger. Don’t squeeze it.

Push the syringe needle into the pinched skin.

Push the plunger with your thumb as far as it will go to inject all of the liquid.

Push it slowly and evenly, keeping the skin pinched.

When the plunger meets the end of the syringe barrel, and all of the medication has been injected, release the pinched skin and gently remove the needle. Following complete injection, the needle guard will automatically extend over the needle and lock as you take your hand off the plunger.



4: AFTER THE INJECTION

Dispose of the Empty Syringe
Immediately dispose of the empty syringe into the sharps container. For your safety and health and for the safety of others, needles and syringes **must NEVER** be re-used. Dispose of sharps container according to your local regulations.
Use a Cotton Ball or Gauze
There may be a small amount of blood or liquid at the injection site, which is normal. You can press a cotton ball or gauze over the injection site and hold for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

INSTRUCTIONS FOR INJECTING FINLIUS FROM A 45 mg/0.5 mL VIAL

Do not shake Finlius Solution for Subcutaneous Injection at any time. Prolonged vigorous shaking may damage the product. If the product has been shaken vigorously, don't use it. Finlius is not to be mixed with other liquids for injection.

1: CHECK VIAL(S) AND ASSEMBLE MATERIALS

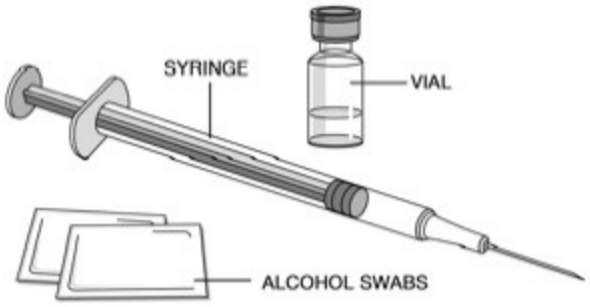
Take the Vial(s) out of the Refrigerator
If your dose is 45 mg you will receive one 45 mg vial. If your dose is 90 mg, you will receive two 45 mg vials. If you receive two 45 mg vials for a 90 mg dose, you will need to give yourself two injections one right after the other. Use a new needle and syringe. Choose a different site for the second injection.

Children weighing less than 60 kg require a dose lower than 45 mg. Make sure you know the proper amount (volume) and type of syringe needed for dosing. If you don't know the amount or type of syringe needed, contact your healthcare provider for further instructions.

Check Expiration Date
Open the box and remove the vial. Check the expiration date on the vial and the label of the box. If the expiration date has passed, don't use it.

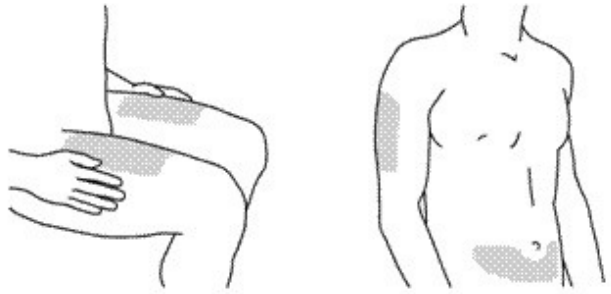
Check Solution in Vial
Make sure the vial is not damaged. Look at the solution or liquid in the vial to make sure that it is clear to slightly opalescent and colorless to slightly yellow. **DO NOT** use if it is frozen, discolored, cloudy or contains particles and contact your healthcare provider for assistance.

Assemble Additional Supplies
Assemble the additional supplies you will need for your injection. These include an antiseptic wipe, a cotton ball or gauze, and a sharps container for syringe disposal.



2: CHOOSING AND PREPARING THE INJECTION SITE

Choose the Injection Site*
Good sites are the top of the thigh and around the tummy (abdomen) but about 2 inches away from the belly button (navel). Avoid, if possible, skin involved with psoriasis. If your caregiver is giving you the injection, they may use the upper arms or buttocks as well.

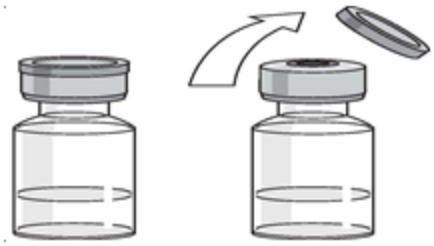


*Areas in gray are recommended injection sites.

Prepare the Injection site
Thoroughly wash your hands with soap and warm water. Wipe the injection site with an antiseptic wipe. DO NOT touch this area again before giving the injection.

3: PREPARING THE DOSE

Remove the cap from the top of the vial but do not remove the stopper. Clean the stopper with an antiseptic wipe.



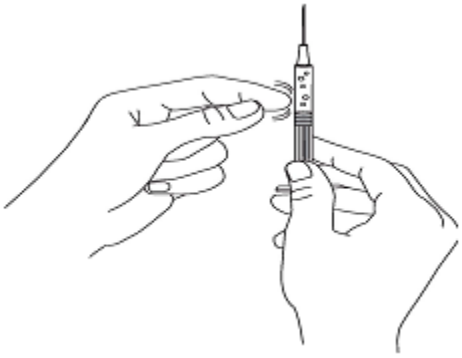
Remove the needle cover from the syringe. Do not touch the needle or allow the needle to touch anything.

Put the vial on a flat surface and push the syringe needle through the rubber stopper.

Turn the vial and the syringe upside down.
For adults and children 6 to 17 years of age, who weigh 60 kg or more, pull on the syringe plunger to fill the syringe with the entire amount (volume) of liquid prescribed by your healthcare provider. It is important that the needle is always in the liquid in order to prevent air bubbles from forming in the syringe.

For children 6 years of age or older who weigh less than 60 kg, the amount of liquid prescribed by your health care provider may be less than 0.5 mL. Your health care provider will recommend how much liquid is needed.

Remove the needle from the vial
Hold the syringe with the needle pointing up to see if it has any air bubbles inside. If there are air bubbles tap the side gently until the air bubbles go to the top of the syringe and press the plunger until all of the air (but none of the liquid) has been removed. Do not lay the syringe down or allow the needle to touch anything.



4: INJECTING THE MEDICATION

Gently pinch the cleaned skin between your thumb and index finger. Don't squeeze it.

Push the syringe needle into the pinched skin.

Push the plunger with your thumb as far as it will go to inject all of the liquid. Push it slowly and evenly, keeping the skin gently pinched.

When the plunger is pushed as far as it will go, take out the needle and let go of the skin.

Press an antiseptic wipe over the injection site for a few seconds after the injection.

Dispose the Empty Syringe and Vial(s)
Discard any unused portion of Finlius in accordance with local requirements. Immediately dispose of the empty syringe into the sharps container. For your safety and health and for the safety of others, vials, needles and syringes must NEVER be re-used. Dispose of sharps container according to your local regulations. Empty vials, antiseptic wipes, and other supplies can be placed in your regular trash.

Use a Cotton Ball or Gauze
There may be a small amount of blood or liquid at the injection site, which is normal. You can press a cotton ball or gauze over the injection site and hold for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

Usual dose:

Psoriasis
For treatment of psoriasis, Finlius is given by injection under the skin.

Adults:
The recommended dose of Finlius is 45 mg at Weeks 0 and 4 then every 12 weeks thereafter. Your healthcare professional may consider treating you as often as every 8 weeks.

90 mg may be used in patients with a body weight greater than 100 kg.

Pediatric Psoriasis (6 years of age or older):
The recommended dose of Finlius based on body weight (as shown below) is given at Week 0 and 4, and then every 12 weeks thereafter.

Weight	Recommended dose of Finlius	Dosage Form
< 60kg	0.75 mg/kg*	Vial
≥ 60 to ≤ 100 kg	45 mg	Pre-filled syringe, vial
> 100 kg	90 mg	Pre-filled syringe

* For patients with body weight < 60 kg, use the vial presentation only. To calculate the volume of injection (mL) for patients < 60 kg, use the following formula: body weight (kg) x 0.0083 (mL/kg). The calculated volume should be rounded to the nearest 0.01 mL and administered using a 1 mL graduated syringe. The calculated volume of injection per kg body weight at time of dosing are also provided in table below. A 45 mg vial is available for pediatric patients who need to receive less than the full 45 mg dose.

Injection volumes of Finlius for pediatric psoriasis patients < 60 kg		
Body weight at time of dosing (kg)	**Dose (mg)**	**Volume of injection (mL)**
15	11.3	0.12
16	12.0	0.13
17	12.8	0.14
18	13.5	0.15
19	14.3	0.16
20	15.0	0.17
21	15.8	0.17
22	16.5	0.18
23	17.3	0.19
24	18.0	0.20
25	18.8	0.21
26	19.5	0.22
27	20.3	0.22
28	21.0	0.23
29	21.8	0.24
30	22.5	0.25
31	23.3	0.26
32	24.0	0.27
33	24.8	0.27
34	25.5	0.28
35	26.3	0.29
36	27.0	0.30
37	27.8	0.31
38	28.5	0.32
39	29.3	0.32
40	30.0	0.33
41	30.8	0.34
42	31.5	0.35
43	32.3	0.36
44	33.0	0.37
45	33.8	0.37
46	34.5	0.38
47	35.3	0.39
48	36.0	0.40
49	36.8	0.41
50	37.5	0.42
51	38.3	0.42
52	39.0	0.43
53	39.8	0.44
54	40.5	0.45
55	41.3	0.46
56	42.0	0.46
57	42.8	0.47
58	43.5	0.48
59	44.3	0.49

In children 6 to 17 of age with psoriasis, it is recommended that Finlius be administered by a health care provider. If your healthcare professional determines that it is appropriate, your caregiver or you may be able to administer Finlius to yourself, after proper training in injection technique using the right type of syringe and the amount (volume) to be injected (see the "**Instructions for injecting Finlius under the skin yourself**".)

Psoriatic Arthritis
For treatment of psoriatic arthritis, Finlius is given by injection under the skin. The recommended dose of Finlius is 45 mg at Weeks 0 and 4 then every 12 weeks thereafter. Alternatively, 90 mg may be used in patients with a body weight greater than 100 kg.

Crohn's disease and ulcerative colitis
For treatment of Crohn's disease or ulcerative colitis, the recommended dose is a single intravenous dose of Finlius I.V. based on body weight (as shown below) followed by 90 mg Finlius given by injection under the skin (subcutaneous).

Weight	Recommended Dose of Finlius I.V.
≤ 55 kg	260 mg
> 55 kg to ≤ 85 kg	390 mg
> 85 kg	520 mg

The recommended dosing schedule for Crohn's disease and ulcerative colitis is as follows:

Treatment number	Time of treatment Route of administration
Treatment 1	Week 0 Intravenous infusion (Finlius I.V.)
Treatment 2	8 weeks after Treatment 1 Subcutaneous injection (Finlius)
Further treatment	Every 8 weeks* Subcutaneous injection (Finlius)

* your healthcare professional will decide whether the treatment interval between injections should be maintained at every 8 weeks or may be extended to every 12 weeks

The BioAdvance® Network has been established to facilitate the administration of Finlius. This network consists of clinics located across Canada that are staffed by qualified healthcare professionals specially trained in the administration of Finlius. Contact your healthcare professional if you have any questions.

Overdose:

Call your healthcare professional if you accidentally inject Finlius more frequently than instructed.

If you think you, or a person you are caring for, have taken too much Finlius, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

If you miss a dose, contact your healthcare provider for guidance.

What are possible side effects from using Finlius?

These are not all the possible side effects you may have when taking Finlius. If you have any side effects not listed here, tell your healthcare professional.

The most common side effects of Finlius are:

- Upper respiratory tract infections such as the common cold
- Infection of the nose and throat
- Dizziness
- Headache
- Sore throat
- Diarrhea
- Nausea
- Vomiting
- Itching
- Back pain
- Muscle aches
- Joint pain
- Feeling very tired
- Redness of the skin where the injection is given
- Pain where the injection is given
- Sinus infection

Finlius is a medicine that affects your immune system. It can increase your risk of getting serious side effects including:

Serious Infections

- Finlius may lower your ability to fight infections. Some infections could become serious and lead to hospitalization. If you have an infection or have any open cuts, tell your healthcare provider before you start using Finlius. If you get an infection, have any sign of an infection such as fever, feel very tired, cough, flu-like symptoms, or warm, red, or painful skin or sores on your body, tell your healthcare provider right away. These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications.
- Your healthcare professional will examine you for tuberculosis (TB) and perform a test to see if you have TB. If your healthcare professional feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with Finlius and during treatment with Finlius.

Cancers

- Finlius may decrease the activity of your immune system, and increase the risk for certain types of cancer. Tell your healthcare professional if you notice any unusual changes to your skin or health status while receiving Finlius treatment.

Serious Skin Conditions

Shedding of skin – increase in redness and shedding of skin over a larger area of the body may be symptoms of erythrodermic psoriasis or exfoliative dermatitis, which are serious skin conditions. You should contact your healthcare professional immediately if you notice any of these signs.

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
VERY COMMON (>10%)			
Infected nose, sinuses or throat (cold)	✓		
COMMON (≥1% and <10%)			
Sore throat, nasal congestion	✓		
Allergic reaction (skin rash)		✓	
UNCOMMON (≥0.1% and <1%)			
Cellulitis (skin infection)		✓	
Vaginal yeast infections	✓		
Tooth abscess/tooth infection		✓	
RARE (≥0.01% and <0.1%)			
Serious allergic reactions (e.g.: swollen face or trouble breathing; symptoms such as cough, shortness of breath, and fever may also be a sign of an allergic lung reaction)			✓
Increase in redness and shedding of skin		✓	

In general, the side effects of Finlius seen in children 6 to 17 years of age are similar to those in adults.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

If you are using Finlius at home, it is important to store the product in your refrigerator at 2-8°C although not in the freezer compartment. Finlius should not be frozen. Keep the product in the original carton to protect from light until the time of use. Do not shake.

If needed, individual Finlius pre-filled syringes may also be stored at room temperature up to 30°C for a maximum single period of up to 30 days in the original carton with protection from light. Record the date when the pre-filled syringe is first removed from the refrigerator and the new expiry date on the carton in the spaces provided. The new expiry date must not exceed the original expiry date printed on the carton. Once a syringe has been stored at room temperature, it should not be returned to the refrigerator. Discard the syringe if not used within 30 days at room temperature storage.

Always keep medicine out of the reach and sight of children.

If you want more information about Finlius:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; https://www.canada.ca/en/health-canada/services/drugs-health-products/drugproducts/drug-product-database.html, the manufacturer's website www.janssen.com/canada or contact the manufacturer, Janssen Inc., at 1-800-567-3331, or 1-800-387-8781.

This leaflet was prepared by Janssen Inc., Toronto, Ontario M3C 1L9

Last revised: June 2023

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr FINLIUS® I.V.
fin li' us'
ustekinumab for injection
Solution for Intravenous Infusion

Read this carefully before you start taking **Finlius I.V.** This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Finlius I.V.**

What is Finlius I.V. used for?

- **Adults with Crohn's disease or ulcerative colitis**

Finlius I.V./Finlius is a prescription medicine that is approved for adults with moderately to severely active Crohn's disease or adults with moderately to severely active ulcerative colitis. For patients with Crohn's disease or ulcerative colitis, the first dose, Finlius I.V., is given by an intravenous infusion, through a needle placed in a vein. Subsequent doses of Finlius are given by injection under the skin.

Crohn's disease (CD) is a chronic inflammatory bowel disorder. Ulcerative colitis is an inflammatory disease of the colon. If you have moderately to severely active Crohn's disease or ulcerative colitis that has not responded to other medications and you are an adult, you may be given Finlius I.V./Finlius to help relieve your symptoms and keep the disease under control. Finlius I.V./ Finlius may help reduce or stop the use of your corticosteroid medication.

How does Finlius I.V. work?

Finlius I.V. blocks the action of two proteins in your body called interleukin 12 (IL-12) and interleukin 23 (IL-23). In people with Crohn's disease and ulcerative colitis, their immune system may attack parts of their body and that attack uses IL-12 and IL-23. Ustekinumab can block the IL-12 and IL-23 from causing the immune system to attack the digestive tract.

What are the ingredients in Finlius I.V.?

Medicinal ingredients: ustekinumab

Non-medicinal ingredients: EDTA disodium salt dihydrate, L-histidine and L-histidine hydrochloride monohydrate, L-methionine, polysorbate 80 and sucrose. No preservatives are present.

Finlius I.V. comes in the following dosage forms:

Finlius I.V. is available as a sterile solution in single-use vials. Each vial contains 130 mg ustekinumab in 26 mL.

Do not use Finlius I.V. if:

- you have a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- you have had an allergic reaction to Finlius I.V. or Finlius or any of the other ingredients in Finlius I.V. See below for a complete list of ingredients in Finlius I.V.
- after the expiration date on the label.
- the seal is broken.
- the liquid is discoloured, cloudy or you can see other particulate matter floating in it.
- you know or think that it may have been exposed to extreme temperatures (such as accidentally frozen or heated).

You should not receive a live vaccine when taking Finlius I.V.

If you used Finlius I.V. while pregnant, tell your baby's healthcare professional about your Finlius I.V. use before the baby receives any vaccine, including live vaccines, such as the BCG vaccine (used to prevent tuberculosis), rotavirus vaccine, or any other live vaccines.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Finlius I.V. Talk about any health conditions or problems you may have, including if you:

- ever had an allergic reaction to Finlius I.V. or Finlius. Ask your healthcare professional if you are not sure.
- have any kind of infection even if it is very minor.
- have an infection that won't go away or a history of infection that keeps coming back.
- have burning when you urinate.
- have diarrhea or abdominal pain.
- have had TB (tuberculosis), notice blood in your phlegm or if you have recently been near anyone who might have TB.
- have or have had any type of cancer.
- have any new or changing skin lesions.
- have recently received or are scheduled to receive a vaccine. Tell your healthcare professional if anyone in your house needs a vaccine. The viruses in some vaccines can spread to people with a weakened immune system and can cause serious problems.
- are receiving or have received "allergy shots", especially for serious allergic reactions.
- are pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding. Finlius I.V. may pass into your breast milk in small amounts.

Contact your healthcare professional immediately:

- if you develop signs of a serious allergic reaction such as skin rash, swollen face, lips, mouth, throat, wheezing, dizziness, trouble swallowing or breathing.
- if you develop headache, vision problems, seizures or change in mental status (for example, confusion).

There is limited experience with Finlius I.V./Finlius in pregnant and breastfeeding women. If you are a woman of childbearing potential, you should use effective contraception when starting Finlius I.V. and talk to your healthcare professional before planning to conceive a child. If you are pregnant or breastfeeding, your healthcare professional will help you decide whether or not to use Finlius I.V./Finlius.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Know the medicines you take. Keep a list of your medicines and show them to your healthcare professionals when you get a new medicine.

The following may interact with Finlius I.V.:

- Finlius I.V. may change the way the body responds to live vaccines.
- Finlius I.V. may interact with other medications that decrease the activity of the immune system.

Your healthcare professional will assess your health before each treatment.

If you have questions, ask your health care provider.

How to take Finlius I.V.:

Usual dose:

Crohn's disease and ulcerative colitis
For treatment of Crohn's disease or ulcerative colitis, the recommended dose is a single intravenous dose of Finlius I.V. based on body weight (as shown below) followed by 90 mg Finlius given by injection under the skin (subcutaneous).

Weight	Recommended Dose of Finlius I.V.
≤ 55 kg	260 mg
> 55 kg to ≤ 85 kg	390 mg
> 85 kg	520 mg

The recommended dosing schedule for Crohn's disease and ulcerative colitis is as follows:

Treatment number	Time of treatment Route of administration
Treatment 1	Week 0 Intravenous infusion (Finlius I.V.)
Treatment 2	8 weeks after Treatment 1 Subcutaneous injection (Finlius)
Further treatment	Every 8 weeks* Subcutaneous injection (Finlius)

* your healthcare professional will decide whether the treatment interval between injections should be maintained at every 8 weeks or may be extended to every 12 weeks

The initial dose of Finlius I.V. for intravenous infusion for Crohn's disease or ulcerative colitis will be given over a period of at least one hour.

The BioAdvance® Network has been established to facilitate the administration of Finlius I.V. This network consists of clinics located across Canada that are staffed by qualified healthcare professionals specially trained in the administration of Finlius I.V. infusions. Contact your healthcare professional if you have any questions.

Overdose:

In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse effects and appropriate symptomatic treatment be instituted immediately.

If you think you, or a person you are caring for, have taken too much Finlius I.V., contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using Finlius I.V.?

These are not all the possible side effects you may have when taking Finlius. If you have any side effects not listed here, tell your healthcare professional.

The most common side effects of Finlius I.V. are:

- Upper respiratory tract infections such as the common cold
- Infection of the nose and throat
- Dizziness
- Headache
- Sore throat
- Diarrhea
- Nausea
- Vomiting
- Itching
- Back pain
- Muscle aches
- Joint pain
- Feeling very tired
- Redness of the skin where the injection is given
- Pain where the injection is given
- Sinus infection

Finlius I.V. is a medicine that affects your immune system. It can increase your risk of getting serious side effects including:
Serious Infections

- Finlius I.V. may lower your ability to fight infections. Some infections could become serious and lead to hospitalization. If you have an infection or have any open cuts, tell your healthcare provider before you start using Finlius I.V. If you get an infection, have any sign of an infection such as fever, feel very tired, cough, flu-like symptoms, or warm, red, or painful skin or sores on your body, tell your healthcare provider right away. These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications.
- Your healthcare professional will examine you for tuberculosis (TB) and perform a test to see if you have TB. If your healthcare professional feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with Finlius I.V.

Cancers

- Finlius I.V. may decrease the activity of your immune system, and increase the risk for certain types of cancer. Tell your healthcare professional if you notice any unusual changes to your skin or health status while receiving Finlius I.V. treatment.

Serious Skin Conditions

Shedding of skin – increase in redness and shedding of skin over a larger area of the body may be symptoms of erythrodermic psoriasis or exfoliative dermatitis, which are serious skin conditions. You should contact your healthcare professional immediately if you notice any of these signs.

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
VERY COMMON (>10%)			
Infected nose, sinuses or throat (cold)	✓		
COMMON (≥1% and <10%)			
Sore throat, nasal congestion	✓		
Allergic reaction (skin rash)		✓	
UNCOMMON (≥0.1% and <1%)			
Cellulitis (skin infection)		✓	
Vaginal yeast infections	✓		
Tooth abscess/tooth infection		✓	
RARE (≥0.01% and <0.1%)			
Serious allergic reactions (e.g.: swollen face or trouble breathing; symptoms such as cough, shortness of breath, and fever may also be a sign of an allergic lung reaction)			✓
Increase in redness and shedding of skin		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Finlius I.V. must be stored in the original package in the refrigerator at 2-8°C (36-46°F) before use. Finlius I.V. should not be frozen. Keep the product in its original carton to protect from light until the time of use. Do not shake. It must be kept out of the reach and sight of children.

If you want more information about Finlius I.V.:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; https://www.canada.ca/en/health-canada/services/drugs-health-products/drugproducts/drug-product-database.html, the manufacturer's website www.janssen.com/canada or contact the manufacturer, Janssen Inc., at 1-800-567-3331, or 1-800-387-8781.

This leaflet was prepared by Janssen Inc., Toronto, Ontario M3C 1L9

Last revised: July 7, 2023

Exhibit “J27”

This is Exhibit “J27” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

Recorded Entry Information : T-873-23

Type : Federal Court

Type of Action : Federal Court

Nature of Proceeding : S. 18.1 Application for Judicial Review

Filing Date : 2023-04-26

Office : Toronto **Language :** English

Recorded Entry Summary Information

Certain public documents in some proceedings are now available for online access in accordance with the Federal Court's Online Access to Court Records – Pilot Project. These documents are identified with a download icon ( ) in the Download column below.

You may obtain copies of other public documents by contacting the Registry. Copies of public documents which are already in electronic format can be sent by e-mail, upon request to their local Registry office (see list of e-mail addresses in the Update #9 and Consolidated COVID-19 Practice Direction (June 24, 2022). Indicate the Court File number in the subject of your email. In the text, you must clearly identify the document number and its name (this information is located in the *Recorded Entry Summary* column).

The availability of documents from the Registry, including through online access, does not grant a copyright licence or permission. Your use of such materials must be in accordance with the *Copyright Act*, RSC 1985, c C-42.

20 records found

Doc	Date Filed	Office	Recorded Entry Summary	Download
null	2024-02-28	Toronto	Letter from Applicant dated 28-FEB-2024 Further to directions of AJ Steele Feb 23 2024...discontinuance and consent was filed Feb 26... received on 28-FEB-2024	
9	2024-02-26	Toronto	Solicitor's certificate of service on behalf of Jordana Sanft confirming service of Doc No. 7 & Doc No. 8 upon Respondent by email on 26-FEB-2024 filed on 26-FEB-2024	
8	2024-02-26	Toronto	Consent on behalf of all parties to Doc No. 7: Notice of Discontinuance filed on 26-FEB-2024	
7	2024-02-26	Toronto	Discontinuance on behalf of Applicant filed on 26-FEB-2024	
null	2024-02-26	Montréal	Acknowledgment of Receipt received from all parties with respect to the Direction from the Court, Id.#15, placed on file on 26-FEB-2024	
null	2024-02-23	Montréal	Oral directions received from the Court: Alexandra Steele, Prothonotary dated 23-FEB-2024 directing that ¿Further to the issuance of the judgement of the Federal Court of Appeal on November 21, 2023 in file A-192-23, the parties are requested to provide the Court with a further status update in respect of this proceeding by March 11, 2024.¿ placed on file on 23-FEB-2024 Confirmed in writing to the party(ies)	
null	2023-10-17	Montréal	Communication to the Court from the Registry dated 17-OCT-2023 re: Letter from Applicant, Id.#13 (ref:GDI)	
null	2023-10-17	Montréal	Letter from Applicant dated 17-OCT-2023 pursuant to the Direction dated August 7, 2023, informing the Court that the date of the hearing of the appeal in file A-192-23 is November 21, 2023. received on 17-OCT-2023	
null	2023-08-07	Montréal	Oral directions received from the Court: Alexandra Steele, Prothonotary dated 07-AUG-2023 directing that Further to the order dated 24-MAY-2023 and the joint status updated dated 2-AOU-2023, the Court prays act of the commencement of an appeal in A-192-23 further to the issuance of the confidential judgment in file T-2627-22 and directs that, as a further status update, the parties inform the Cour of the date for the hearing of the appeal once it is known. placed on file on 07-AUG-2023 Confirmed in writing to the party(ies)	
null	2023-08-02	Montréal	Communication to the Court from the Registry dated 02-AUG-2023 re: Letter from Applicant, Id.#10 (Ref:GDI)	
null	2023-08-02	Montréal	Letter from Applicant dated 02-AUG-2023 providing the Court with a status update of the file. received on 02-AUG-2023	

null	2023-05-24	Montréal	Acknowledgment of Receipt received from all parties with respect to the Order from the Court, doc.#6, placed on file on 24-MAY-2023	1731
6	2023-05-24	Montréal	Order dated 24-MAY-2023 rendered by Alexandra Steele, Prothonotary Matter considered without personal appearance The Court's decision is with regard to Letter from Applicant dated 19-MAY-2023 Result: granted 2. The present Application is stayed pending a final resolution of the STELARA Application (T-2627-22), including any appeals. 4. Within forty-five (45) days of the date of issuance of the judgment on the judicial review of the STELARA Application in file T-2627-22 (first instance), the parties shall provide the Court with a status update. 5. The stay of the present application may be lifted at the request of either party thereto, in writing to the Court, within thirty (30) days after the expiration of the final appeal period or the determination of the final appeal in the STELARA Application. Filed on 24-MAY-2023 copies sent to parties entered in J. & O. Book, volume 1596 page(s) 59 - 61 Interlocutory Decision	
null	2023-05-19	Montréal	Communication to the Court from the Registry dated 19-MAY-2023 re: letter from Applicant, Id.#6 (Ref:GDI)	
null	2023-05-19	Toronto	Letter from Applicant dated 19-MAY-2023 write on behalf of parties to request a stay of this proceeding by way of informal request...on consent with draft order(forwarded to CMT Montreal) received on 19-MAY-2023	
5	2023-05-04	Toronto	Solicitor's certificate of service on behalf of LEAH BOWES confirming service of DOC 4 upon Applicant by EMAIL on 04-MAY-2023 filed on 04-MAY-2023	
4	2023-05-04	Toronto	Notice of appearance on behalf of Respondent filed on 04-MAY-2023	
3	2023-04-27	Toronto	Service copy of Doc. No. 1 with proof of service upon Respondents on 27-APR-2023 filed on 27-APR-2023	
2	2023-04-27	Ottawa	Order dated 27-APR-2023 rendered by Chief Justice Crampton Matter considered without personal appearance The Court's decision is with regard to Motion ex proprio motu Result: "PURSUANT to Rules 47 and 384 of the Federal Court Rules; IT IS HEREBY ORDERED THAT: 1. This proceeding shall continue as a specially managed proceeding. 2. Pursuant to Rule 383, Associate Judge Alexandra Steele is assigned as Case Management Judge in this matter." Filed on 27-APR-2023 copies sent to parties entered in J. & O. Book, volume 1592 page(s) 91 - 92 Interlocutory Decision	
1	2023-04-26	Toronto	Notice of application with regard to Judicial Review (s.18) filed on 26-APR-2023 Certified copy(ies)/copy(ies) transmitted to Director of the Regional Office of the Department of Justice Tariff fee of $50.00 received: yes	

Exhibit “J28”

This is Exhibit “J28” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

JAMP Pharma Group signs a landmark partnership agreement for the commercialization of five biosimilar medicines in Canada Français

NEWS PROVIDED BY
JAMP Pharma Corporation →
Jan 14, 2020, 06:00 ET

BOUCHERVILLE, QC, Jan. 14, 2020 /CNW Telbec/ - Canadian pharmaceutical company JAMP Pharma Group has signed an exclusive agreement with global speciality biopharmaceutical company Alvotech for the Canadian commercial rights to five biosimilars. The current market value of the branded sales for these five biosimilars is estimated to be exceeding $2 billion annually in Canada.

"We are thrilled with this partnership, as it will allow the JAMP Pharma Group to become a major player and partner in this market while continuing to expand our traditional generic portfolio, which should surpass 500 products by 2022. We now have six biosimilars in our short-term new product pipeline, and this will have a positive impact on both the company's future and patient access to these important medicines. The JAMP Pharma Group continues to be driven by our mission to offer more affordable options to Canadian patients."

- Louis Pilon, CEO of JAMP Pharma Group

Important news for the health sector in Canada

This partnership agreement will accelerate JAMP's unprecedented growth, reinforce its leadership position in the Canadian pharmaceutical industry and reaffirm its commitment to improving access to affordable medicines both for patients and the company's Canadian partners.

In concrete terms, the partnership allows for the creation of several new jobs and the expansion of the company's head office and laboratories in Boucherville.

"We are very excited to become a major biosimilar company in the Canadian market and look forward to collaborating with all stakeholders to make these new options available to Canadian patients as soon as possible. While the penetration rate of biosimilars remains very low, we are encouraged by the decision by officials in British Columbia and Alberta to transition all existing patients to one of the 18 biosimilars available in Canada."

- Bruno Mäder, Managing Director of Orimed Pharma and Head of Biosimilars for JAMP Pharma Group

A strategic partner of choice

Alvotech is a fully integrated specialty biopharmaceutical company focused exclusively on developing and manufacturing high-quality biosimilar medicines in their new state-of-the-art facility in Reykjavik, Iceland. Alvotech's pipeline includes biosimilar product candidates aimed at treating autoimmune, oncological and inflammatory conditions. The strategic partnership with JAMP Pharma Group extends Alvotech's fully integrated value chain from cell line development to commercial manufacturing. JAMP Pharma Group's existing commercial infrastructure and expertise will allow Canadian patients to benefit from safe and effective biosimilars as well as the JAMP Care™ patient support program, while providing significant cost savings to the healthcare system.

"Alvotech is proud to join forces with JAMP Pharma Group, a leading pharmaceutical company in Canada. We believe that our portfolio breadth and fully integrated development model will allow us to become a worldwide leader in this market."

- Anil Okay, Executive VP, Business Development for Alvotech

About JAMP Pharma Group

JAMP Pharma Group is a privately owned Canadian company headquartered in the Montréal area. Having sustained its phenomenal growth for more than 10 years, JAMP Pharma Group has a portfolio of more than 250 molecules and is the leader in product launches in the generic pharmaceutical industry in Canada based on Health Canada approvals from January to December 2019. The Group also has in excess of 160 products in its over-the-counter division with a diverse range of vitamin, supplement and natural product brands, as well as Orimed Pharma's prescription products.

Biosimilar medicines in Canada

A biosimilar is a biologic drug that is highly similar to a reference biologic drug already authorized for sale and no longer protected by a patent. Health Canada regulates biosimilars as new drugs under the Food and Drugs Act and Food and Drug Regulations. Biosimilars are approved for sale based on the same rigorous regulatory standards for quality, efficacy and safety as all other biologic drugs.

Biosimilars are not the same as generic drugs. Generic drugs are small, chemically synthesized molecules containing medicinal ingredients identical to their reference products. A biosimilar and its reference biologic drug can be shown to be highly similar, but not identical. This is because biologic drugs are often large and complex molecules and made from living cells rather than

chemicals. As a result, they are naturally variable.

SOURCE JAMP Pharma Corporation

or media requests : Véronique Blais, TACT, 514 241-2686; Sophie Jacques, Communication & Marketing Director, JAMP Pharma Group

Exhibit “J29”

This is Exhibit “J29” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

Press release February 1, 2022

BIOJAMP: A Range of Biosimilars for a Seamless Approach

- BIOJAMP™, a division within the JAMP Pharma Group, is dedicated to improving and simplifying the complex world of biosimilars for patients and healthcare professionals.
- BIOJAMP™ and its JAMP CareTM patient support program offer a seamless experience for patients and healthcare professionals.
- BIOJAMP™ also aims to promote a range of products that will offer significant savings to provinces and insurers.
- BIOJAMP™ has acquired the commercial rights to a portfolio of biosimilar products which, in combination with the Group's other launches, will position it at the forefront of Canada's pharmaceutical industry.

BOUCHERVILLE, February 1, 2022 — The JAMP Pharma Group, a Montreal-based Canadian pharmaceutical company founded over 30 years ago, announced today the creation of its all-new division, BIOJAMP™. Its mission is to offer biosimilar products aimed at improving the experience of patients and healthcare professionals, at a considerably lower cost than the reference product. By creating this division, the JAMP Pharma Group is displaying its desire and potential to establish itself as a Canadian leader in the biosimilars market.

To achieve this ambitious objective in the biologics market, already a multi-billion-dollar industry in Canada, BIOJAMP™ intends to set itself apart from the competition by simplifying the complex process of transitioning to biosimilars. BIOJAMP™ and its JAMP Care™ support program will also make access to treatment more affordable, while providing a range of additional services without compromising the program's simplicity.

This new division within the JAMP Pharma Group will play an important role in the objectives of provinces and insurers looking to increase recurring annual savings through the use of biosimilars. The JAMP Pharma Group is focusing all its efforts on becoming a key actor and consolidating its mission: help build a future where everyone can live full and healthy lives.
A Vital Partnership

It is worth noting that the creation of BIOJAMP™ is primarily made possible through an exclusive agreement with Alvotech, a world-class biopharmaceutical company entirely specialized in developing and manufacturing high-quality biosimilar medicines. Aligning Alvotech's fully integrated model with BIOJAMP™'s commercial infrastructure and expertise will give Canadian patients access to a wide range of biosimilar products while significantly reducing healthcare system costs. This agreement and JAMP Pharma Group's consistent rapidly paced launches are strategic imperatives that support the Group's ambitions to become Canada's largest pharmaceutical company.

Quotes

« At JAMP Pharma Group, we're always listening to the needs of Canadians and healthcare professionals, as Canadians ourselves. The launch of Simlandi™, the first product to be commercialized by BIOJAMP™, is a novel formulation of adalimumab, never launched by a Canadian company despite the fact that this formulation is established as a standard of care in the United States and Europe. We'd be hard pressed to find a better example to clearly illustrate our commitment to meeting the specific needs of patients and healthcare professionals.

– **Bruno Mäder**, President and COO, JAMP Pharma Group

« BIOJAMPTM aims to simplify the experience of patients by reducing barriers and facilitating the transition process. As an example, we are proud to have developed an auto-injector designed for patients with dexterity challenges, who will now be able to operate the Simlandi™ auto-injector more confidently. We will also commercialize a new and unique-to-Canada 80 mg/0.8 mL, format which will reduce the number of injections for certain types of patients.

– **Thierry Lavoie**, Director of Marketing & Business Development, BIOJAMP™

About JAMP Pharma Group

The Jamp Pharma Group is a Canadian-owned company headquartered in the Montreal area. Having experienced remarkable growth over the past 10 years, the JAMP Pharma Group is active in all segments of the pharmaceutical market thanks to a portfolio of close to 300 molecules. The Group is among the industry leaders in terms of annual prescription volume(1). With nearly 40 new products approved by Health Canada in the past year, the JAMP Pharma Group is the Canadian leader in product launches(2), broadening the new treatment options available in Canada, including many specialty drugs. The Group also has a Wampole—Laboratoire Suisse Division with more than 180 over-the-counter products including a wide range of vitamins, supplements, and natural products, as well as prescription and branded products from its subsidiary Orimed Pharma.

Follow us on LinkedIn

For more information

Sophie Jacques
Director of Communications, Events and Professional Services
Cell: 514-260-7105 sjacques@jampharma.com

[1] Pharmaceutical manufacturers with the highest reported prescription volume in Canada from August 2016 to August 2021. Based in part on data obtained under licence from IQVIA Solutions Canada Inc. on the following information service: CompuScript, August 2016 to August 2021. All rights reserved. This statement is not necessarily that of IQVIA Solutions Canada Inc. or any of its affiliates or subsidiaries.

[2] Number of Notices of Compliance, Health Canada, from April 1, 2020, to March 31, 2021. (Public information available on the Health Canada website.)

L'article BIOJAMP: A Range of Biosimilars for a Seamless Approach est apparu en premier sur JAMP Pharma.

Exhibit “J30”

This is Exhibit “J30” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

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A Commissioner for Taking Affidavits, etc.

Arash Rouhi

Press Release

JAMP Pharma Launches SIMLANDI, a NEW High-Concentration, Low Volume, Citrate-Free formulation, Biosimilar to Humira, in Canada

PUBLISHED: APRIL 14, 2022

Ref: CNW

SIMLANDI™ provides patients access to high-concentration, low volume, citrate-free formulations of adalimumab, in 40 mg/0.4 mL and 80 mg/0.8 mL presentations, not available in Canada before this week

SIMLANDI™ is the first adalimumab biosimilar product launched by a Canadian-based company, JAMP Pharma Group

The creation of BIOJAMP™ Pharma along with the introduction of the JAMPCare™ patient support program are designed to simplify the transition of patients to SIMLANDI™

BOUCHERVILLE, QC, April 13, 2022 /CNW/ - JAMP Pharma Group ("JAMP Pharma"), a Canadian-owned pharmaceutical company headquartered in the Montreal area, announced today the launch of SIMLANDI™, a high-concentration, low-volume, citrate-free, biosimilar to Humira® (adalimumab) developed and manufactured by Alvotech. The biosimilar, with its 100 mg/mL adalimumab in 40 mg/0.4 mL and 80 mg/0.8 mL presentations, is the first biosimilar candidate to be commercialized by BIOJAMP™, a biosimilar division of JAMP Pharma Group.

"We are pleased to be the first Canadian company to offer adult patients in Canada access to a high-concentration, citrate-free form of adalimumab. SIMLANDI will also offer a unique 80 mg/0.8 mL dose that can reduce the number of starting injections by 50% for certain patients. This will be of particular interest to adult patients with conditions such as moderately to severely active ulcerative colitis and Crohn's disease," said Louis Pilon, CEO of JAMP Pharma Group.

"It is with great pride that we announce our first BIOJAMP commercial launch. This is a great milestone for the JAMP Pharma Group, it will help lower cost to the Canadian health care system and most importantly it brings added value to patients who will now have access to this high-concentration biosimilar of Humira®", said Bruno Mader, COO of JAMP Pharma Group.

In January 2022, JAMP Pharma and Alvotech announced Canadian approval of SIMLANDI, a high-concentration biosimilar candidate to Humira® (adalimumab), which was developed under the name AVT02 by Alvotech.

SIMLANDI is a recombinant fully human immunoglobulin G1 (IgG1) kappa monoclonal antibody (mAb) that specifically binds to tumor necrosis factor-α (TNF) and blocks its interaction with the p55 (TNFR1) and p75 (TNFR2) cell surface TNF receptors, thereby neutralizing the effect of TNF in inflammatory conditions.

In February 2022, JAMP Pharma announced the creation of BIOJAMP™ as part of its goal to establish itself as a leader in the Canadian biosimilars market. Both BIOJAMP™ and its JAMPCare™ patient support program are

SIMLANDI.

In Canada, SIMLANDI has been authorized for sale for the following indications: rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, adult ulcerative colitis, adult and adolescent (12 to 17 years of age weighing ≥ 30 kg) hidradenitis suppurativa, plaque psoriasis and adult and pediatric uveitis.

About JAMP Pharma Group

The JAMP Pharma Group is a Canadian-owned company headquartered in the Montreal area. Having experienced remarkable growth over the past 10 years, the JAMP Pharma Group is active in all segments of the pharmaceutical market with a portfolio of close to 300 molecules. The Group is among the industry leaders in terms of annual prescription volume[1] and is the Canadian leader in product launches[2]. The Group also has a Wampole-Laboratoire Suisse Division with more than 180 over-the-counter products.

(1) Pharmaceutical manufacturers with the highest reported prescription volume in Canada from August 2018 to August 2021. Based in part on data obtained under license from IQVIA Solutions Canada Inc. on the following information service: CompuScript, August 2018 to August 2021. All rights reserved. This statement is not necessarily that of IQVIA Solutions Canada Inc. or any of its affiliates or subsidiaries.

(2) Total number of notices of compliance (NOC), Health Canada, from April 1, 2020, to March 31, 2021. (Public information available at https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/notice-compliance.html)

SOURCE JAMP Pharma Group

For further information: JAMP Pharma GROUP, Media Relations, Alexandra Lewicki, M.Sc, Director, Marketing & Communications, 514 238-6520, alewicki@jamppharma.com

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Exhibit “J31”

This is Exhibit “J31” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

Notice of Compliance Information

From Health Canada

New search

Notice of Compliance date :

2023-11-15

Manufacturer :

JAMP PHARMA CORPORATION

Product type:

Biologic

NOC with conditions:

No

Submission type:

New Drug Submission (NDS)

Submission class:

Other

Canadian reference biologic drug:

STELARA

Brand 1 of 1 :

JAMTEKI

Product 1 of 2 :

Drug identification number: 02543044

Dosage form(s): Solution

Route(s) of administration: Subcutaneous

Medicinal ingredient(s):

Ingredient	Strength
USTEKINUMAB	90 MG/ML (calculated as base)

Product 2 of 2 :

Drug identification number: 02543036

Dosage form(s): Solution

Route(s) of administration: Subcutaneous

Medicinal ingredient(s):

Ingredient	Strength
USTEKINUMAB	45 MG/0.5ML (calculated as base)

New search

Application information

- Search tips
- Notice of Compliance terminology
- Frequently asked questions

Related information

- Notice of Compliance listings
- MedEffect Canada
- Adverse Drug Reaction - veterinary drugs
- Drug Product Database

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Date modified: 2022-11-25

Exhibit “J32”

This is Exhibit “J32” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

JAMP Pharma Group announces the commercial launch and product availability for PrJamteki™, the first biosimilar of Stelara® (ustekinumab) in Canada

Français

NEWS PROVIDED BY
JAMP Pharma ➞
Mar 01, 2024, 14:26 ET

- *PrJamteki™ was the first ustekinumab biosimilar to receive marketing authorization in Canada[1].*
- *PrJamteki™ is the second biosimilar developed under the exclusive partnership in Canada between JAMP Pharma Group and Alvotech.*
- *This second biosimilar launch in 2 years is a very important step, enabling BioJAMP™ to reinforce its leadership role in the Canadian biopharmaceutical industry.*

BOUCHERVILLE, QC, March 1, 2024 /CNW/ - JAMP Pharma Group ("**JAMP Pharma**"), a Canadian-owned pharmaceutical organization headquartered in the Greater Montreal area, announced today the commercial launch and product availablity for Jamteki™, a biosimilar of Stelara® (ustekinumab).

The currently approved presentations of Jamteki ™ are the 45mg/0.5mL pre-filled syringe with passive safety device for subcutaneous injection (PFS-SD) and the 90mg/mL PFS-SD. This is the second JAMP Pharma biosimilar to receive marketing authorization. In 2022, JAMP launched Simlandi®, a biosimilar of Humira® (adalimumab).

"*JAMP Pharma Group entered the biosimilars market by creating BioJAMP™ and introducing its very first biosimilar, Simlandi®. This important step in our portfolio advancement showcases our commitment to evolve in this market,*" said Louis Pilon, President and CEO at JAMP Pharma Group. "*It represents an opportunity for significant savings for provinces and insurers. BioJAMP™ aims to simplify the patient journey by reducing barriers and facilitating the transition process, notably with JAMP Care™, our patient support program, which offers a seamless experience for patients and healthcare professionals.*"

In February 2022, JAMP Pharma announced the creation of BioJAMP™ as part of its goal to establish itself as a leader in the Canadian biosimilars industry. BioJAMP™ and the JAMP Care™ patient support program are both designed to simplify the transition process to biosimilar medicines for patients and caregivers.»

Use of trademarks

Humira® is a registered trademark of AbbVie Biotechnology Ltd. Stelara® is a registered trademark of Johnson & Johnson.

About JAMP Pharma Group

JAMP Pharma Group is a Canadian organization headquartered in Boucherville, in the greater Montreal area. Having experienced exceptional growth over the past 10 years, JAMP Pharma Group is present in all segments of the pharmaceutical market with a portfolio of over 325 molecules and is one of the industry leaders in terms of annual prescription volume[2]. With over 130 new products authorized for sale by Health Canada in the past three years, JAMP Pharma Group is the Canadian leader in product launches[3], thereby constantly providing new and improved treatment options for Canadians, including many specialty drugs. The addition of a new local manufacturing site supports JAMP Pharma Group's vision of becoming the largest Canadian-owned pharmaceutical company.

In addition to its generic division, JAMP Pharma Group has several divisions such as Orimed Pharma®, BioJAMP™, Wampole®, Laboratoire Suisse, and Cosmetic Import, also offering prescription and branded products, biosimilars, and 180 over-the-counter products, as well as a varied range of vitamins, supplements, and natural health products. The JAMP Care™ patient support program is designed to assist both patients, and healthcare professionals in the use of specialty drugs and biosimilars offered by JAMP Pharma Group.

Website: JAMP Pharma Group (**https://www.jamppharma.ca/en/**)

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[1] According to the Notice of Compliance database on Health Canada's website.

[2] Based on internal data.

[3] Based on internal data.

SOURCE JAMP Pharma

JAMP Pharma Group, Alexandra Lewicki, M.Sc., Marketing & Communication Director, alewicki@jamppharma.com

Exhibit “J33”

This is Exhibit “J33” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

Biologics: Targets and Therapy

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REVIEW

Remicade® (infliximab): 20 years of contributions to science and medicine

This article was published in the following Dove Press journal:
Biologics: Targets and Therapy

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Anja Geldhof[1]
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Abstract: On August 24, 1998, Remicade® (infliximab), the first tumor necrosis factor-α (TNF) inhibitor, received its initial marketing approval from the US Food and Drug Administration for the treatment of Crohn's disease. Subsequently, Remicade was approved in another five adult and two pediatric indications both in the USA and across the globe. In the 20 years since this first approval, Remicade has made several important contributions to the advancement of science and medicine: 1) clinical trials with Remicade established the proof of concept that targeted therapy can be effective in immune-mediated inflammatory diseases; 2) as the first monoclonal antibody approved for use in a chronic condition, Remicade helped in identifying methods of administering large, foreign proteins repeatedly while limiting the body's immune response to them; 3) the need to establish Remicade's safety profile required developing new methods and setting new standards for postmarketing safety studies, specifically in the real-world setting, in terms of approach, size, and duration of follow-up; 4) the study of Remicade has improved our understanding of TNF's role in the immune system, as well as our understanding of the pathophysiology of a range of diseases characterized by chronic inflammation; and 5) Remicade and other TNF inhibitors have transformed treatment practices in these chronic inflammatory diseases: remission has become a realistic goal of therapy and long-term disability resulting from structural damage can be prevented. This paper reviews how, over the course of its development and 20 years of use in clinical practice, Remicade was able to make these contributions.

Keywords: Remicade, infliximab, monoclonal antibody, immune-mediated inflammatory disease, TNF inhibition, Crohn's disease, rheumatoid arthritis

Plain language summary

Prompted by the recent twentieth anniversary of the first approval of Remicade® (infliximab; Janssen Biotech, Inc., Horsham, PA, USA), a first-in-class monoclonal antibody tumor necrosis factor α (TNF) inhibitor, the authors have written this review in order to recognize the drug's contributions to science and medicine. Remicade's first therapeutic indication, Crohn's disease, was followed by another five indications, all of which are immune-mediated inflammatory diseases (IMIDs). A common factor in these diseases is increased expression of the cytokine TNF, which drives the underlying inflammation causing them. Through inhibition of TNF, this chronic inflammation can be suppressed and the disease successfully treated. In the course of Remicade's development and its use in clinical practice, several important firsts were achieved. Remicade established the proof of concept that targeted therapy (ie, blockade of a single inflammatory mediator) can be a successful treatment approach for IMIDs. It demonstrated

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that there is a role for monoclonal antibodies in the treatment of chronic diseases. The need to establish its safety profile led to the development of new methods and standards for post-marketing commitment studies. Studies in current indications, in indications where it was not efficacious, and of its safety profile have taught us much about the immune system and greatly improved our understanding of the pathophysiology of several IMIDs. Lastly, the availability of Remicade and other TNF inhibitors has transformed the practice of medicine in these diseases, where more ambitious goals of therapy are now possible. Each of these advancements has helped to bring about a revolution in medicine that is still ongoing today.

Introduction

On August 24, 1998, the monoclonal antibody (mAb) Remicade® (infliximab; Janssen Biotech, Horsham, PA, USA) received approval from the US Food and Drug Administration (FDA) for the treatment of Crohn's disease (CD), thereby becoming the first tumor necrosis factor-α (TNF) inhibitor available for use in clinical practice. In the ensuing years, this initial indication was followed by approval in another five adult and two pediatric chronic inflammatory conditions both in the USA[1] and around the globe (Figure 1). Beyond

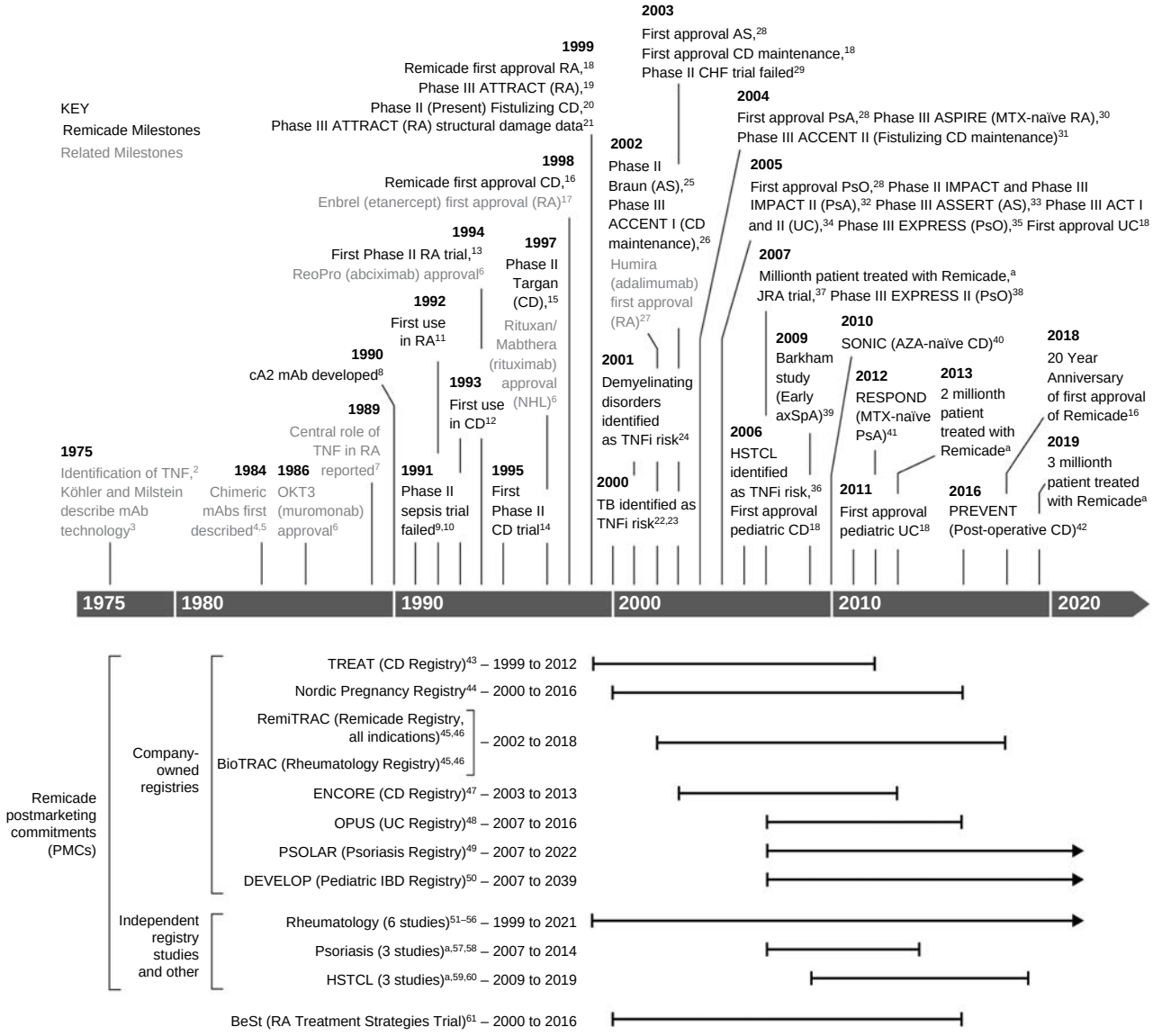


Figure 1 Key milestones in the development of Remicade.
Note: [a]Janssen, data on file.
Abbreviations: AS, ankylosing spondylitis; axSpA, axial spondyloarthritis; CD, Crohn's disease; CHF, congestive heart failure; HSTCL, hepatosplenic T-cell lymphoma; IBD, inflammatory bowel disease; JRA, juvenile rheumatoid arthritis; MTX, methotrexate; mAb, monoclonal antibody; NHL, non-Hodgkin's lymphoma; PBO, placebo; PsA, psoriatic arthritis; PsO, psoriasis; RA, rheumatoid arthritis; TB, tuberculosis; TNF, tumor necrosis factor; TNFi, TNF inhibition; UC, ulcerative colitis.

offering a welcome new treatment option for patients, it has contributed to several important advances in science and medicine, which will be the focus of this review.

Remicade's approval represented the culmination of two independent sets of research that began in 1975 when both TNF and hybridoma technology, the method for producing monoclonal antibodies, were first described in the literature.[2,3] Subsequent research on TNF identified its role not only in host response, but also in the pathophysiology of a number of immune-mediated inflammatory diseases (IMIDs), such as CD and rheumatoid arthritis (RA). This observation led to the question of whether blockade of TNF could serve as a treatment for these diseases. At the time, conventional treatments for IMIDs, such as immunosuppressants and corticosteroids, treated symptoms of disease, but not the underlying pathophysiology, and were associated with both limited efficacy and side effects.

However, the feasibility of targeted therapy in this setting was unknown. In a complex network of inflammatory mediators with pleiotropic, sometimes overlapping functions, could inhibiting a single cytokine such as TNF suppress inflammation in a clinically meaningful way? How could such a cytokine be inhibited? Because of their high ligand specificity and affinity, mAbs were obvious candidates, but had not met expectations as therapeutics. Could they achieve their potential? These questions were first answered in 1992 when Remicade, then known simply as cA2, was used to confirm the hypothesis that the inflammation driving RA is mediated by TNF and can be suppressed by its blockade.[11]

The development of Remicade up to that point and since then has been a classic example of how an improvement in understanding of pathophysiology can lead to a therapeutic breakthrough, which in turn leads to a deeper understanding of pathophysiology. Each new learning led to another question to be answered, which has resulted in the development of a significant body of scientific and medical research: a literature search for the word "infliximab" today reveals more than 13,000 publications, a number that approaches 50,000 when including other TNF inhibitors such as etanercept (Enbrel®; Immunex Corporation, Thousand Oaks, CA, USA) and adalimumab (Humira®; AbbVie, North Chicago, IL, USA). Many of the learnings are now common knowledge, but in 1992 were hypotheses. It is only with hindsight that we can put them into perspective (Figure 1).

This article reviews these learnings as they developed over time: the discovery of TNF; Remicade's clinical development, primarily in RA and CD, which are its earliest and most prominent indications; its evaluation in other diseases; the establishment of its safety profile; and its role in changing clinical practice. It is important to note that the participants in this scientific journey were not only Janssen and its commercial partners and local distributors (Merck, Sharp and Dohme [MSD] in Europe, Turkey, and Russia, and Mitsubishi Tanabe Pharmaceutical Corporation in Japan, Taiwan, and Indonesia), butalso a large number of independent researchers. Their collective work demonstrates that the learnings from a drug do not stop at the end of its formal development, but can continue for years afterward.

With the recent 20-year anniversary of Remicade's first approval in 1998, it is fitting to reflect on its contributions to science and medicine.

TNF is a key driver of inflammation

In 1975, Carswell et al described an experiment in which tumor regression was observed in mice injected with endotoxin from the pathogenic bacterium *Serratia marcescens*. They isolated a substance in the serum of these mice that led to this regression and named it "tumor necrosis factor" (TNF).[2] In 1985, Beutler et al studied a factor which caused cachexia, a wasting syndrome, by acting on lipoprotein lipase and other metabolic pathways.[62] This factor, which they called "cachectin", was later found to be TNF. Simultaneously, Dayer et al, while searching for a factor that mediated shock, isolated a substance from cells of monocytic lineage which was also found to be TNF.[63]

These three independent discoveries of TNF in separate fields of research display vividly the central and complex role that it plays in the immune system. It is a key driver and regulator of the body's inflammatory response[64] and is involved in immune surveillance and homeostasis.[65,66]

TNF is not usually detectable in healthy populations, but is increased in both serum and tissue under inflammatory and infectious conditions, and after tissue injury.[67] It is one of the first cytokines to appear in the blood after injury or stress and does so within minutes,[65] secreted primarily by macrophages and monocytes, but also by other immune cells, eg, neutrophils, T cells, and natural killer (NK) cells, as well as non-immune cells.[67] The concentration of TNF in serum correlates with the severity of infection. Other pro-inflammatory cytokines, such as interleukin (IL)-6 and IL-1, appear later and are at least in part dependent on prior release of TNF.[65] The 24-kDa membrane-bound form of TNF (tmTNF) is cleaved by a metalloproteinase enzyme, TNF-α-converting enzyme (TACE), to release a 17-kDa soluble form (sTNF). Both forms are biologically active.[67] They mediate their effects

through binding to either of two receptors, TNFR1 (p55) or TNFR2 (p75). TNFR1 is expressed on most cell types and is generally activated by sTNF, while TNFR2 is expressed primarily on immune, specifically T-regulatory, and endothelial cells and is preferentially activated by tmTNF.[65,68,69] TNFR1 seems to be primarily involved in the inflammatory response and mediating apoptosis while TNFR2 appears to be important for tissue repair, immune modulation, and homeostasis.[65,69]

TNF exerts its pleiotropic effects via a number of mechanisms, such as macrophage activation, differentiation and phagosome formation,[64] activation of neutrophils and NK cells, and promotion of cell adhesion, apoptosis, and cellular proliferation.[70] These mechanisms contribute to the body's common manifestations of inflammation, eg, fever, vasodilation/edema, sleep disruption, regulation of coagulation and tissue degeneration, as well as to the manifestations of downregulation of the inflammatory response, eg, promotion of immune modulation, tissue regeneration, formation and maintenance of granulomas, immune surveillance, and homeostasis.[66,67] TNF's functions are seemingly contradictory: it plays a role in both tissue degeneration and tissue repair, cellular proliferation and apoptosis, and has anti-tumor and tumor pro-growth properties.[65] These functions are, in fact, complementary. Succinctly stated, in a time- and context-dependent manner, TNF drives a rapid and vigorous inflammatory response triggered by infection or injury (primarily via sTNF/TNFR1), and also functions to limit the extent and duration of this inflammatory response when the trigger has been resolved (primarily via tmTNF/TNFR2).[69] These dual roles will, in part, explain later observations in patients treated with TNF inhibitors.

Studies in the 1980s and 1990s showed that levels of TNF were increased in a number of pathophysiological conditions. In patients with sepsis, elevated levels of TNF appeared to correlate with mortality. Moreover, peak elevation in monocyte TNF expression correlated with septic episodes.[71] Overexpression was also observed across seemingly unrelated conditions, often in the absence of infection. Elevated levels were present in the mucosa and stools of patients with inflammatory bowel disease (IBD), and mucosal cells expressing TNF had been detected in patients with CD.[72] Pro-inflammatory cytokines such as TNF and IL-1 were detected in the synovial fluid of patients with RA, and TNF surface receptors were found to be upregulated in active RA tissues.[73]

These findings led to the question: if TNF is a driver of inflammation and these conditions are primarily diseases of chronic inflammation, could blockade of TNF be a successful treatment strategy in these conditions?

Two key proofs of concept are established with Remicade

Would blocking a single cytokine be effective in these complex immune-mediated diseases? How could such a cytokine be blocked?

The advent of monoclonal antibodies

Traditional development of pharmaceuticals in the past had been empirical, where potential agents were not targeted to a specific mediator of disease and their mechanism of action was not precisely understood.[65] In IMIDs, while conventional drugs such as steroids and immunosuppressants are beneficial, they have broad unspecific effects and are characterized by limited efficacy in itself or efficacy constrained by unacceptable toxicity. A deeper understanding of the pathophysiology of disease would have offered the possibility of testing a new approach to pharmaceutical development, where targeting specific mediators of disease provides benefit with fewer toxicities.

In the 1980s and 1990s, the most readily available approach to targeted therapy was through the use of mAbs, the largest class of therapeutic proteins derived from recombinant DNA techniques, known as biologics. However, 10–20 years after the publication of Köhler and Milstein first describing them,[3] they had not met expectations as therapeutics.[74] The mAbs available at that time were fully murine and were associated with a number of limitations. As foreign proteins, they were immunogenic and associated with high anti-drug antibody (ADA) rates, which resulted in both safety implications and a negative effect on pharmacokinetics (PK). In addition, murine mAbs were poor at inducing antibody effector function in humans. As late as 1993, only one mAb had received regulatory approval for clinical use, Janssen's muromonab, also known as OKT3, for short-term use in transplant rejection with concomitant immunosuppression, a setting in which ADA risk was limited.[6]

Yet, advances in mAb technology were coming to fruition at that time. Under the assumption that replacing the murine content of mAbs with human equivalents would both reduce the risk of ADA and improve effector function, researchers used new molecular biology

techniques to develop chimeric mAbs, which are produced from genes whose DNA sequences are approximately 75% human, where only the DNA sequence for the variable domain within the antigen-binding fragment (Fab) remains murine.[4–6] The assumption proved correct and in 1994, Janssen's abciximab (ReoPro®; Janssen Biotech, Horsham, PA, USA), a Fab fragment, became the first chimeric mAb to receive regulatory approval, for the prevention of platelet-mediated thrombosis during angioplasty.[6] The first whole chimeric mAb to receive regulatory approval was rituximab (Rituxan®; Genentech, South San Francisco, CA, USA; MabThera®; Roche Registration GmbH, Grenzach-Wyhlen Germany) in 1997 for use in lymphoma. Both were approved for single or short-term use, leaving questions about long-term use of mAbs unanswered.[6]

In the early 1990s, Janssen's Immunology unit (then known as Centocor) developed the chimeric anti-TNF mAb, cA2.[8] Based on data showing that TNF blockade prevented septic shock in animals given a lethal dose of endotoxin,[71,75] Janssen selected sepsis as the initial focus for the clinical development of cA2. Sepsis was an obvious candidate for targeted therapy with mAbs because of its high rate of mortality, which increased the acceptability of possible adverse drug reactions (ADRs), and the need for short-term therapy, limiting the possibility of immunogenicity as a concern. However, in the preliminary clinical study, there were no differences in patterns of cytokine activation or mortality with cA2 relative to placebo,[9,10] and the program was discontinued. Most researchers in the field concluded that TNF inhibition failed in sepsis because blocking a single cytokine could not work in diseases characterized by a complex mixture of redundant inflammatory mediators.[76] Based on these results, the expectations for targeted therapy in other inflammatory conditions were low.

Proof of concept in RA and CD

However, in parallel to the research in sepsis, Ravinder (Tiny) Maini and Marc Feldmann at the Kennedy Institute in London had completed research suggesting that blockade of a single cytokine could reap therapeutic benefit in an IMID. When evaluating a batch of synovium samples from patients with active RA, they observed elevated levels of pro-inflammatory cytokines in all of them.[65] This was striking, since such cytokines are usually produced for short periods only (hours to 2 days), and suggested that in RA their production was continuous. The key breakthrough came in 1989, when Brennan et al suggested for the first time that TNF may be a pivotal cytokine in the pathophysiology of RA.[7] Their study, in which several pro-inflammatory cytokines (TNF, IL-1, IL-6, granulocyte-macrophage colony-stimulating factor) were neutralized one by one, revealed that blocking TNF in synovial culture led to the inhibition of the others. This was consistent with the observation that TNF is one of the first cytokines to appear after injury or stress and led to the concept of a pro-inflammatory cascade at work in RA, with TNF at its beginning.

Based on these observations, in 1993, Elliott et al of the same group in London conducted a proof-of-concept study in humans, where 20 patients with severe RA were treated with either two 10 mg/kg or four 5 mg/kg infusions of cA2, given 2 weeks and 4 days apart, respectively.[11] Positive clinical improvements, as measured by swollen and tender joint counts and pain, and biochemical responses, as measured by reduced levels of inflammatory mediators, were observed in all patients, providing the first evidence that TNF blockade reduced inflammation and improved symptoms in RA. The effect faded after a few weeks.

Elliott et al proceeded to conduct a 73-patient randomized, placebo-controlled trial of a single infusion of two doses (1 mg/kg and 10 mg/kg) of cA2 in RA.[13] Both doses proved highly effective (combined dose groups with a 61% clinical response [Paulus 20%] vs 8% for placebo at week 4, $P<0.001$), but the maximal improvement and its duration were dose dependent. The rate of adverse events was similar across the cA2 arms and the placebo group. As found in the first study, the benefits disappeared within a few weeks. In a first exploration of retreatment, several initial responders from the first study were given cA2 for up to three additional cycles administered upon relapse.[77] The patients regained their responses, but they were again temporary, and the time to relapse generally shortened with each successive cycle, raising concerns about ADAs developing over time (four of seven patients were ADA positive).

Gastroenterologists, who had observed increased levels of TNF in patients with CD, also explored its blockade as a possible treatment. In 1993, the group of Sander van Deventer at the Academic Medical Centre in Amsterdam reported on a female patient, age 12 years, with CD who was non-responsive to conventional therapies and received cA2 as a compassionate-use treatment.[12] She received two infusions of cA2 10 mg/kg 2 weeks apart and responded immediately after the first dose. Clinical and endoscopic remission was observed, but, as with RA, this was

temporary, with symptoms returning after 3 months. Van Dullemen et al from the same group in Amsterdam then conducted an open-label proof-of-concept study of a single dose of cA2 (10 mg/kg or 20 mg/kg) in 10 patients with steroid-non-responsive CD.[14] Within 4 weeks, eight patients showed normalization of their Crohn's Disease Activity Index (CDAI) scores and near-complete healing of mucosal ulcerations, images of which merited display on the cover of the journal in which the data were published (Figure 2). The average duration of response after a single infusion was 4 months, and cA2 was well tolerated among all patients.

This small, uncontrolled study supported the hypothesis that TNF was a major contributor to the pathophysiology of CD and paved the way for Targan et al to conduct a 12-week multicenter, double-blind, placebo-controlled trial in 108 patients with treatment-resistant CD.[15] In 1997, they reported that 65% of patients receiving a single dose of cA2 (5, 10, or 20 mg/kg) had a clinical response by week 4 compared with 17% of placebo-treated patients ($P<0.001$). The rates of adverse events were similar among treatment groups. Rutgeerts et al explored retreatment in this trial, where patients with an initial response to cA2 were given an additional four open-label infusions of 10 mg/kg every 8 weeks (q8w) beginning 12 weeks after the initial infusion.[78] Similarly to the previous experience in RA, they found that the initial benefit of cA2 could be regained and, owing to the regular q8w retreatment schedule rather than waiting for relapse, it was also sustained for the duration of the study. cA2 was well tolerated and the rate of immunogenicity was low (10%).

These studies showed that blocking one cytokine, TNF, could have profound, if temporary, clinical benefits in both RA and CD. The benefit observed in both conditions was profound and rapid. Moreover, the lack of significant safety issues despite these benefits was encouraging. While the cause of the TNF-driven inflammation was still unknown, and its blockade was not a cure, a possible method to suppress it had been found, suggesting potential for clinical use. However, for this therapeutic strategy to work, it was clear that sustained TNF blockade would be necessary. Initial experience with retreatment was positive, but would it work in the long term?

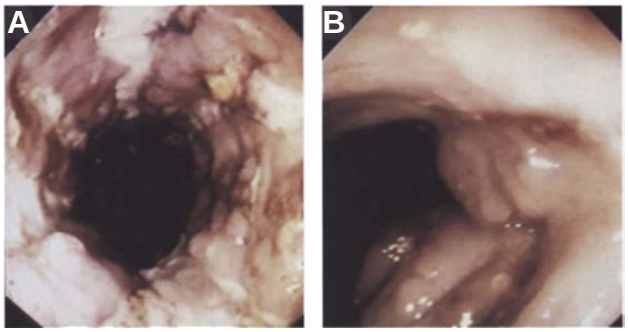


Figure 2 Healing of colonic ulcerations in a Crohn's disease patient **(A)** before treatment and **(B)** 4 weeks after a single infusion of Remicade 10 mg/kg.
Notes: *Gastroenterology* by American Gastroenterological Association. Reproduced with permission of W.B./Saunders Co., from Treatment of Crohn's disease with anti-tumor necrosis factor chimeric monoclonal antibody (cA2). van Dulleman HM, van Deventer SJ, Hommes DW, et al. *Gastroenterology*, volume 109, issue 1, 1995.[14]

How can dose and concomitant medications influence the rate of efficacy and immunogenicity? Phase II trial in RA

The possibility of long-term TNF blockade with cA2 as a treatment strategy for chronic inflammatory diseases raised three fundamental questions: 1) Could mAbs be administered repeatedly as long-term therapy? Immunogenicity was the primary concern as it could be associated with ADRs (eg, allergic or hypersensitivity reactions) or limits on efficacy (neutralization and clearance of the mAb); 2) Would long-term TNF blockade succeed, or would the disease circumvent this blockade and restore the chronic inflammation via another pathway? 3) Would long-term TNF blockade be associated with an unacceptable safety risk? Given the function of TNF, infections and malignancies were of particular concern. Clinical development in RA and CD proceeded, starting with the first of these questions, immunogenicity.

The relationship between dose, PK, efficacy, safety, and immunogenicity of cA2 was first studied in a phase II, double-blind, placebo-controlled RA trial, conducted in 1995–1996, evaluating cA2 alone or in combination with methotrexate (MTX), an immunomodulator and the gold-standard conventional synthetic disease-modifying antirheumatic drug (csDMARD) in RA.[79] In the trial, 101 patients with clinically active disease despite receiving MTX were randomized to receive cA2 at 1, 3, or 10 mg/kg, with or without MTX, or placebo plus MTX, at weeks 0, 2, 6, 10, and 14, and were followed through week 26. The rationale for an induction regimen at weeks 0 and 2 followed by 4-week intervals thereafter was two-fold: 1) that high-dose induction would suppress inflammation rapidly and profoundly, and 2) that early, high systemic exposure of the immune system to an antigen, in this case cA2, could result in increased tolerance, thereby reducing immunogenicity.

Approximately 60% of patients in all dose groups had responded by week 2, but the degree and duration of response varied by dose and MTX use. Patients receiving cA2 1 mg/kg without MTX experienced a rapid decline in response, while patients receiving 3 or 10 mg/kg without MTX showed sustained responses. In all three dose groups, the response was longer in duration when combined with MTX. Serum cA2 concentrations were stable in patients receiving 3 or 10 mg/kg alone or in combination, though consistently higher in those receiving MTX. In contrast, patients receiving 1 mg/kg without MTX showed an elimination of cA2 in the serum by the end of the 4 weeks, whereas stable, albeit low, levels were maintained in patients receiving MTX. On the important question of immunogenicity, there were two key observations: rates of ADA were lower for all doses when combined with MTX and were inversely related to cA2 dose administered (Figure 3).

These findings demonstrated not only that retreatment with TNF blockade could be effective in sustaining the initial treatment benefit, but also how immunogenicity of mAbs could be reduced: a high-dose induction regimen was associated with tolerance to cA2, levels of immunogenicity were inversely proportional to dose, and co-administration with MTX both reduced immunogenicity and improved the PK of cA2.

First approval of Remicade: CD

Despite the initial proof-of-concept study of targeted TNF blockade with cA2 being conducted in RA, CD was selected as the first indication for commercial development because it was believed to have a more expedited path to regulatory approval owing to its severity in patients not responding to conventional therapies.

Having completed the Targan study in luminal CD,[15] the next trial was conducted in fistulizing CD, a debilitating complication observed in as many as 20% of CD patients where no therapy had been shown to be effective. Present et al evaluated the efficacy of cA2 to close draining fistulas in 94 patients randomized to receive an induction dose at 0, 2, and 6 weeks of placebo, or 5 or 10 mg/kg of cA2, and then followed through week 18.[20] The primary endpoint was closure of ≥50% of fistulas for at least two consecutive visits 4 weeks apart. The response rate was 26% in placebo patients compared with 68% (P=0.002) and 56% (P=0.02) in the 5 and 10 mg/kg groups, respectively. The safety results were consistent with those observed in the initial studies.

The Targan and Present studies thus demonstrated the safe and effective use of cA2 in treatment-resistant, moderate-to-severe CD, and were the basis for its first regulatory application. The FDA granted accelerated review and approved cA2, renamed Remicade (infliximab), on August 24, 1998.[16] Approval by the European Medicines Agency (EMA) in Europe was granted a year later, followed by approvals in Brazil (2000), Canada (2001), Japan (2002), and over 100 other countries (Janssen, data on file).

Importantly, the FDA and other health authorities granted approval for single treatment with Remicade, but recognized the need for maintenance treatment in CD and required that Janssen study it in the phase III setting as a condition of approval.

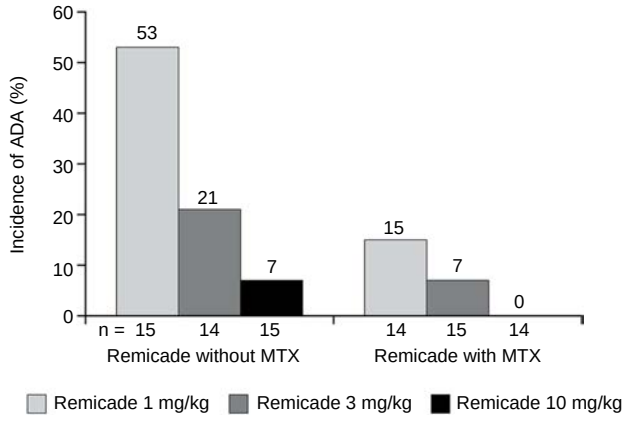


Figure 3 Incidence of ADAs in a phase II trial of MTX-refractory RA patients, by Remicade dose and use of concomitant MTX. ADAs were measured by a drug-sensitive immunoassay.
Note: Data from Maini et al.[79]
Abbreviations: ADA, anti-drug antibody; MTX, methotrexate; RA, rheumatoid arthritis.

Can long-term blockade of TNF lead to sustained suppression of inflammation? Phase III trials in RA and CD

Maintenance treatment was first studied in the phase III ATTRACT trial, which evaluated Remicade over a 2-year period in moderate-to-severe RA despite treatment with MTX.[19] Patients, all of whom remained on stable doses of MTX, were treated with an induction regimen (infusions at weeks 0, 2, and 6) of either placebo or Remicade 3 or 10 mg/kg, followed by infusions of the same dose administered every 4 weeks (q4w) or q8w thereafter (with placebo infusions as needed to maintain the blind). The clinical effects of all four Remicade groups were superior to placebo and similar to each other at the primary endpoint, the proportion of patients who achieved ≥20% improvement in the

American College of Rheumatology response criteria (ACR20) at 6 months (50.0% in the 3 mg/kg q8w group [standard approved dose] vs 20.0% in the placebo group, $P<0.001$), and were sustained through the 2-year duration of the trial with a mild dose response.[80] This dose response, combined with another trial evaluating dose escalation for Remicade in RA, START,[81] led to the approval of dose increase above 3 mg/kg in RA for lack of initial response or later loss of response.

In CD, maintenance treatment with Remicade was studied in the phase III ACCENT I and II trials for luminal and fistulizing disease, respectively.[26,31] Both trials had a randomized withdrawal design, where all patients were initially treated with Remicade, after which responders were randomized either to Remicade maintenance therapy (5 or 10 mg/kg in ACCENT I or 5 mg/kg in ACCENT II) or placebo maintenance q8w for 1 year. Patients who lost response to treatment crossed over to a dose of Remicade 5 mg/kg higher than their randomized dose. In ACCENT I, at crossover, the dose was administered upon symptom return, allowing the evaluation of episodic use of Remicade. In ACCENT II, the regular q8w maintenance schedule was continued after crossover. Both studies met their primary endpoints, which were clinical remission and time to loss of response at week 30 in ACCENT I and median time to loss of response (≥50 reduction in number of draining fistulas) in ACCENT II. In both studies, the initial Remicade induction response waned in patients randomized to placebo maintenance, while the benefits were largely sustained in patients randomized to continue Remicade (with a dose response in ACCENT I). Moreover, dose escalation resulted in regaining response in patients who lost their initial response.[82] Episodic retreatment with Remicade in ACCENT I revealed important lessons. While response was regained, outcomes were generally worse and led to higher levels of ADA than in patients who maintained a regular q8w maintenance schedule.[83] In both ACCENT studies (as in ATTRACT), ADA development was associated with an increased risk of infusion reactions and subsequent loss of response.[26] These observations, confirmed independently,[84] provided support to the then novel, now accepted, hypothesis of an important dynamic of immunogenicity and serum drug levels: not only do ADAs lead to low serum levels of drug, but low serum levels lead to increased ADAs.[85] It is now well understood that maintaining target levels of the drug is important to minimize the development of ADAs.

Thus, the phase II/III program had answered all three initial questions about long-term TNF blockade with Remicade: 1) mAbs could be administered repeatedly as maintenance therapy, and several strategies were identified to reduce the risk of ADA; 2) sustained TNF blockade could result in long-term suppression of disease; 3) to the degree that the safety profile of a drug could be assessed with fewer than 2,000 patients treated for ≤2 years, and considering the efficacy observed, the overall benefit–risk profile was considered acceptable (see "Establishing the safety profile of Remicade", later in this review). On the basis of the results of the ATTRACT and ACCENT I/II trials, Remicade was approved as induction and maintenance therapy for RA in 1999 and as maintenance therapy for CD in 2003.

Is TNF blockade disease-modifying?

At the time of the initial approvals in CD and RA, it was not known whether TNF blockade would be disease-modifying and thereby inhibit the progressive, irreversible structural damage caused by these diseases. This question was first answered in RA, where joint destruction is a hallmark of the disease and a predictor of poor functional outcome and disability. The ATTRACT study was the first to show that progression of joint damage could be inhibited with TNF blockade. The mean increase in radiographic progression score at 1 year (using the Sharp/van der Heijde score [SHS]), the co-primary endpoint of the trial, was 0.6 for Remicade across all doses versus 7.0 for the MTX group ($P=0.001$), indicating inhibition of joint damage progression in the majority of Remicade-treated patients, which was unprecedented for any therapy at that time (Figure 4).[21] This effect was sustained through to the end of the 2-year trial.[80] Importantly, the inhibition of progression was observed regardless of whether patients had a clinical response to Remicade or not. Further subgroup analysis showed that inhibition of joint progression occurred in patients with early disease as well as those with established disease, another important finding.

Analogous work was done in the CD clinical trials, where the endpoints studied included the effect of Remicade on mucosal healing and the need for surgery. The original observation by Derkx et al[12] and van Dullemen et al,[14] that Remicade healed the mucosa in CD patients, was confirmed in ACCENT I, where the healing (defined as the absence of mucosal ulcerations in all segments where they had been observed on endoscopy at baseline) was observed as early as the end of induction and was sustained through to the end of the trial: 50% of initial responders receiving q8w maintenance

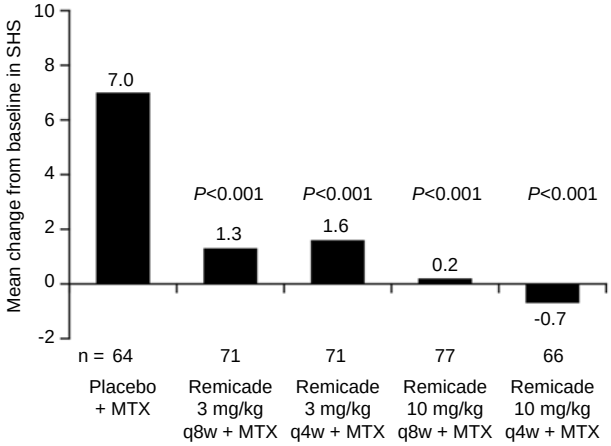


Figure 4 Progression of structural damage in RA at week 54 in the ATTRACT trial.
Notes: Data from Lipsky.[21] *P*-values vs placebo + MTX arm.
Abbreviations: MTX, methotrexate; q4w, every 4 weeks; q8w, every 8 weeks; SHS, Sharp/van der Hejde score.

therapy had complete mucosal healing at 1 year compared with only 7% of initial responders receiving episodic maintenance therapy (*P*=0.007).[82] In addition, in both ACCENT I and ACCENT II, Remicade maintenance therapy was associated with a reduced rate of hospitalizations and surgeries.[89,90]

The inhibition of joint destruction and the mucosal healing effects with Remicade in patients with RA and CD demonstrated that TNF blockade was not just an effective agent on clinical symptoms, but was also disease-modifying, implying an impact on the course of the disease. Research into the exact mechanism of Remicade's effect followed.

What is Remicade's mechanism of action? Analyses from RA and CD clinical trials

It was of interest to determine whether the TNF-dependent inflammatory cascade observed in the initial synovial cell culture experiments77 occurred in vivo. In RA patients receiving Remicade, rapid decline in serum IL-6 levels on the day of treatment confirmed that a TNF-dependent cytokine cascade was indeed occurring.[91] Reductions in other pro-inflammatory mediators and chemokines were also observed.[10] Similarly, C-reactive protein (CRP, a serum marker of systemic inflammation) was observed to decline rapidly after administration of Remicade.[19] Detailed mechanistic studies were performed, and multiple aspects of the disease were found to improve, including immune function, joint function and hematological parameters.[65] Immunohistological studies were conducted to investigate changes in the synovium, where reductions in the expression of adhesion molecules and in cell infiltration were observed, as were reductions in angiogenic factors and angiogenesis.[10] Taylor et al demonstrated in a neutrophil radiolabeling study that the influx of granulocytes was reduced by approximately 50% in the joints within 2 weeks of a single dose of Remicade, indicating that reduced recruitment of these and other leukocytes to the joints is an important aspect of the mechanism of anti-TNF therapy.[92]

Similar mechanistic studies were performed in CD. As with RA, Remicade treatment of CD patients was associated with a rapid reduction of CRP.[15] Histological evaluation of colonic biopsies revealed a reduction in detectable TNF after treatment and provided evidence of reduced infiltration of inflammatory cells and other inflammatory markers at these sites. Analysis of lamina propria mononuclear cells of the intestinal mucosa showed that Remicade treatment caused a reduction in the number of cells capable of expressing TNF and interferon-γ.[93,94]

As an antibody, Remicade functions in two ways: it binds directly to s/tmTNF via its Fab (antigen-binding) region and has a functional Fc (constant) region. Through both, its possible mechanisms of action of TNF inhibitors generally fall into two categories: 1) blockade of TNF-receptor-mediated signaling through neutralization of sTNF and tmTNF; and 2) removal of TNF-expressing cells by induction of Fc- or tmTNF-mediated effector mechanisms, such as antibody-dependent cellular cytotoxicity (ADCC) and apoptosis (Table 1). The relative contribution of these mechanisms to Remicade's efficacy remains uncertain and possibly differs by disease. For example, the role of anti-TNF-induced apoptosis of immune cells in reducing inflammation in RA synovial tissue is unclear,

while evidence exists for such a process in the bowel mucosa in IBD.

Early clinical evidence that the mechanism of action of anti-TNF therapy in CD differs from RA was the observation that etanercept, a p75(TNFR2)-IgG Fc receptor fusion protein, did not show efficacy in CD.[95] Certolizumab (Cimzia®; UCB, Smyrna, GA, USA), a PEGylated IgG Fab fragment, demonstrated efficacy in CD, but seemingly less so than Remicade and adalimumab (both of which are full antibodies), especially in induction of clinical response.[96] A comparison of the differing characteristics of the TNF inhibitors tested in CD provides insight into possible explanations for these differences. All TNF inhibitors bind to both sTNF and tmTNF, but the nature of this binding differs between them. Remicade and adalimumab, as full antibodies, are bivalent; ie, capable of binding two molecules of TNF simultaneously, enabling them to form complexes.[97] Certolizumab and etanercept are both monovalent. Remicade, adalimumab, and certolizumab have high affinity for tmTNF, while etanercept has lower affinity for tmTNF than the antibodies.[94] Remicade and adalimumab have fully functional Fc fragments, while etanercept has lower Fc activity than the full mAbs and certolizumab has no Fc fragment at all.[94] Together, this evidence suggests that in CD, in addition to the neutralization of TNF, one or more effector mechanisms are involved in the resolution of inflammation and mucosal healing (Table 1). Research continues today to determine exactly which mechanisms contribute to the efficacy of these agents.

The results of mechanistic studies of TNF inhibitors combined with their demonstrated efficacy confirmed the role of TNF in the pathogenesis of both RA and CD. The next question was whether TNF inhibition would be an effective therapeutic strategy in other conditions characterized by TNF elevation.

TNF elevation does not always mean TNF mediation

Is TNF blockade effective in diseases beyond CD and RA?

Remicade approval in additional IMIDs

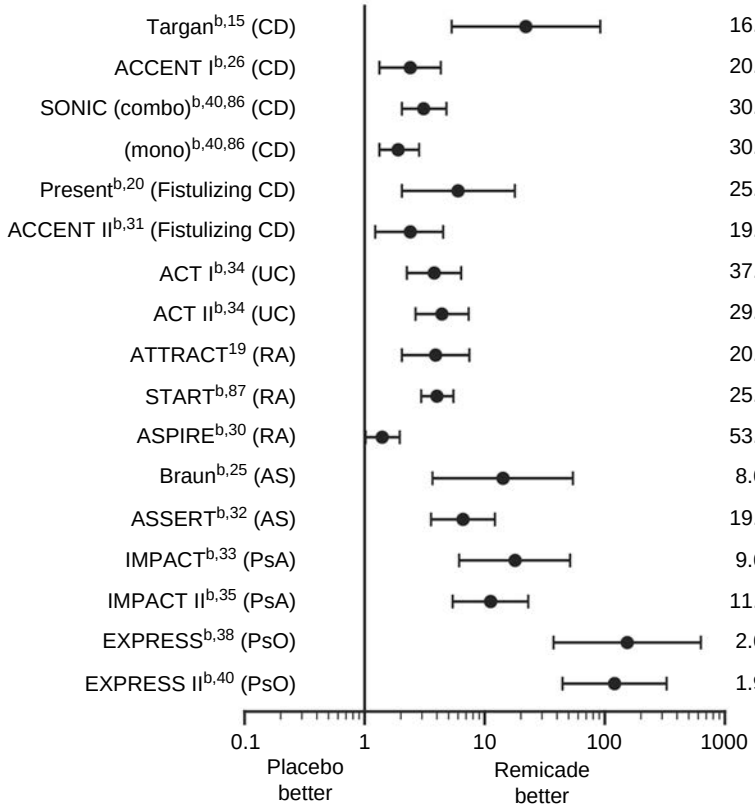
The first evidence of efficacy of TNF blockade beyond RA and CD came from anecdotal reports in clinical practice, in which patients treated with Remicade for CD experienced improvements in extraintestinal manifestations of their disease, specifically ankylosing spondylitis (AS)[98] and psoriasis (PsO).[99] These findings led to clinical development in these indications. Psoriatic arthritis (PsA) and ulcerative colitis (UC) were also studied owing to their related pathogenesis to RA and CD. Health authority approvals for AS, PsA, PsO, and UC were received between 2003 and 2006, followed by pediatric CD (2006) and pediatric UC (2011).[18]

The efficacy of Remicade in each of these conditions was comparable with that seen in RA and CD (Figure 5), and these results brought new insights to the understanding of the pathogenesis of each. For instance, effective treatment of UC,

Table 1 Possible mechanisms of clinical efficacy of TNF blockade with Remicade

Mechanism of action	RA, AS, PsA, and PsO	IBD (CD and UC)
Mechanisms involving the Fab (antigen binding) region		
Blocking TNFR1 and TNFR2 activity via binding and neutralization of s/tm TNF	√	√
Reverse (outside-to-inside) signaling via binding to tmTNF		√
Apoptosis of lamina propria activated T cells		√
Suppression of cytokine secretion		√
Mechanisms involving the Fc (constant) region		
Induction of CDC on tmTNF-expressing target cells (via C1q binding)		√
Induction of ADCC on tmTNF-expressing target cells (via FcγRIIIa binding expressed on effector cells)		√
Induction of regulatory macrophages in mucosal healing		√

Abbreviations: ADCC, antibody-dependent cellular cytotoxicity; AS, ankylosing spondylitis; CD, Crohn's disease; CDC, complement-dependent cytotoxicity; IBD, inflammatory bowel disease; PsA, psoriatic arthritis; PsO, psoriasis; RA, rheumatoid arthritis; sTNF, soluble TNF; tmTNF, transmembrane TNF; UC, ulcerative colitis.



Trial (Indication)	Primary endpoint: Placebo (%)	Remicade[a] (%)	Odds ratio (95% CI)	*P*-value
Targan[b,15] (CD)	16.7	81.5	22.0 (5.2, 93.6)	< 0.001
ACCENT I[b,26] (CD)	20.9	38.9	2.4 (1.3, 4.4)	0.003
SONIC (combo)[b,40,86] (CD)	30.0	56.8	3.1 (2.0, 4.9)	< 0.001
(mono)[b,40,86] (CD)	30.0	44.4	1.9 (1.3, 2.9)	0.006
Present[b,20] (Fistulizing CD)	25.8	67.7	6.0 (2.0, 18.2)	< 0.002
ACCENT II[b,31] (Fistulizing CD)	19.4	36.3	2.4 (1.2, 4.6)	0.009
ACT I[b,34] (UC)	37.2	69.4	3.8 (2.2, 6.5)	< 0.001
ACT II[b,34] (UC)	29.3	64.5	4.4, 2.6, 7.5	< 0.001
ATTRACT[19] (RA)	20.5	50.0	3.9 (2.0, 7.6)	< 0.001
START[b,87] (RA)	25.5	58.0	4.0 (2.9, 5.6)	< 0.001
ASPIRE[b,30] (RA)	53.6	62.4	1.4 (1.04, 2.0)	0.028
Braun[b,25] (AS)	8.6	52.9	14.2 (3.6 ,55.4)	< 0.0001
ASSERT[b,32] (AS)	19.2	61.2	6.6 (3.5, 12.4)	< 0.001
IMPACT[b,33] (PsA)	9.6	65.4	17.9 (6.0, 52.5)	< 0.001
IMPACT II[b,35] (PsA)	11.0	58.0	11.2 (5.3, 23.5)	< 0.001
EXPRESS[b,38] (PsO)	2.6	80.4	153.8 (36.7, 644.6)	< 0.0001
EXPRESS II[b,40] (PsO)	1.9	75.5	120.6 (43.6, 334.2)	< 0.001

Trial	Design[a]	Population	Primary endpoint
Targan[b,15]	Single infusion PBO vs single infusion Remicade 5 mg/kg	CD	Clinical response at Week 4
ACCENT I[b,26]	PBO vs Remicade 5 mg/kg in responders to single infusion of Remicade 5 mg/kg	CD	Clinical remission at Week 30
SONIC (combo)[b,40,86]	PBO + AZA vs Remicade 5 mg/kg + AZA	AZA-naïve CD	Corticosteroid-free remission at Week 26
(mono)[b,40,86]	PBO + AZA vs Remicade 5 mg/kg + PBO capsules[c]		
Present[b,20]	Induction PBO vs induction Remicade 5 mg/kg	Fistulizing CD	50% reduction in number of draining fistula for 2 consecutive visits
ACCENT II[b,31]	PBO vs Remicade 5 mg/kg in Remicade 5 mg/kg induction responders	Fistulizing CD	Absence of draining fistula at Week 54[d]
ACT I[b,34]	PBO vs Remicade 5 mg/kg	UC	Clinical response at Week 8
ACT II[b,34]	PBO vs Remicade 5 mg/kg	UC	Clinical response at Week 8
ATTRACT[19]	PBO + MTX vs Remicade 3 mg/kg + MTX	MTX-IR RA	ACR20 at Week 30
START[b,87]	PBO + MTX vs Remicade 3 mg/kg + MTX	MTX-IR RA	ACR20 at Week 22[d]
ASPIRE[b,30]	PBO + MTX vs Remicade 3 mg/kg + MTX	MTX-naïve RA ≤3 yrs duration	ACR20 at Week 54[d]
Braun[b,25]	PBO vs Remicade 5 mg/kg	AS	50% improvement in BASDAI at Week 12
ASSERT[b,32]	PBO vs Remicade 5 mg/kg	AS	ASAS20 at Week 24
IMPACT[b,33]	PBO vs Remicade 5 mg/kg	PsA	ACR20 at Week 16
IMPACT II[b,35]	PBO vs Remicade 5 mg/kg	PsA	ACR20 at Week 14
EXPRESS[b,38]	PBO vs Remicade 5 mg/kg	PsO	75% improvement in PASI score at Week 10
EXPRESS II[b,40]	PBO vs Remicade 5 mg/kg	PsO	75% improvement in PASI score at Week 10

Figure 5 Efficacy of Remicade in pivotal phase II/III clinical trials in adult indications: odds ratio of primary endpoint.

Notes: [a]Most trials evaluated multiple doses of Remicade. In the treatment arms shown (the generally approved doses), the Remicade dosing regimen tested was induction (infusions at weeks 0, 2, and 6) followed by q8w maintenance, with the exceptions of the Targan and Present studies, where single infusion and induction only, respectively, were tested, and of the AS trials (Braun and ASSERT), where induction followed by q6w maintenance was tested. [b]Janssen, data on file. [c]PBO of AZA. [d]Major secondary endpoint. The primary endpoint was a continuous variable for which an odds ratio was not calculated.

Abbreviations: ACR20, American College of Rheumatology 20% response; AS, ankylosing spondylitis; ASAS20, Ankylosing Spondylitis Activity Score 20% response; AZA, azathioprine; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; CD, Crohn's disease; MTX, methotrexate; MTX-IR, methotrexate inadequate responders; PASI 75, Psoriasis Area and Severity Index 75% reduction; PBO, placebo; PsA, psoriatic arthritis; PsO, psoriasis; q6w, every 6 weeks; q8w, every 8 weeks; RA, rheumatoid arthritis; UC, ulcerative colitis.

previously viewed to be a Th2-mediated disease, with the blockade of TNF, a cytokine associated with Th1-mediated diseases such as RA, CD, and psoriasis, contributed to a reassessment of the Th1/Th2 paradigm in the pathogenesis of IBD.[100] Treatment of PsA with Remicade demonstrated that TNF drives the inflammation not just in joint-related signs and symptoms and structural damage,[101] but also in its other major clinical manifestations, such as PsO, enthesitis, and dactylitis.[32] In AS, TNF inhibition demonstrated efficacy on signs and symptoms of disease, but, in contrast to RA and PsA, it had no apparent effect on structural damage in clinical trials, despite a reduction in bone/spinal inflammation as measured by magnetic resonance imaging (MRI). Later non-randomized studies suggested that TNF blockade reduces progression of structural damage in the long term (≥2 years).[102,103] In psoriasis, two targeted therapies (alefacept, an anti-CD2 agent, and efalizumab, an anti-CD11 agent) were approved by the FDA and the latter by the EMA, but had modest efficacy, and in the case of efalizumab, emerging safety issues in the postmarketing setting. They were later removed from the market.[104–106] In contrast, TNF inhibitors provided evidence that targeted systemic therapy could have both proven efficacy and acceptable safety in the setting of psoriasis.

Unsuccessful clinical indications of TNF blockade

In addition to the approved indications, both Janssen and independent investigators have evaluated Remicade in other disorders associated with elevated TNF, including both other IMIDs, such as asthma and multiple sclerosis (MS), and diseases not generally characterized as IMIDs, such as infectious diseases, cancer, and cardiovascular conditions (Table 2). In each of these disorders, there were mechanistic, in vitro and/or animal data supporting the hypothesis that TNF blockade could be beneficial. In a few, such as systemic lupus erythematosus (SLE) and cancer, there was reason to believe that TNF blockade could either exacerbate the disease or treat it, reflective of the multiple functions of TNF. However, even in these

Table 2 Diseases beyond approved indications where Remicade was studied as treatment

IMIDs	Non-IMIDs
Alcoholic hepatitis[107]	**Infectious disease**
Atopic dermatitis[108]	Hepatitis C[132]
Asthma[a] (Janssen, data on file)	HIV/AIDS[133]
Autoimmune hepatitis[109]	Sepsis[a,9,76]
Behcet's disease[110,111]	**Malignancy**
Giant cell arteritis (GCA)[a] (vasculitis, Wegener's disease, polymyalgia rheumatica)[112–114]	Ovarian cancer[134]
	Renal cancer[135]
Graft versus host disease[115]	Myelodysplastic syndrome[136]
Hydradenitis suppurativa[116]	Non-small cell lung cancer (weight loss)[137]
Juvenile rheumatoid arthritis[b,37]	Pancreatic cancer (cachexia) [a,138]
Kawasaki disease[117,118]	Prostate cancer (pain, biomarkers)[139]
Multiple sclerosis[a,119]	**Cardiovascular disease**
Pemphigus vulgaris[120]	Congestive heart failure (CHF) [a,29]
Polymyositis[121]	Hypertension[140]
Primary sclerosis cholangitis (PSC)[122]	**Mental health**
Sarcoidosis[a,123,124]	Depression[141]
Scleroderma[125]	Bipolar disorder[142]
Sjogren's syndrome[126]	**Endocrinology**
Systemic lupus erythematosis (SLE)[127–129]	Metabolic syndrome[143]
Type 1 Diabetes[130]	**Other**
Uveitis[a,111,131]	Age-related macular degeneration[144]
	Chronic obstructive pulmonary disease (COPD) [a,145]
	Endometriosis (pain)[146]
	Sciatica[147]

Notes: [a]Janssen-sponsored study. [b]A randomized, placebo-controlled trial was conducted to evaluate Remicade plus MTX for the treatment of polyarticular-course juvenile rheumatoid arthritis (JRA). While Remicade produced an important, rapid, and durable clinical effect in children with JRA at 1 year, the difference between Remicade and placebo was not statistically significantly different at the primary endpoint, ACR Pediatric 30 criteria at week 14, and thus regulatory approval was not obtained. Of note, the sample size was reduced, as one site of this trial was excluded owing to potential patient unblinding.[37]
Abbreviation: IMID, immune-mediated inflammatory disorder.

conditions, the unmet medical need and the potential benefit justified testing TNF blockade as a treatment.

In several of the IMIDs, efficacy was observed in initial clinical studies, but for various reasons full development did not follow. Based on small studies, Remicade received regulatory approval in Japan for two rare diseases prevalent in the Japanese population, Behçet's and Kawasaki disease.[110,111,117,118] In hidradenitis suppurativa and uveitis, initial studies suggesting efficacy with Remicade led to the development and approval of other TNF inhibitors in these indications.[116,131,148] In autoimmune hepatitis and SLE, efficacy was observed in proof-of-concept studies, but was outweighed by the negative safety profile,[109,127–129] and in sarcoidosis and asthma, only marginal benefit was observed in formal phase II trials and development was discontinued.[123] In the remaining IMIDs evaluated (Table 2), Remicade showed no or only short-term clinical benefit. In all non-IMIDs studied, TNF blockade with Remicade proved ineffective or insufficiently effective to justify further clinical development.

In two instances, unexpected safety signals arose in clinical studies with Remicade. Despite preclinical evidence that TNF blockade improved an animal model of MS,[119] two patients with rapidly progressive MS treated with Remicade in a phase I safety trial experienced a transient increase in the number of gadolinium-enhancing lesions and other signs suggestive of immune activation and increased disease activity.[119] A similar worsening of symptoms was found in a double-blind placebo-controlled study in MS with another TNF inhibitor, lenercept,[149] and in clinical practice TNF inhibitors have been associated with cases of new onset and exacerbation of central and peripheral nervous system demyelinating disorders, such as optic neuritis and Guillain–Barré syndrome.[150]

In the second situation, preclinical and early clinical data suggested that TNF played an important role in the pathogenesis and progression of congestive heart failure (CHF). Yet in the phase II ATTACH study of 150 patients with stable class III or IV CHF, short-term TNF blockade with Remicade showed no clinical benefit, and high doses (10 mg/kg) were associated with an elevated risk of death or hospitalization.[29] Poor outcomes were also observed with etanercept in clinical trials of patients with CHF, confirming that TNF blockade is not an effective strategy in the treatment of moderate-to-severe CHF.[151]

What are the possible reasons for failure of TNF blockade?

Two possible explanations for the lack of demonstrated benefit of Remicade in these indications, both related to trial design, are that the dose or duration of treatment was not sufficient or that, as proof-of-concept studies, the trials were underpowered and unable to detect a benefit. However, given the general understanding of Remicade dosing, and the consistency of results across multiple trials with other TNF inhibitors, it seems more likely that TNF blockade is simply not the right treatment strategy in these diseases. But why not?

In the non-IMID indications, investigators identified two main possible explanations for lack of effect of TNF blockade. First, the inflammation in these diseases is possibly not driven by TNF, but rather the high production of TNF could be a downstream effect. Alternatively, the inflammation, even if TNF driven, is just one of several ongoing pathologies such that suppressing it does not have an impact on the disease as a whole.

It is less clear why TNF blockade works so effectively in some IMIDs with elevated TNF, but is ineffective or leads to worsening in others. It is possible that the timing of treatment with respect to disease course or the selected patient population was not optimal. Sarcoidosis, similar to CD, is both granulomatous in nature and mediated by Th1. Theoretically, TNF blockade should have been effective, yet the phase II trial showed only marginal benefit with Remicade. The investigators noted that one possible explanation for the trial's results is that it included patients with stable disease, which may have diminished a possible response to Remicade, owing to a lack of inflammation and/or high levels of fibrosis, which TNF blockade would not treat. An exploratory subgroup analysis revealed that patients with severe disease were more likely to benefit. Janssen subsequently conducted another phase II trial with a follow-up TNF inhibitor, golimumab (Simponi®; Janssen Biotech, Horsham, PA, USA), enrolling specifically this severe population, and yet again only marginal benefit was observed.[152] The sarcoidosis experience emphasizes the challenge of identifying a suitable population for a targeted treatment (eg, patients with TNF-driven disease) even when a sound understanding of the disease pathophysiology is present.

Another possible explanation for the lack of benefit in IMIDs treated with TNF blockade is that the ongoing inflammation is not TNF-driven, not solely TNF-driven, or not TNF-driven at each stage of disease, ie, where drivers of inflammation change over time or in different circumstances. It is known that the inflammation in IMIDs has different etiologies, mediated by Th1, Th2, and/or the more recently discovered Th17 responses. Elevated levels of TNF are associated with diseases thought to be driven by Th1 and/or Th17 responses, such as RA and CD. A number of the diseases where Remicade failed to work are thought to be Th2-mediated, including asthma (Janssen, data on file) and scleroderma,[125] where TNF, although elevated, is possibly not central to the underlying inflammation. In others, multiple pathways could be active. For instance, in view of the negative results with Remicade in Sjögren's syndrome[126] and atopic dermatitis,[108] investigators speculated that TNF blockade could have shifted the balance of Th1/Th2-mediated inflammation in favor of Th2. Whereas recent research has shown that some diseases, such as PsO and CD, can be effectively treated by blockade of cytokines elevated in either the Th1 or Th17 pathway,[35,40,153,154] others perhaps require blockade of both. One analysis, for instance, suggested that the inflammation in giant cell arteritis (GCA) is driven by cytokines from both the Th1 and Th17 pathways and successful treatment will require blockade of both.[155]

Several hypotheses have been proposed for worsening disease with TNF blockade. In the MS trials, investigators identified possible mechanisms by which TNF blockade could lead to further immune activation contributing to the disease's pathogenesis or to interruption of TNF-mediated tissue repair via TNFR2.[150,156] In CHF, disease worsening occurred despite decreases in both CRP and IL-6 with Remicade treatment. This led the investigators to propose that cytokine activation, including TNF, was beneficial, serving as part of the body's adaptive response to CHF, and that blocking it disrupted this response.[29]

It is clear that despite an improved understanding of the immune system, there are still many unknowns. The learnings from these trials have demonstrated that TNF's effect and, by extension, those of TNF blockade, are context driven and are difficult to predict. Remicade is effective in a number of IMIDs with a TNF-driven inflammatory component. In the other diseases where Remicade was studied, the results have provided useful insights into their pathophysiology and helped researchers in the search for new therapeutic targets.

Establishing the safety profile of Remicade

As Remicade was both the first TNF inhibitor and the first mAb to be used in chronic diseases, there was little precedent to draw upon, leaving researchers to hypothesize on its safety profile. Given the physiological role of TNF in host defense and immune surveillance, Remicade was expected to be associated with an increase in infections and, over the long term, malignancy, specifically lymphoma. As a foreign protein, Remicade also brought concerns of immunogenicity and consequent allergic and hypersensitivity reactions. Finally, as with any new drug, but in particular with this new form of targeted therapy, there were concerns about unforeseen risks.

The process of fully defining Remicade's safety profile took years and is still ongoing (Table 3). It has required Janssen to use a combination of data sources: phase II/III clinical trials, routine pharmacovigilance, postmarketing studies, large clinical databases, and independent research. Depending on the frequency of a given ADR, eg, common, uncommon, rare, and unexpected, different data sources and methods of analysis have been utilized. Several examples are described in this section to demonstrate how this was done.

What could the phase II/III program tell us?

The number of patients exposed to Remicade across the trials completed at the time of initial approval was not large (<200 patients in CD, approximately 500 across all clinical trials), yet based on this limited experience, the observed profile was aligned with expectations of TNF blockade. In Remicade-treated patients across all trials, ADAs were observed in 28.3% of patients. One or more infusion reactions occurred in 15.9% of patients (in 7.6% of infusions) (Janssen, data on file), most of which were mild to moderate in severity. Other than infusion reactions, allergic/hypersensitivity reactions were infrequent. Infections, including serious infections, occurred at a higher rate in patients treated with Remicade than with placebo (21.0% vs 11.0% for infections and 2.4% vs 1.8% for serious infections, respectively) (Janssen, data on file). Malignancies, including lymphomas, were observed, but were too infrequent to assess any possible association with Remicade (seven malignancies, of which five were lymphoid). One unexpected phenomenon, an increase in the risk of autoimmunity, was identified. In Remicade-treated patients, there was a net increase in new anti-nuclear

Table 3 Overview of Remicade's safety profile

Adverse event	Role of TNF/immune pathways
Acute and delayed hypersensitivity reactions	• Infused proteins generate acute infusion reactions via unclear mechanisms. Most are mild to moderate[45,157,158] • Allergic and (delayed) hypersensitivity reactions are also possible[45,157,158]
Serious infections, including opportunistic infections, TB, and hepatitis B reactivation	• Serious infections, including tuberculosis, bacterial infections, including sepsis and pneumonia, invasive fungal, viral, and other opportunistic infections have been observed in patients treated with TNF inhibitors[70,159,160] • TNF is critical for the clearance of intracellular pathogens[93] • Immune responses against viral pathogens can be also mediated by TNF[93] • Neutropenia may occur after TNF inhibitor administration, increasing risk of opportunistic infections[64] • TNF helps form and maintain granulomas in TB and induces apoptosis of TB-infected cells[161]
Malignancy, including lymphoma, leukemia, Merkel cell carcinoma, melanoma, cervical cancer, HSTCL, and pediatric malignancy	• Malignancy, especially lymphoma, is a known risk of immunosuppression[162] • Mechanistic studies have also shown that TNF has tumor-promoting potential under certain conditions[163] • Postmarketing surveillance suggests that there is relatively low risk of malignancy with TNF inhibitor treatment[55,164]
SLE and lupus-like syndrome	• Lupus-like syndrome has been observed in patients treated with TNF inhibitors[70] • TNF inhibition has been associated with the formation of anti-nuclear antibodies (ANA), anti-DNA antibodies, anticardiolipin antibodies, and antihistones[70] • Increased cell lysis in patients treated with TNF inhibitors may lead to exposure to self-antigens[165]
Hematologic reactions	• Pancytopenia, leucopenia, neutropenia, and thrombocytopenia have been reported in patients receiving TNF inhibitors[166]
Demyelinating disorders	• TNF inhibitors have been associated with cases of new onset or exacerbation of CNS demyelinating disorders, including multiple sclerosis, and peripheral demyelinating disorders, including Guillain-Barré syndrome[150] • The role of TNF in demyelinating disorders are still under investigation[150] • TNF has pleiotropic functions at different stages of autoimmune demyelination that may promote neuronal damage or potentially provide protective functions during CNS pathogenesis[150]
Congestive heart failure	• Clinical trial data evaluating TNF blockade as a treatment for heart failure have shown a worsening of disease in patients with NYHA class III-IV CHF[167] • There have been postmarketing reports of worsening and new-onset CHF in patients receiving TNF inhibitors[167] • Compromised myocytes express TNF on their membranes and TNF inhibitors might kill those cells through apoptosis or CDC[165]
Hepatobiliary events and hepatotoxicity	• In clinical trials, sporadic two- to three-fold liver function test elevations have been observed in patients treated with TNF inhibitors[166] • Isolated cases of hepatic failure have been reported in patients treated with TNF inhibitors[168] • Genetically susceptible individuals may generate an idiosyncratic (rare and unpredictable) immune response after inhibition of the TNF pathway[169]

Abbreviations: CDC, complement-dependent cytotoxicity; CHF, congestive heart failure; CNS, central nervous system; HSTCL, hepatosplenic T-cell lymphoma; NYHA, New York Heart Association; SLE, systemic lupus erythematosus; TB, tuberculosis; TNF, tumor necrosis factor.

antibodies (ANA) of 12% (from 24% to 36% of Remicade-treated patients), and anti-dsDNA antibodies developed in 9% of patients (from 0% to 9%). Isolated cases of (reversible) lupus-like syndrome were observed (Janssen, data on file). Viewed in the context of moderate-to-severe CD unresponsive to conventional therapies, this benefit–risk profile was viewed as positive, and Remicade received approval for CD.

As clinical development in additional indications proceeded, the phase II/III/IIIb trial database increased in size and had, by the end of development in 2016, grown to over 10,000 patients in more than 50 trials conducted across the globe in the six approved adult indications, and included pediatric populations in RA, CD, and UC (Janssen, data on file). While this was a much larger data set than was available at the time of initial approval, it was still not sufficient to fully establish Remicade's safety profile, a situation typical of clinical development programs. Clinical trials enroll a highly selected patient population and are not designed to detect rare safety events or events with long latency periods. To remedy this, manufacturers employ routine pharmacovigilance activities to monitor a drug's safety profile in clinical practice, the key part of which includes analysis of safety events reported to the company and in the medical literature.

What was the scale of the challenge of defining Remicade's safety profile? Common, uncommon, rare, and unexpected adverse events

Considering that a number of foreseeable risks needed further quantification and qualification, routine pharmacovigilance activities were not sufficient to define Remicade's emerging safety profile. For this purpose, postmarketing commitment (PMC) safety studies were agreed with or required by the health authorities for each new indication as it was granted. (In this manuscript, the term PMCs will be used collectively to refer to all studies agreed with or required by health authorities as a follow-up measure to provide additional data on safety or efficacy in the post-approval setting, known as postmarketing requirements [PMRs] and postmarketing commitments [PMCs] for the FDA, and postapproval measures [PAMs] for the EMA.)

The primary goals of the PMCprogram were to evaluate Remicade's long-term safety, specifically infections and malignancies, and its safety in vulnerable populations where it was expected to be used, specifically, pediatric patients and women exposed during pregnancy. The program was also to serve as a data source and hypothesis-generating tool for other possible adverse events.

A major consideration for the health authorities when determining the scope of the PMC program was the estimation of how broadly Remicade was to be used. It was indicated for six different diseases, which were serious but not generally regarded as life-threatening in nature. Moreover, their collective prevalence consisted of millions of patients. Given that the indicated diseases themselves differed in demographics, background safety risks, comorbidities, and conventional therapies, key safety questions would sometimes need to be evaluated separately by therapeutic area, ie, rheumatology, gastroenterology, and dermatology, and occasionally for each individual indication, ie, CD and UC. With the need to study Remicade in multiple diseases, as well as in demographically and geographically diverse populations, the PMC program needed to include tens of thousands of patients and would take years to execute.

The majority of the Remicade PMCs have sourced data from prospective, observational registries of specific diseases. Registries, while neither randomized nor containing the level of detail collected in controlled clinical trials, have the advantages of large size, long duration of patient treatment and follow-up, and inclusion of a broad population reflecting real-world use. Where registries already existed, Janssen initiated collaborations to meet its PMC requirements. When such independent initiatives were not sufficiently available, de novo disease registries were set up by Janssen and its commercial partners.

In total, the Remicade PMC program in approved indications consisted of seven company registries, 12 registries studies (ie, those based on analyses from independent registries), and three additional studies addressing specific safety topics (Table 4). Of the registries/registry studies, one included patients across all indications, seven included patients with rheumatic diseases, five were in IBD, including two pediatric registries, four were in PsO, and two evaluated Remicade in pregnancy across multiple indications. All seven company registries were designed and recruited by Janssen or its partners specifically to address Remicade PMCs. In general, the registry-based PMCs had two key design features: 1) they followed Remicade patients as well as comparator cohorts, including those receiving conventional therapies, and later, when

Table 4 Remicade postmarketing commitment program

Study name	Indication	Study title	Location	No. Remicade patients[a]	No. total patients[a]	Patient follow-up time
Registries/ registry studies						
RemiTRAC[45]	All	Remicade Treatment Registry Across Canada	Canada	1,632	1,632	Until last infusion
TREAT[43]	CD	The Crohn's Therapy, Resource, Evaluation and Assessment Tool Registry	USA, Canada	3,440	6,273	Med 6.36 years; max 12.54 years
ENCORE[47]	CD	Crohn's Disease European National Registry. A Prospective, Observational, Postmarketing Safety Surveillance Registry of Patients Treated with REMICADE or Standard Therapy	EU	1,839	2,662	5 years
OPUS[48]	UC	Ulcerative Colitis European Registry. A Prospective, Observational, NonInterventional, Postmarketing Safety Surveillance Program	EU	1,355	2,239	5 years
DEVELOP[50]	Ped IBD	A Multicenter, Prospective, Long-term, Observational Registry of Pediatric Patients with Inflammatory Bowel Disease	Global	4,107	6,070	20 years
PedIBD Registry[170]	Ped IBD	The Pediatric Inflammatory Bowel Disease Collaborative Research Group Registry	USA, Canada	568	1,736	Mean 2.4 years (Remicade), max 8.3 years
BioTRAC Rheumatology[46]	RA, AS, PsA	Biologic Treatment Registry Across Canada Rheumatology	Canada	1,390	1,390	As long as exposed to Remicade
CORRONA[51]	RA, PsA	Consortium of Rheumatology Researchers of North America	USA, Canada	6,669	35,350	Up to 8 years
NDB[52]	RA, PsA, AS	National Data Bank for Rheumatic Diseases Infliximab Study	USA	9,055	23,394	5 years
ARTIS[53]	RA, PsA, AS	Antirheumatic Therapies in Sweden	Sweden	2,898	9,139	Min 5 years
BIOBADASER[54]	RA, PsA, AS	Spanish Registry of Adverse Events of Biological Therapies in Rheumatic Diseases	Spain	3,204	6,754	Min 5 years
BSRBR[55]	RA, PsA, AS	British Society of Rheumatologists Registry of anti-TNFα Treated Patients and Prospective Surveillance Study for Adverse Events Surveillance of Infliximab	UK	4,837	8,611	Min 5 years
RABBIT[56]	RA, PsA, AS	Long-term Observation of Treatment with Biologics in Rheumatoid Arthritis	Germany	610	5,263	5 years
PSOLAR[49]	Psoriasis	A Multicenter, Open Registry of Patients with Extensive and/or Disabling Plaque Psoriasis Who Are Candidates for Systemic Therapy Including Biologics	Global	2,360	12,090	8 years

(*Continued*)

Table 4 (Continued).

Study name	Indication	Study title	Location	No. Remicade patients[a]	No. total patients[a]	Patient follow-up time
PsoBEST[57]	Psoriasis	Observational, Noninterventional, Postmarketing Safety Surveillance Program in Psoriasis	Germany	107	2,272	5 years
BADBIR[58] NPTR (Janssen, data on file)	Psoriasis Psoriasis	British Association of Dermatologists Biological Interventions Register Nordic Psoriasis Tumor Registry	UK Sweden, Denmark	151 892	1,580 25,936	5 years Max 5 years
C0168T71[44]	All (Pregnancy)	Exposure to REMICADE (Infliximab) During Pregnancy in Patients with Inflammatory Bowel Disease, RA, PsA, AS and PsO: A Review and Analysis of Birth Outcomes from the Swedish, Danish, and Finnish Medical Birth Registries	Sweden, Denmark, Finland	270	7,636[b] 2,155,535[c]	1 year
PRIORITY (Janssen, data on file)	IBD (Pregnancy)	Pregnancy and Infant Outcomes Research Initiative Utilizing Data from the United States Based PIANO Registry on Inflammatory Bowel Disease	USA	248	641	1 year
Total: all registries/registry studies				**43,632**	**160,668**	
Total: including T71 pregnancies from the general population					**2,308,567**	
Other PMCs						
HSTCL-PALGA[59]	All	A Retrospective Review of Reports of Hepatosplenic T-cell Lymphoma in the Dutch National Database of Pathology (Pathologisch-Anatomisch Landelijk Geautomatiseerd Archief [PALGA]), a Database of Pathology Results for The Netherlands	Netherlands	0	12	13 years
HSTCL-Kaiser Permanente[60]	All	Epidemiologic Study of Hepatosplenic T-cell Lymphoma	USA	1	150	N/A
HSTCL-Biobank (Janssen, data on file)	IBD	A Research Study to Bank Samples for Future Evaluation to Identify Biomarkers that Predispose Patients with Crohn's Disease and Ulcerative Colitis to Develop Hepatosplenic T-Cell Lymphoma (HSTCL)	USA, Canada	Ongoing	Ongoing	N/A

Notes: [a]Patient numbers reported in this table might differ from those provided in the cited publication, as patients continued to enroll post-publication. [b]Including patients in study with anti-TNF-indicated diseases exposed to Remicade, other TNF inhibitors, or non-biologic conventional treatments. [c]Including all pregnancies in the national databases, ie, including the general population.

Abbreviations: AS, ankylosing spondylitis; CD, Crohn's disease; EU, European Union; IBD, inflammatory bowel disease; N/A, not applicable; ped, pediatric; PMC, postmarketing commitment; PsA, psoriatic arthritis; RA, rheumatoid arthritis; TNF, tumor necrosis factor; UC, ulcerative colitis.

they became available, those exposed to other biologics; and 2) Janssen committed to long-term patient follow-up, ranging from 5 to 20 years. The three additional studies were designed specifically to evaluate the risk of hepatosplenic T-cell lymphoma (HSTCL) with Remicade.

To date, approximately 44,000 patients exposed to Remicade and 117,000 patients in the comparator cohorts have been included in the PMC program, a figure which does not include patients followed in local post-approval safety monitoring programs, such as those required in Japan. From the beginning of each PMC through study closure, health authorities worldwide receive comprehensive reports on a regular basis providing updated analyses of key safety risks to support the prescribing information. Several of these PMCs are still ongoing today.

How can registries inform us about common adverse events?

The major common adverse event to be studied in the PMC program was infection, including the subgroup of serious infections. TREAT, a US-based Janssen registry in CD started in 1999, is a good example of the scale and design needed for this purpose. Over 5 years it enrolled two cohorts, those receiving treatment with Remicade and those receiving conventional therapies, and followed them until it was closed in 2012. It was the largest registry in IBD at the time, enrolling more than 6,000 patients with a median follow-up time of 6.36 years.[43]

Importantly, TREAT served as a data source also for studying the risks in conventional treatments. At the time of initiation of the program, thorough understanding of the risk of serious infection with conventional medications (specifically corticosteroids, analgesics, and the immunosuppressants thiopurines and MTX) was lacking. It was necessary in the Remicade PMC registries to gain an understanding of the background risks of these conventional agents as Remicade itself, used mostly after or in combination with these therapies, could not be judged in the absence of such knowledge. Similar understanding on the interactions between certain disease characteristics, such as severity and the risk of infection, was also required to understand the risks of Remicade and was also obtained from TREAT.

Analyses in TREAT confirmed the increased risk of serious infections with Remicade observed in the phase II/III program (unadjusted rates: 2.04 and 1.00 per 100 patient-years for Remicade and conventional therapies, respectively; adjusted HR=1.43, 95% CI 1.11 to 1.84, P=0.006).[171] Further analysis revealed that other significant predictors of serious infection were older age, use of prednisone, narcotic analgesics, moderate/severe disease, colonic disease, and disease duration at enrollment. The ENCORE and OPUS PMC registries in Europe for CD and UC, respectively, yielded confirmatory results to these findings and showed that results were generalizable for patients treated in clinical practice across geographic borders.[47,48]

In rheumatology, data from several biologics registries in the USA and Europe were published indicating a similar association between TNF inhibitors and serious infection risk to that found in CD,[172,173] with similar additional risk factors for serious infection such as disease severity. It was also established that there is a time-dependent increase in serious infection risk, where the maximum risk is reached within the first 6 months of therapy, with a gradual decline thereafter.[159,174,175]

Can registries inform us about uncommon events?

TREAT also demonstrated how registries can be used to better characterize the risk of uncommon events, for example lymphoma, for which they are often not adequately powered despite their size and duration. During the 13 active years of TREAT, just 15 cases of lymphoma were reported, evenly distributed between the Remicade and conventional therapy cohorts.[43] Owing to this limited number of cases, predictors associated with the risk of lymphoma could not be further estimated in regression models. This low rate of lymphoma was also an occurrence in registries across the other indications.[48,55,175–178] Although an increased risk in patients treated with Remicade could not be excluded with these limited numbers, they suggested that there was a relatively low rate of lymphoma with TNF blockade, and that this rate did not differ from that observed with conventional therapies or from the background rate in these diseases. Additional studies, especially meta-analyses including population-wide data, suggested that an increased risk is associated with profound persistent immunosuppression, eg, combination therapy with thiopurines and TNF inhibitors, and with cumulative disease activity.[162,179–181]

Can big data play a role in evaluating uncommon safety risks?

To establish an association between treatment and an uncommon event such as lymphoma, much larger sample sizes are needed than can be found in most registries. After 20 years on the market, the number of patients treated with TNF inhibitors as a class is large enough and technology has improved enough to enable analyses with the power necessary for low-frequency events. Lemaitre et al published a study from the French National Health Insurance Database (SNIIRAM) evaluating the incidence of lymphoma among 189,000 IBD patients with median follow-up of 6.7 years.[182] In this study, 336 patients had claims for lymphoma, which was sufficient for statistical analysis. The lymphoma incidence rate was found to be 0.26 per 1,000 person-years in IBD patients exposed to neither TNF inhibitors nor thiopurines, 0.54 in patients exposed to thiopurines, 0.41 in patients exposed to TNF inhibitors, and 0.95 in patients exposed to combination therapy. Adjusted HRs were 2.6 for thiopurines, 2.41 for TNF inhibitors, and 6.11 for the combination, relative to those unexposed to these drugs, all of which were statistically significant. As this study was based on administrative databases, clinical information, such as disease activity, smoking history, disease phenotype, and information on inflammatory burden, was not available to the authors, and the relative role of these risk factors could not be determined.

An analysis of similar size was also conducted in RA. Eleven biologics registries participated in a collaborative project to investigate the risk of malignancy, including lymphoma, associated with use of TNF inhibitors in RA.[55] Among 124,997 patients, 533 lymphomas were reported. Consistent with smaller analyses that did not suggest an increased risk of lymphoma with TNF inhibition or other treatments over and above the elevated risk already present in patients with active RA,[175–177] this large, multiregistry study confirmed comparable crude lymphoma rates across treatment cohorts and showed further that lymphoma subtype distribution was similar in biologic-naïve patients with RA and those treated with TNF inhibitors.[55]

How have PMCs continued to evolve?

Janssen's registries initiated later in Remicade's life cycle benefited from learnings from the early experience. An example of this is PSOLAR, begun in 2007 as a PMC for Remicade in psoriasis. Enrollment in the Remicade cohort was ended in 2013 and by which time this registry had enrolled over 12,000 patients with psoriasis. Going beyond TREAT, PSOLAR was a disease-based registry, allowing all patients with comparable psoriatic disease to enter, irrespective of treatment status.[49] Where TREAT could not include patients receiving other biologics because none was available at the time, PSOLAR included other TNF inhibitors and, later, other new biologic classes. Further, PSOLAR provided external validity and generalizability as the participating sites represented a mix of community-based, academic, and/or hospital-affiliated practices from around the globe. It also included formal sample size calculations permitting signal detection of adverse events, whereby hypotheses could be generated for later analyses. Lastly, Janssen took measures to ensure the objectivity and transparency of PSOLAR. In contrast to registries of academic or professional organizations, whose independence was implied, possible bias introduced by Janssen's conflicts of interest was a concern with its company-owned registries. To address this, PSOLAR enlisted from inception a formal steering committee with leaders in their respective fields, whose role was to ensure that the integrity of the registry would be maintained by reviewing, approving, and monitoring research projects, and by driving the interpretation and dissemination of results. Strict publication rules were stipulated in advance, chief among them having independent experts as leading authors.

PMCs evaluating long-term safety in special (vulnerable) populations require unique design considerations. To evaluate the risk of malignancy in pediatric patients with IBD, Janssen designed the global DEVELOP registry, where children treated with Remicade or other therapies were enrolled and are being followed for 20 years.[50] Achieving this length of follow-up requires extensive patient retention efforts owing to administrative and healthcare system challenges. For instance, at the age of 18, registry participants transition from pediatric care under the supervision of DEVELOP investigators to adult care by clinicians not involved in the registry. Similarly, in some countries, a lack of a personal identifier makes tracking patients across different healthcare providers over time difficult. Yet these efforts have served their purpose. An interim analysis from DEVELOP published in 2017, based on 5,766 patients with a median follow-up time of 4.7 years, indicated that Remicade therapy was not associated with an increased risk of malignancy compared

with a matched general population.[50] The data further demonstrated a trend toward an increased risk of malignancy in thiopurine-exposed patients, irrespective of biologic exposure, reinforcing findings from other independent research efforts in adults.[162,179]

Setting up a pregnancy registry with sufficient power to detect possible safety signals posed particular challenges and required an innovative approach to address. After review of existing databases and discussion with experts, Janssen learned that in the Nordic countries, government-held nationwide healthcare databases, including complete birth registries, could be linked to the local biologics registries. Working with data access providers in Sweden, Denmark, and Finland, Janssen was able to design a study which accrued patients starting from 2000. After 10 years, it had finally accrued enough women exposed to Remicade during pregnancy for a meaningful analysis. The national databases included a total of 2,155,535 births collected between 2000 and 2013, from which the outcomes of 270 births in women exposed to Remicade during pregnancy could be compared with 906 births in women exposed to other TNF inhibitors, 6,460 births in women with similar diseases exposed to non-biologic conventional treatments, and births in the general population.[44] Additional information on the infants born to these women was collected during their first year of life.

The study found that exposure to Remicade was not associated with increased rates of congenital anomalies or infant death, the most relevant medical outcomes of interest to health authorities. Remicade in combination with conventional immunosuppressive treatments was associated with other adverse birth outcomes (eg, low birth weight). However, this was not observed with Remicade monotherapy. The potential contribution of exposure versus severity of underlying disease in these outcomes remains unclear.

Janssen's first experience with combining and linking population-based databases established a proof of principle and led to other, similar collaborations for Remicade (Table 4) (NPTR, HSTCL-Kaiser Permanente) and other drugs in its portfolio (Janssen, data on file).[183]

How can rare and unexpected events be detected?

Perhaps the biggest challenge to establishing the safety profile of a drug is the detection of rare and idiosyncratic safety events. Even large databases are not of sufficient size to detect, analyze, or quantify such events, so special methods are needed. Janssen, like all pharmaceutical companies, relies on healthcare professionals to report to the company any ADRs occurring in patients treated with their drugs (known as spontaneous reporting). When the company identifies a possible safety signal, a full investigation is triggered. This includes trending analyses of events reported to the company over time (itself a complex process requiring accurate estimates of patients exposed to the drug by indication, age, geography, etc, for which Remicade demanded special methods), disproportionality analyses comparing rates with Remicade with rates observed across all other drugs in the company safety database, detailed clinical follow-up on each case report, a literature review of the adverse event, analyses from the clinical trial database and PMC registries, and consultation with experts. If necessary, mechanistic and preclinical studies to help understand the observation are also conducted. Finally, regular communication with health authorities is required.

A well-known example of signal detection from spontaneous reports is that of tuberculosis (TB) in patients treated with Remicade. Both the phase II/III trials and the PMCs included sites located primarily in North America and Western Europe, and enrolled a population of patients at relatively low risk of being exposed to TB. In 2000, once use of Remicade in clinical practice started to grow and included patients from a broad geographic area, Janssen began receiving spontaneous reports of disseminated TB in patients treated with Remicade.[22,23,160] The company's ensuing investigation found independent research ongoing at that time, which revealed a role of TNF in maintaining granulomas, which are responsible for sequestration of *Mycobacterium tuberculosis* and sustaining latency of disease, and in the induction of apoptosis of TB-infected cells. Inhibition of TNF disrupts these immune responses and likely leads to breakdown of granulomas and reactivation of latent TB infections.[184]

Perhaps the most prominent example of detecting a rare adverse event with Remicade is that of HSTCL, a very rare and usually fatal form of lymphoma. It occurs predominantly in adolescent and young males, in whom widespread use of Remicade began only with its approval in pediatric CD in 2006. After several cases were reported,[36] Janssen committed to monitoring its various data sources, including the PMC registries, for additional cases. However, given the rarity of HSTCL and its occurrence in a specific, small subgroup of patients, no cases were found in the existing

registries and it was unlikely that many would be found in the future. The company then agreed with health authorities to conduct three PMCs specifically for the study of HSTCL: 1) an analysis to calculate the incidence of HSTCL in IBD using the claims databases of Kaiser Permanente, a US health insurance company[60] 2) a study of the incidence and prevalence of HSTCL in the general population and in IMIDs using PALGA, a nationwide network and registry of histopathology and cytopathology centers in the Netherlands[59] and 3) a Janssen study to collect samples from IBD patients diagnosed with HSTCL to identify biomarkers that may allow earlier identification of a patient's risk of developing HSTCL. After extensive review of each case of HSTCL in IBD patients both with and without treatment with Remicade identified in Janssen's global safety database, the FDA's MedWatch system, and the medical literature, analysis showed that nearly all cases occurred in patients treated either with thiopurines only or with a combination of TNF blockade and thiopurines, with few cases in patients receiving TNF inhibitor monotherapy.[36,60] The Remicade prescribing information was updated accordingly to warn prescribers of the possible risk.

As with the examples of lymphoma and pregnancy, the HSTCL experience demonstrated the challenges of identifying sufficient cases of rare and even low-frequency events despite routine pharmacovigilance activities and a PMC program comprised of studies with both large populations and long-term follow-up. Combined with a lack of information on possible confounding factors, there are limits to the ability to draw firm conclusions from these data sources on the quantitative (eg, incidence rates) and qualitative (eg, event subtypes, predictors, latency, severity) aspects of these risks. Nevertheless, the Remicade postmarketing safety program has provided and continues to provide essential information needed to assess the risk profile of Remicade, and has confirmed the overall positive benefit–risk balance originally observed in the clinical development program.

What has Remicade's safety profile taught us about the physiological role of TNF and the effects of TNF blockade?

The profile of safety events associated with TNF blockade has been of great interest to researchers from an immunological perspective. Commonly compared with conventional immunosuppression, TNF blockade differs from it mechanistically. Where immunosuppressants prevent activation and proliferation of lymphocytes, TNF inhibitors, by virtue of blocking a single cytokine, are a targeted approach to modulating immune responses and therefore are not broadly immunosuppressive.[93,94] While its safety profile is similar to that of conventional immunosuppressants, specific blockade of TNF does not have the off-target effects of many immunosuppressants or steroids, nor is there evidence of cumulative toxicity with TNF blockade.[66,185] It is noteworthy that blockade of a cytokine so central to host defense can be blocked without a greater and broader risk of adverse effects.

The study of Remicade has confirmed and refined much of what was known about TNF. It plays a complex role in innate immunity, particularly against mycobacterial, invasive fungal, and (other) intracellular infections, and, not surprisingly, its blockade is associated with a small increase in these and other opportunistic infections.[93] Similarly, reports of reactivation of hepatitis B infections confirm the role of TNF in the immune response against certain viral pathogens.

Less clear is the extent of effect that TNF inhibitors have on immune surveillance against malignancies, including lymphomas. Whereas data from large registries of patients with RA (see Table 4) indicate that disease activity, rather than TNF antagonism, is likely to be responsible for the observed increased risk of lymphoma, data from large IBD studies[182] suggest a possible increase, albeit small, associated with TNF blockade. Specific malignancies, such as Merkel cell carcinoma, melanoma, and leukemia, have also been associated with TNF blockade. Investigation on these and other malignancies continues.

Use of TNF blockade has also led to an unexpected finding, paradoxical adverse events, defined as the occurrence of a pathological condition that usually responds to a drug. For example, TNF inhibitors are effective in psoriasis, yet psoriatic skin lesions have been reported as an adverse event following TNF inhibitor treatment for other conditions.[186] The mechanism of this is unclear, but one hypothesis posits that inhibiting TNF may, in certain settings, increase the production of other cytokines, such as interferons and IL-17s, underlying the role of alternative inflammatory pathways in the pathogenesis of these diseases.[186] Another line of investigation suggests that TNF blockade could lead to the downregulation of T-regulatory cells which would normally modulate TNF-driven inflammation.[187,188] It is a fascinating observation and yet another example of the use of TNF blockade bringing new insights to our understanding of the immune system.

Once identified, how are safety risks to be mitigated?

The final step in the risk-management process consists of the actions a company should take to mitigate safety risks once they have been identified. Routine measures include updating the product's prescribing information with a warning and description of the event, and inclusion in the company's standard medical information, educational, and promotional materials. When these measures are insufficient, a manufacturer can implement additional risk mitigation activities. In the case of Remicade, several risks have led to the need for such extra measures. An example is the risk of mycobacterial and invasive fungal infections, where cases of delayed or missed diagnoses were still occurring in TNF inhibitor-treated patients despite routine risk-mitigation measures. In response, Janssen implemented a global educational program on the risk of these infections. In the USA, this took the form of a formal Risk Evaluation and Mitigation Strategy, as per FDA requirements, where communication and education tools for physicians were developed and deployed emphasizing the importance of maintaining a high index of suspicion for opportunistic infections in Remicade-treated patients, the need for screening measures and possible pretreatment, and how these infections should be managed. In Europe, Janssen and its partners were required not only to implement educational activities, but also to demonstrate their effectiveness by evaluating levels of awareness among physicians of the risks and how to reduce them. There were also educational efforts aimed at patients, the most important of which was a reminder card to be given at the beginning of therapy notifying them of specific risks and the need to inform all healthcare providers responsible for their care that they are on Remicade. After review of the outcomes of these programs and consultation with the health authorities, the formal requirements of the additional measures have been fulfilled and Janssen continues routine activities to this day.

Changes in treatment paradigms due to the advent of TNF blockade

Therapeutic advances often lead to changes in treatment paradigms. In the case of TNF inhibitors, the impact was extensive as it occurred across several relatively common diseases which are chronic, progressive, and often accompanied by disability and severe comorbidities, and where standard treatments had remained unchanged for years. The breakthrough of Remicade and other TNF inhibitors set off a revolution, leading to a reassessment of conventional therapies, changes in treatment goals and new treatment strategies. These paradigm shifts occurred in parallel across indications, as the learnings from one informed the others.

When Remicade first became available, its use was limited to patients who had failed conventional therapies. Clinical experience confirmed the efficacy observed in the phase II/III trials and clinicians soon learned how to optimize the results further. Better patient management methods mitigated safety risks such as infusion reactions and infections.[157,158,189,190] By treating the underlying pathophysiology of disease, TNF blockade offered the possibility of treating multiple manifestations with a single therapy. Many patients could be treated for years at a time, with both sustained response and an acceptable tolerability,[66,185] a welcome departure from standard treatments.[191,192]

Within a few years, the positive experience with Remicade in clinical practice led researchers to ask several questions about expanding its use. If treatment stops structural damage and avoids long-term, irreversible sequelae of disease, why wait until the structural damage is manifest before using it? Would treating early, perhaps even as an alternative to conventional treatments, avoid the damage in the first place?

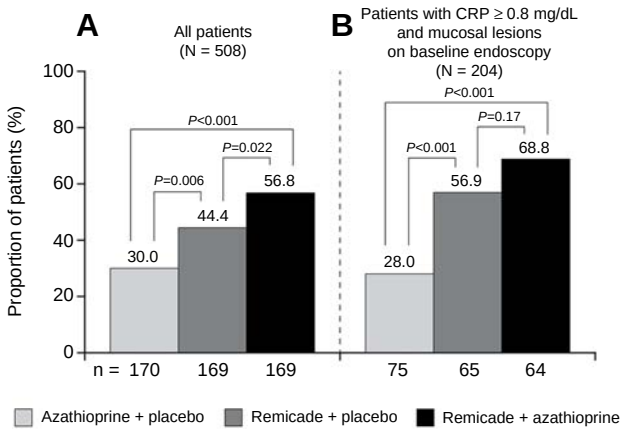


Figure 6 SONIC trial: primary endpoint (steroid-free remission) at week 26 in (**A**) all patients and (**B**) patients with elevated CRP (≥0.8 mg/dL) and mucosal lesions at baseline. **(A)** From Colombel JF, Sandborn WJ, Reinisch W, et al. Infliximab, azathioprine, or combination therapy for Crohn's disease. *N Engl J Med*. 2010;362:1383–1395. Copyright © 2010 Massachusetts Medical Society. Reprinted with permission from Massachusetts Medical Society;[40] and (**B**) from Colombel JF, Sandborn WJ, Reinisch W, et al. Infliximab, azathioprine, or combination therapy for Crohn's disease. *N Engl J Med*. 2010;362(15):1383–1395. Supplementary Material. Copyright © 2010 Massachusetts Medical Society. Reprinted with permission from Massachusetts Medical Society.[84]
Abbreviation: CRP, C-reactive protein.

Could TNF blockade be used earlier in the disease course?

IBD

In CD, initial studies exploring the use of Remicade in patients early in the course of disease were conducted by independent investigators. GETAID, a French IBD study group, investigated Remicade in steroid-refractory patients and D'Haens et al conducted the Step-up-Top-down study evaluating Remicade in early CD.[193,194] Both studies suggested that early use may be beneficial, and led to SONIC, a Janssen-sponsored phase III study, which compared Remicade with the standard maintenance treatment in CD, azathioprine (AZA, a thiopurine), rather than testing its effect where this treatment had failed.[40]

In SONIC, CD patients naïve to AZA and early in the course of disease (median duration of disease 2.4 years) were randomized to one of three treatment arms: AZA alone, Remicade alone, and the combination of AZA and Remicade. The primary endpoint was the new gold standard of efficacy, corticosteroid-free clinical remission at week 26, and was achieved in 30.0% of patients receiving AZA alone, 44.4% of patients receiving Remicade alone (P=0.006), and 56.8% of patients receiving the combination (P<0.001) (Figure 6). Importantly, endoscopic assessment of the healing of mucosal lesions demonstrated a similar pattern of results across the three groups. The incidence of ADA was lower in the combination group (0.9%) compared with Remicade alone (14.6%), consistent with that observed with the combination of Remicade and MTX in RA. Safety was comparable in all three groups. These results showing the superiority of both Remicade regimens versus AZA triggered a reassessment of the use and timing of not only TNF blockade but also AZA in CD.

A study of similar design in UC, UC-SUCCESS, showed comparable results.[195] The researchers explored whether Remicade, either as monotherapy or in combination with AZA, was superior to AZA alone in patients who were failing corticosteroids and naïve to AZA. The combination was superior to either agent alone for induction of steroid-free remission at week 16, the primary endpoint, and resulted in greater improvement in quality of life of UC patients. Remicade, both as monotherapy and in combination with AZA, was more likely to achieve a clinical response and mucosal healing than in those treated with AZA alone.[195] Remicade was also assessed as an alternative to standard therapies, intravenous steroids and cyclosporine, in the management of severe, acute UC, an emergent, life-threatening form of the disease usually resulting in colectomy. Remicade proved to be better than intravenous steroids[196] and equal to cyclosporine[197] at avoiding colectomy, but with the benefits of improved tolerability, ease of use, and the possibility of use as a maintenance therapy.

Rheumatology indications

In RA, the exploration of earlier use followed a similar trajectory. The first signal that Remicade could be used early in the course of disease was from an ATTRACT subgroup analysis of patients with shorter duration of disease (<3 years) and therefore lower baseline levels of joint damage than the trial's full population. Results suggested that Remicade provided long-term benefits in this subgroup by preventing radiographic progression and preserving joint integrity,[198] and supported the hypothesis of a window of opportunity to avoid joint damage early in the disease, after which it would appear and begin to impair normal function.[199–201]

This analysis led to ASPIRE, a phase III trial to assess formally the use of Remicade in patients with severely active RA naïve to MTX and disease duration <3 years, in which patients were randomized to either MTX alone or MTX in combination with Remicade for 1 year.[30,202] This trial demonstrated that the combination provided both clinical and structural benefits early in the course of disease compared to MTX alone. A similar trial, RESPOND, was performed with Remicade in patients with PsA and who were naïve to MTX, helping to establish the efficacy of early use of TNF blockade in that disease as well.[41]

Earlier use of TNF blockade in AS was explored in another independent study from Barkham et al, where patients with very early inflammatory back pain (indicative of future AS) were randomized to Remicade or placebo.[39] Compared with placebo at week 20, patients receiving Remicade had a greater reduction in inflammatory lesions, as measured by total MRI score, and better scores on clinical and patient-reported outcomes. This was the first study to show that TNF blockade was effective for early sacroiliitis or "preradiographic" axial spondyloarthritis (axSpA), ie, without structural damage on X-ray and therefore not (yet) AS.

Although the results from these trials were positive, there were several reasons not to implement earlier use of TNF blockade. While generally well tolerated, it is not risk free and its use in larger populations with earlier, possibly milder forms of disease raised questions about the balance of benefits versus risks. Moreover, less costly conventional

therapies, while perhaps inferior to TNF blockade, were still effective drugs, particularly in RA and psoriasis, where the benefits of MTX, for example, are substantial. Clinicians then asked two questions, the answers to which might guide decisions on early use of TNF blockade. Were there predictors of response which might help to identify the subgroups of patients most likely to need and to benefit from early TNF blockade (eg, patients at high risk of rapid progression) or not likely to respond to TNF blockade at all? Had conventional therapies and treatment strategies been optimized or was there still room to improve them?

Are there predictors of response which can identify patients who will benefit from (early) treatment with TNF inhibition? Are there predictors of lack or loss of response?

Predictors of response

SONIC was relevant not only because it identified the optimal maintenance therapy for early symptomatic control, but also because of its implications in the context of CD as a progressive disease, where early suppression of the underlying inflammation could lead to avoidance of permanent structural bowel damage characteristic of its later stages. Subgroup analyses from SONIC revealed that patients with objective signs of inflammation at baseline, specifically mucosal lesions and/or elevated levels of CRP, had relatively greater benefit of therapy compared with the trial population as a whole. In the subgroup with both characteristics, 69% of patients receiving combination therapy were in steroid-free remission at week 26 (Figure 6).[86] This confirmed that it was now possible not only to identify but also to treat patients at early risk of progression due to inflammation.

In early RA, an analysis from ASPIRE evaluated a range of baseline patient characteristics and found that swollen joint counts, rheumatoid factor positivity, and increased serum markers of inflammation (erythrocyte sedimentation rate [ESR] and/or CRP) were all predictors of both disease progression and response to TNF blockade. Visual matrices based on these parameters were then developed to identify populations at high risk of rapid radiographic progression (Figure 7). In the trial, these patients were unlikely to respond to MTX alone, but benefited from its use combined with Remicade.[203] ASPIRE was helpful in understanding when MTX alone was sufficient and when early combination therapy was warranted.

The Barkham study in axSpA had shown that early sacroiliitis could be treated before substantial damage to the spine had occurred, providing an impetus for early use

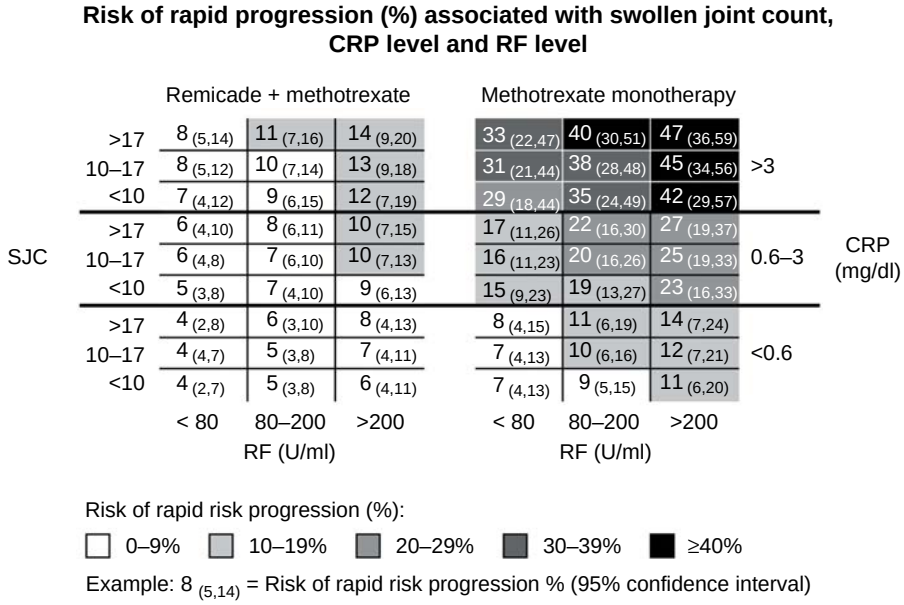


Figure 7 Prediction model of rapid radiographic progression in RA: matrix model from the ASPIRE trial in MTX-naïve, early RA. Rapid progression was defined as a threshold change in modified Sharp/van der Heijde (SHS) score of ≥5 units/year. From Vastesaeger N, Xu S, Aletaha D, et al. A pilot risk model for the prediction of rapid radiographic progression in rheumatoid arthritis. *Rheumatology.* 2009;48(9):1114–1121. doi:10.1093/rheumatology/kep155. Reproduced by permission of Oxford University Press on behalf of the British Society for Rheumatology.[203]

Abbreviations: CRP, C-reactive protein; MTX, methotrexate; RA, rheumatoid arthritis; RF, rheumatoid factor; SJC, swollen joint count, 28 joints assessed.

of TNF blockade.[39] However, for this early use to be practical, there was a need for better differential diagnosis of axSpA from other causes of back pain. Research found that patients with back pain >3 months beginning before the age of 45 years in the presence of human leukocyte antigen-B27 positivity or sacroiliitis combined with typical features of SpA (eg, extraspinal manifestations, response to NSAIDs, family history) were likely to develop axSpA. This led to the formal definition of a new disease entity, non-radiographic axial spondyloarthritis (nr-axSpA), now recognized for clinical trial purposes and by health authorities as a new indication.[204,205] In the case of AS, therefore, the option to treat early with TNF inhibitors had led to a fundamental reassessment of disease.

Possible reasons for lack or loss of response

As efficacious as TNF blockade is, not all patients respond and many patients who do will lose their response over time. In Remicade clinical trials across all indications, as well as in trials of other TNF inhibitors, 20–40% of patients did not respond to induction therapy (primary non-response) (Figure 4), and in clinical use another 5–15% have been observed to lose response annually thereafter (secondary non-response).[206,207] Considerable effort has gone into understanding and predicting non-response in the hope of further optimizing therapy with Remicade and other TNF inhibitors.

Causes for this treatment failure generally fall into two categories.[208] The first is insufficient dosing. This can be due to several reasons, such as fast drug clearance, high inflammatory burden, and ADAs, and can frequently be resolved with dose escalation.[81,82,209] To identify possible underdosing, both monitoring of serum drug levels and ADA testing have become common in the management of patients on TNF inhibitors, particularly in IBD.[210–212]

The second cause of lack or loss of response is more interesting from a pathophysiological perspective, and more difficult to address: the inflammation behind the disease in these patients is perhaps not (or not consistently) driven by TNF. In IBD, for example, the European Crohn's and Colitis Organisation (ECCO), a leading professional organization in the field, held a workshop on reasons for failure of TNF inhibition and hypothesized that TNF-independent (or not fully dependent) pathways may be involved in inflammation or that TNF blockade even induces or promotes pro-inflammatory pathways, reminiscent of the reasons for the failure of TNF blockade in other diseases or for paradoxical adverse events.[213] New agents targeting different inflammatory mediators have already proven to be effective, including specifically in patients who do not respond to or have lost response to TNF inhibition, such as inhibitors of IL-12/23 and integrin-α4β7 in IBD,[212,214] of IL-6, T-cells, and B-cells in RA,[215,216] and of IL-17 and IL-23 in psoriasis.[153,217] Independent studies aimed at identifying predictors of response to TNF inhibition have evaluated a wide range of genetic, serum protein, or transcriptomic markers. Several potential predictors of response have been identified and may be helpful for guiding clinical decision in the future.[218,219]

Had conventional therapies been fully optimized? Treatment strategy trials in RA and CD

The availability of highly efficacious TNF inhibitors for RA renewed interest among rheumatologists in optimizing csDMARDs, alone or in combination, and the use of accelerated step-up therapy when they were not working. Confident in the knowledge that treatment alternatives with biologics existed if conventional therapies failed, physicians now monitored patients frequently in the expectation of high levels of efficacy, a practice known as “tight control”, and moved on to the next line of therapy if their treatment goal had not been met (and reduced treatment if it had), a practice now known as “treat-to-target”.[220–222] The question at hand was which of the various treatment strategies available, now including TNF inhibitors, was most likely to treat RA patients successfully?

This question was answered with the BeSt trial, an independent study conducted in the Netherlands, whose elegant design compared the safety and efficacy of the key therapeutic strategies in RA available to rheumatologists.[223] BeSt was a 10-year, multicenter clinical trial of csDMARD- and TNF inhibitor-naïve, early (≤2 years) RA patients randomized to one of four treatment strategies: sequential csDMARD monotherapy (group 1), step-up csDMARD combination therapy (group 2), initial csDMARD combination therapy with tapered high-dose prednisone (group 3), and initial combination therapy of Remicade plus MTX (group 4). Patients were assessed every 3 months, “tight control”, and treatment was adjusted according to a predefined treatment progression in each arm based on the ability to achieve low disease activity (LDA), a score ≤2.4 on the RA Disease Activity Score (DAS), “treat-to-target”. The overall objective of the study was to compare a step-up

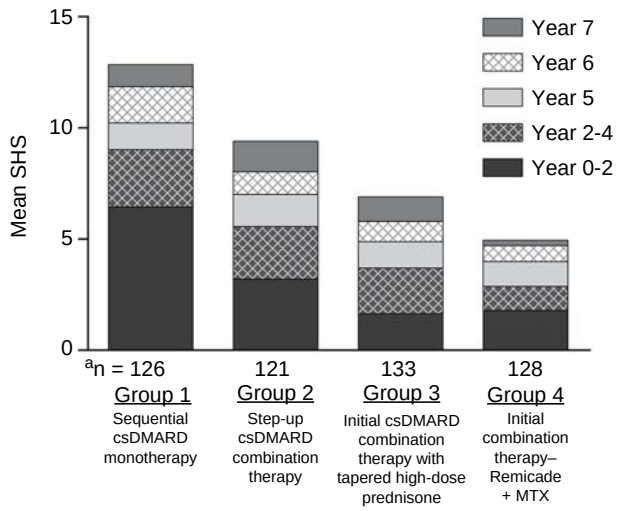


Figure 8 Cumulative progression of joint damage through year 7 in BeSt. Reproduced with permission from Van den Broek M, Lems WF, Allaart CF. BeSt practice: the success of early-targeted treatment in rheumatoid arthritis. *Clin Exp Rheumatol*. 30(4 Suppl 73):S35–S38. Copyright © 2012 *Clinical and Experimental Rheumatology SAS*.[225] [a]Sample size represents the population originally randomized to each arm. Numbers of patients at the end of each year of follow-up differed.
Abbreviations: csDMARD, conventional synthetic disease-modifying anti-rheumatic drug; MTX, methotrexate; SHS, Sharp/van der Heijde score.

approach (groups 1 and 2) with an aggressive approach (groups 3 and 4). Of note, groups 1, 2, and 3 could also receive Remicade plus MTX at some point during follow-up via progression to later steps of treatment if LDA was not achieved. Patients in group 4 could stop Remicade and even MTX if certain LDA and remission targets were achieved and sustained.[223,224]

At the end of year 1, mean scores on the Health Assessment Questionnaire (HAQ) were better with early aggressive treatment compared to the early step-up approach (P=0.009). Median increases in total radiographic joint score were higher in groups 1 and 2 than in groups 3 and 4 (P<0.001) and lowest of all in group 4, with no significant differences in adverse event or withdrawal rates among groups.[223] Annual assessments during the trial revealed how graduation to the next steps in the treatment algorithm based on achieving LDA or not led to smaller amounts of joint progression each successive year, highlighting the possibility of avoiding such damage by the use of an aggressive strategy early in the treatment timeline (Figure 8).[225]

After a decade of a treat-to-target approach in the BeSt study, radiographic progression remained low in all arms (mean increase in SHS at year 10 was estimated to be 14.2, 14.1, 14.6, and 8.9 in groups 1 to 4, respectively, P=0.046 for group 1 vs group 4) and functional ability approached normality for all groups (mean HAQ 0.6). Patients originally randomized to the combination of Remicade plus MTX (group 4) had the lowest structural damage and disability rates[61] and the lowest need to progress in the assigned treatment algorithm. Early aggressive treatment in groups 3 and 4 was not associated with worse safety outcomes, probably due to the overall improvement of symptoms of disease. The rate of mortality in the trial across all four arms was not increased compared with the normal population, which was unexpected for this disease and possibly related to effective suppression of inflammation. This unique study of treatment strategies in patients with early RA showed that a tight-control, treat-to-target approach prevents long-term progression of structural damage and disability, and that an early aggressive approach leads to better results than an early step-up approach.

In IBD, gastroenterologists asked questions similar to those asked in BeSt. Beyond SONIC and UC-SUCCESS, several trials of TNF inhibitors have investigated a variety of treatment strategies, including accelerated step-up therapy versus conventional treatment strategies (Step Up, Top Down, REACT),[194,226] managing patients based on clinical symptoms alone or serum levels of drug (TAXIT, TAILORIX),[227,228] basing treatment decisions on symptoms alone or in combination with objective markers of disease, such as fecal calprotectin (FCal) and CRP (CALM),[229] and how best to prevent recurrence post-surgery (PREVENT, POCER).[42,230] The results of these trials and others have led to conclusions parallel to those drawn from BeSt.

How has TNF blockade influenced treatment guidelines and health authority requirements for next-generation drugs?

Many of the changes in practice patterns made as a result of the use of TNF inhibitors have become standard and can be found in the treatment guidelines for each of their indicated diseases (Table 5). Across several leading professional organizations in IBD, such as ECCO and the American College of Gastroenterology (ACG),[212,214,252] CD and UC are recognized to be progressive diseases leading to irreversible damage in a substantial number of patients, driven in large part by inflammation that can be suppressed with TNF blockade. Goals of therapy are now steroid-free remission, rather than clinical response, and should include reductions in objective measures of inflammation, such as CRP and FCal, healing of the inflamed mucosa,[253] and ultimately, improved quality of life. Moreover, physicians should evaluate patients individually and frequently, stratify by risk, and take a proactive approach to achieving treatment goals. Should these goals not be met within designated times, eg, 6 months, then the treatment should be optimized.[232,254] Use of steroids should be limited and monotherapy with azathioprine is now discouraged.[255]

Table 5 Changes in treatment practices in the TNF era

Pre-biologics era	Biologics era
IBD[211,231–235]	
• Reactive disease management with intermittent monitoring	• Proactive, treat-to-target disease management with tight monitoring and shared patient/physician decision-making
• Symptomatic control with five ASAs, antibiotics, antidiarrheals, and narcotics; corticosteroids and thiopurines used as standard of care	• Steroid sparing strategy; avoidance of narcotics; avoidance of thiopurine monotherapy • Use of TNF inhibitors and other targeted therapies upon failure of first-line therapy
• No individualized treatment approach	• Individualized treatment approach considering patient characteristics, disease severity, prognostic factors, biomarkers, comorbidities, and therapeutic drug monitoring
• Treatment goals: ○ Induction/maintenance of clinical response ○ Suppression of disease-progression and bowel damage not addressed ○ Improvement in QoL and other PROs only secondary	• Treatment goals ○ Clinical, biologic (eg, CRP, FCal), and endoscopic remission ○ Prevention of irreversible bowel damage and long-term disability ○ Normalization of QoL and PROs ○ Comorbidities managed or avoided
RA,[215,216,236,237] **AS,**[238,239] **PsA**[240–243]	
• Reactive disease management with intermittent monitoring; symptomatic control (not using composite disease activity measures)	• Proactive, treat-to-target disease management with tight monitoring using of composite disease activity measures and shared patient/physician decision-making
• Corticosteroids, NSAIDs, and csDMARDs used as standard of care	• Early aggressive use of NSAIDS (AS) or csDMARDs with short-term corticosteroids (RA, PsA) • Use of TNF inhibitors and other targeted therapies upon failure of first-line therapy • Treatment tapering upon sustained remission
• No individualized treatment approach	• Individualized treatment approach considering patient characteristics, disease severity, prognostic factors, and comorbidities
• Treatment goals ○ Improvements in signs and symptoms ○ Suppression of disease-progression and structural damage not addressed ○ Improvement in QoL and other PROs only secondary	• Treatment goals ○ Remission or at least low disease activity (LDA) ○ Normalization of physical function and prevention of structural damage ○ Normalization of QoL and other PROs ○ Comorbidities managed or avoided
PsO[244–251]	
• Intermittent and cycling of therapies due to safety concerns	• Proactive, treat-to-target disease management with tight monitoring and shared patient/physician decision-making
• Phototherapy, topicals, or systemics used as standard of care, but associated with safety concerns and monitoring burden	• Phototherapy, topicals, or systemics used only for mild disease or as add-on therapy in moderate-to-severe disease; • Long-term maintenance therapy with TNF inhibitors and other targeted therapies
• No individualized treatment approach	• Individualized treatment approach considering patient characteristics, disease severity, prognostic factors, and comorbidities

(*Continued*)

Table 5 (Continued).

Pre-biologics era	Biologics era
• Treatment goals ○ PASI 50 ○ Improvement in QoL and other PROs only secondary	• Treatment goals ○ PASI 90 or PGA 0 or at least PASI 75 ○ Normalization of QoL and other PROs ○ Comorbidities managed or avoided

Abbreviations: AS, ankylosing spondylitis; 5-ASAs, aminoslicylates; CRP, C-reactive protein; csDMARD, conventional synthetic disease-modifying anti-rheumatic drug; FCal, fecal calprotectin; IBD, inflammatory bowel disease; NSAID, non-steroidal anti-inflammatory drug; PASI, Psoriasis Area and Severity Index; PGA, Physician Global Assessment; PRO, patient-related outcome; PsA, psoriatic arthritis; PsO, psoriasis; QoL, quality of life; RA, rheumatoid arthritis; TNF, tumor necrosis factor.

In RA, leading professional organizations, such as the European League Against Rheumatism (EULAR) and ACR,[215,216] now incorporate the general principles of tight control and treat-to-target in their treatment guidelines: early assessment of prognostic factors to weigh risk of disease progression; immediate use of MTX in combination with short-term steroids as a preferred first-line therapy; assessment of response to therapy every 3–6 months, including objective markers of inflammation, with LDA, if not clinical remission, and inhibition of joint progression as treatment goals; and continued and quick progression to the next line of therapy when treatment goals are not met.

Even in psoriasis, where Remicade is often overlooked because of the preference for subcutaneous TNF inhibitors and next-generation biologics, it was recognized early on for its quick onset of action and high degree of efficacy.[106] The advent of biologics has led to more stringent treatment goals and earlier treatment.[246] Prior to their availability, a 50% reduction in a patient's Psoriasis Area and Severity Index (PASI) score, measuring the proportion of skin covered with psoriatic plaques, was the goal of therapy. With today's new therapies, an improvement of this limited magnitude would likely trigger a change in therapy, with the goal being at least a 75% reduction in PASI and an improved quality of life (Dermatology Life Quality Index ≤5). With the next-generation biologics, IL-23 and IL-17 inhibitors, 90% PASI reductions and even full clearance of disease are realistic goals. While this disease lacks a long-term structural damage component found in the other indications of TNF blockade, it is associated with compromised psychosocial status, which the evidence suggests might be limited or even reversed with successful treatment.[256] Treatment guidelines now reflect tight-control and treat-to-target approaches with use of TNF inhibitors and other biologics recommended if phototherapy and conventional systemic agents fail to provide an adequate response.[241] Some experts go further and consider that with the long-term experience gathered with the use of biologics, no reason supports reserving them for second-line use.[185,217,257]

The improvement in outcomes offered by TNF inhibitors has also contributed to changes in the requirements of health authorities for the evaluation of new treatments. This is most evident in RA, where, for example, both the EMA and the FDA require greater improvement in symptoms than before TNF inhibitors were available. Where both had previously required evidence of improvement in single or composite measures of disease activity (eg, tender and swollen joint counts, ACR20), remission or measures of LDA should now be considered as evidence of efficacy.[258–260] The availability of improved therapies has provided a rationale for limiting the exposure of patients to placebo or ineffective therapies for a prolonged period of time; treatment longer than 12 weeks should include either an active comparator as the control or provisions for escape to rescue treatment for patients with active disease. Both health authorities recognize that demonstrating a benefit on structural damage is increasingly difficult because joint erosions are now unlikely to develop in this setting.

In both CD and UC the pattern is similar. Major health authorities today consider clinical remission, as opposed to response, to be an appropriate endpoint on which to evaluate a drug's efficacy. Moreover, while necessary, symptomatic response is no longer adequate. Both the FDA and the EMA now also require evidence of endoscopic improvement of disease, in recognition of mucosal inflammation as the underlying cause.[261–265]

Summary and conclusion

In 1992, when Janssen first provided the cA2 antibody to the Kennedy Institute to test the hypothesis that inflammation in RA is driven by TNF and could be suppressed with TNF blockade, no one could have foreseen the contributions the drug would make to science and medicine over the subsequent 20+ years. As described in this review, the learnings from Remicade can be divided into five categories, ranging from principles of drug development to practice of medicine to our understanding of the immune system.

First, Remicade was one of the first mAbs to establish the proof of principle of their use as the highly targeted therapies imagined at the time of their introduction in 1975, and was the first to establish a role for them in chronic diseases. Early studies with Remicade demonstrated how to administer mAbs while limiting their immunogenicity, enabling them to be used long term. Combined with the success of other early mAbs, eg, rituximab, trastuzumab, and related constructs, eg, etanercept, they have come of age, with more than 60 approved for use targeting a variety of specific mediators, over 30 of which are in chronic diseases.[266,267] At least 250 mAbs are in development today.[268] Research has already moved from chimeric to fully human mAbs and continues to advance to next-generation agents, such as bispecific antibodies and antibody–drug conjugates.[266]

Second, the proof of principle that targeted therapy could be an effective strategy to treat IMIDs was first demonstrated with Remicade. Despite the complexity of the immune system, initial studies confirmed that, at least in some diseases, the inflammatory response works in cascades; and inhibition of a single cytokine initiating a cascade can have a profound effect on disease. Targeted blockade of a single cytokine can yield a safety profile generally consistent with that of conventional immunosuppressants, yet without their cumulative and off-target toxicity risks and with a degree of efficacy well beyond what they provide. Today, most new drugs in development, biologics and small molecules alike, target specific mediators of disease.

Third, the Remicade postmarketing safety surveillance program, including both PMCs and routine pharmacovigilance, has been pioneering in establishing methodological and operational requirements for safety studies and in setting standards for design, scale, rigor, and duration of follow-up, specifically in the real-world setting. The program provided new understanding of the risks of conventional therapies and of the diseases themselves, knowledge that is essential when judging the relative risks and benefits of new therapies. Innovative solutions, such as use of big data, claims databases, and combining various data sources, have been established as feasible and acceptable methods of safety monitoring. Strong working relationships with a large network across academia are required to access existing data sources and to seek independent expertise in study design, conduct, and interpretation of results. Similarly, cooperation and transparency with health authorities are imperative, as is a commitment to publish results. Above all, adequate resources need to be allocated by the company, often for years, to handle the volume of work and to provide the expertise required across multiple disciplines.

Fourth, Remicade, surely one of the most rigorously studied biologics in medicine today, has taught us much about the role of TNF in the immune system and in the pathophysiology of several diseases. TNF drives the inflammation found in several IMIDs and does so in early as well as late disease. Conversely, the lack of benefit of TNF blockade in a number of diseases where it is elevated indicates that TNF elevation does not always mean that inflammation is mediated by or dependent on TNF. The studies where TNF blockade was not successful were not without scientific benefit, as they provided insights into the pathophysiology of these diseases. The effective use of TNF blockade in some diseases has given us hope that targeted therapy might work in others, and has fueled research that has already led to the approval of drugs targeting other components of the immune system (cytokines, receptors, integrins). Study of TNF blockade has also confirmed much of what was suspected about TNF's role in the immune system, in particular regarding infection, and broadened it further, as seen in demyelinating disorders, CHF, and paradoxical adverse events. Importantly, studies with Remicade and subsequent TNF inhibitors demonstrated that certain cytokines with a broad function in the immune system can be blocked without triggering an unacceptable level of safety risk.

The final category of Remicade's contributions is its influence on the practice of medicine. Across six different diseases, the improved efficacy of Remicade and other TNF inhibitors compared with conventional therapies has led to more ambitious treatment goals. Rather than just reducing symptoms, TNF blockade was able to address the underlying pathophysiology driving these diseases, thereby modifying their course, such that irreversible damage to the joints and the bowel could be avoided. This led to earlier treatment, use of predictors of disease progression and response, tighter monitoring and the use of treat-to-target approaches, and a reassessment of conventional therapies to optimize their safety and efficacy. In the case of rheumatology, csDMARDs, in particular MTX, experienced new life as therapies. In the case of IBD, the limitations of steroids and thiopurines became apparent. Clinical research on TNF inhibitors has led to different ways of assessing disease, the most vivid example being AS, where use early in the course of the disease led to the definition of a new disease entity, nonradiographic axial SpA. Lastly, the availability of TNF blockade has led to higher standards for assessing new therapies.

Even today, the list of learnings is still growing. Several studies in the Remicade PMC program are still ongoing (Table 4). Other studies continue to refine the use of TNF inhibitors in such areas as combinations with conventional therapies,

predictors of response, dose titration, and possible discontinuation after successful, sustained response. Independent investigators are conducting proof-of-concept studies with Remicade as treatment for various conditions not yet evaluated, including bipolar disorder, hypertension, and type 1 diabetes (Table 2). The study of the effect of TNF blockade on long-term comorbidities continues, prompted by the hypothesis that the inflammation driving IMIDs is also a contributor to these comorbidities, ie, cardiovascular complications or colorectal cancer in UC.

Perhaps Remicade's most important legacy is the impact it has had on the lives of many of the estimated 3 million patients it has been used to treat (Janssen, data on file). Recent studies across its indications have found that patients treated today with Remicade have lower levels of disease activity and shorter duration of disease at the time of initiation of treatment than in the past, resulting in lower rates of disability and improved quality of life. When combined with the patients receiving other TNF inhibitors, this amounts to a substantial decrease in the burden of some of the most common IMIDs in our society.[269–273] Amid Remicade's other considerable contributions to science and medicine, on which this manuscript has focused, this contribution to public health is perhaps the most important of all.

Abbreviation list

ACR, American College of Rheumatology; ACR20, 20% reduction in ACR response criteria; ADA, anti-drug antibody; ADCC, antibody-dependent cellular cytotoxicity; ADR, adverse drug reaction; AS, ankylosing spondylitis; axSpA, axial spondyloarthritis; AZA, azathioprine; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; CD, Crohn's disease; CDAI, Crohn's Disease Activity Index; CHF, congestive heart failure; CNS, central nervous system; CRP, C-reactive protein; csDMARD, conventional synthetic disease-modifying anti-rheumatic drug; DAS, disease activity score; DLQI, Dermatology Life Quality Index; ECCO, European Crohn's and Colitis Organisation; EMA, European Medicines Agency; Fab, (antibody) fragment antigen-binding; Fc, (antibody) fragment constant; FCal, fecal calprotectin; FDA, US Food and Drug Administration; GM-CSF, granulocyte-macrophage colony-stimulating factor; HAQ, Health Assessment Questionnaire; HSTCL, hepatosplenic T-cell lymphoma; IBD, inflammatory bowel disease; IgG, immunoglobulin G, antibody type G; IL, interleukin; IMID, immune-mediated inflammatory disease; JRA, juvenile rheumatoid arthritis; LDA, low disease activity; mAb, monoclonal antibody; MRI, magnetic resonance imaging; MS, multiple sclerosis; MTX, methotrexate; NHL, non-Hodgkin's lymphoma; NK, natural killer; nr-axSpA, non-radiographic axial spondyloarthritis; NSAID, non-steroidal anti-inflammatory drug; NYHA, New York Heart Association; p75, another name for TNFR2; PASI, Psoriasis area and severity index; PBO, placebo; PGA, Physician Global Assessment; PK, pharmacokinetics; PMC, postmarketing commitment; PRO, patient-reported outcome; PsA, psoriatic arthritis; PsO, psoriasis; QoL, quality of life; q4w, every 4 weeks; q8w, every 8 weeks; RA, rheumatoid arthritis; SHS, Sharp/van der Heijde score; SJC, swollen joint count; SLE, systemic lupus erythematosus; SpA, spondyloarthritis; sTNF, soluble TNF; TB, tuberculosis; tmTNF, transmembrane TNF; TNF, tumor necrosis factor; TNFR1, TNF receptor 1, also known as p55; TNFR2, TNF receptor 2, also known as p75; UC, ulcerative colitis; VEGF, vascular endothelial growth factor.

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Disclosure

RM, AG, and IA are current employees of Janssen Pharmaceuticals and stockholders in Johnson & Johnson, Janssen's parent company. TS is a former Janssen employee and a stockholder in, and receives a pension from Johnson & Johnson. The authors report no other conflicts of interest in this work.

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Exhibit “J34”

This is Exhibit “J34” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

Government of Canada Gouvernement du Canada

Product information

From Health Canada

New search

The product monograph is developed by a drug sponsor according to guidelines published by Health Canada that provide direction on the content and format. The veterinary labelling is developed by the drug sponsor according to the Food and Drug Regulations. While Health Canada reviews the product monograph or the veterinary labelling as part of the drug review process, it remains the responsibility of the drug sponsor to ensure that the product monograph or the veterinary labelling is complete and accurate.

Current status:

Marketed

Current status date:

2011-11-22

Original market date: [1]

2001-06-14

Product name:

REMICADE

Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section.

DIN:

02244016

1800

Product Monograph/Veterinary Labelling:

Date: 2024-03-26

Product monograph/Veterinary Labelling (PDF version ~ 175K)

Company:

JANSSEN INC
19 Green Belt Drive
Toronto
Ontario
Canada M3C 1L9

Class:

Human

Dosage form(s):

Powder For Solution

Route(s) of administration:

Intravenous

Number of active ingredient(s):

1

Schedule(s):

Schedule D , Prescription

American Hospital Formulary Service (AHFS): [3]

92:36.00

Anatomical Therapeutic Chemical (ATC): [4]

L04AB02 INFLIXIMAB

Active ingredient group (AIG) number: [5]

0144162001

List of active ingredient(s)

Active ingredient(s)	Strength
INFLIXIMAB	100 MG / VIAL

Risk Management Plans [7]

A Risk Management Plan (RMP) for this product was submitted.

Additional Risk Minimization Measures
Patient Wallet Card
Patient Education
Healthcare Professional Education

Pharmacovigilance/Monitoring Activity
Registry

New search Same active ingredient group number

Footnotes

1 The earliest marketed date recorded in the Drug Product Database.

3 The American Hospital Formulary Service permits an easy review of information on a group of drugs with similar activities and uses and allows the reader to determine quickly the similarities and differences among drugs within a group. *AHFS® Pharmacologic/Therapeutic Classification*© used with permission. © 2022, the American Society of Health-System Pharmacists, Inc. (ASHP). The Data is a part of the AHFS Drug Information®; ASHP is not responsible for the accuracy of transpositions from the original context.

4 The purpose of the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification system is to be used as a tool for drug utilization research in order to improve quality of drug use. Drugs are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutical properties. 1802

5 The AIG number is a 10 digit number that identifies products that have the same active ingredient(s) and ingredient strength(s). The AIG is comprised of three portions:

- the first portion (2 digits) identifies the number of active ingredients,
- the second portion (5 digits) identifies the unique groups of active ingredients(s),
- the last portion (3 digits) identifies the active ingredient group strength. The strength group has a tolerance of -2% to +10%.

7 Refer to the Health Canada Guidance Documents - "Submission of Risk Management Plans and Follow-up Commitments" as well as "Submission of targeted Risk Management Plans Follow-up Commitments for Prescription Opioid-containing Products" for additional details.

Application information

Search tips

Drug product database terminology

Drug product database data extracts

Related information

MedEffect Canada

Adverse drug reaction - veterinary drugs

Notice of compliance database

Licensed natural health products database

Contact us

Content support

Technical support

Version 4.0.2

Date modified: 2024-02-28

Exhibit “J35”

This is Exhibit “J35” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

INVESTIGATION

How a blockbuster drug tells the story of why Canada's spending on prescriptions is sky high

Remicade, a drug that treats arthritis and Crohn's disease, has been a runaway success in Canada. But, as Kelly Grant reports, its rise reveals vulnerabilities of a fractured system

KELLY GRANT > HEALTH REPORTER

PUBLISHED OCTOBER 20, 2018
UPDATED OCTOBER 23, 2018

A technician at Mount Sinai Hospital demonstrates how Remicade, a drug to treat Crohn's disease, would be administered. Remicade has a much higher market share than in Canada than in other developed countries, and Canadians also pay a higher price.

CHRIS DONOVAN/THE GLOBE AND MAIL

More below• The backstory to this report

On Feb. 29, 2016, a curious fax landed in the hands of Michael Ritchie, a supervisor in the hospital pharmacy at Toronto's Sunnybrook Health Sciences Centre.

It was an out-of-the-blue letter from Janssen, a unit of the pharmaceutical giant Johnson & Johnson, offering a discount on Remicade, a medication that eases the often harrowing symptoms of patients with Crohn's disease, ulcerative colitis and rheumatoid arthritis.

Normally, it is priced at $987.56 for each of the three or four vials required at every IV infusion.

But Janssen was prepared to give Sunnybrook – and, as it turned out, every other hospital in Canada – an unusual deal. "As a valued partner for Janssen," the letter began, "we are pleased to offer you a reduced hospital price of $0.01 for Remicade … inpatient use."

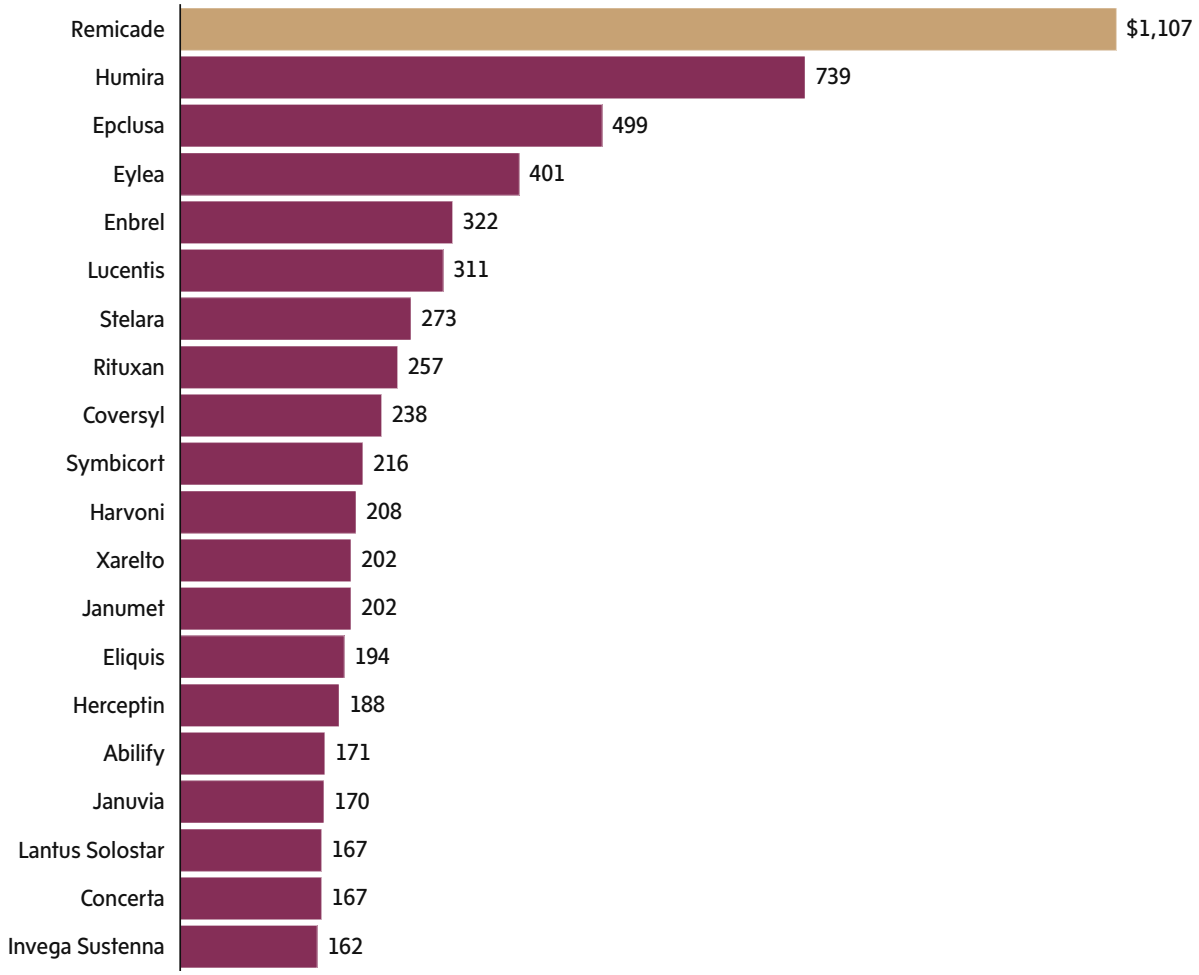
In an e-mail to his boss, Mr. Ritchie skewered the audacious offer with an exaggerated subject line: "Remicade bribe."

At the time, Janssen was facing competition from a new kind of drug called a biosimilar – a cheaper alternative that is almost, but not quite, the equivalent of a generic. The new version retailed for $525 a vial, about half the price of Remicade. Provincial governments and some private insurers were planning to promote the cheaper option by dictating that new patients would be covered only for this newer drug.

Janssen's penny-a-vial offer is one of several aggressive tactics The Globe and Mail uncovered in an investigation into the juggernaut that is Remicade. With $1.1-billion in sales in 2017, it is Canada's top-selling drug by revenue, according to the pharmaceutical analytics company IQVIA, and one of the most lucrative in the country's history. It is one of only two drugs to eclipse a billion dollars in sales in Canada in a single year.

To protect Remicade's market share, Janssen has signed confidential pricing deals with insurers, covering more than 90 per cent of privately insured Canadians; taken the Quebec government to court over its decision to stop covering Remicade for new patients; deployed a deep discount to separate Prince Edward Island from the federal-provincial-territorial alliance that negotiates drug deals; and attempted to dissuade physicians and patients from choosing biosimilars.

Top 20 drugs by annual sales in Canada, 2017
in millions of dollars



THE GLOBE AND MAIL, SOURCE: IQVIA

DATA SHARE

Read more below about how The Globe obtained the data for this story, and read letters about drug pricing between the maker of Remicade and the Patented Medicine Prices Review Board.

The Globe investigation also found that Janssen has for years paid Canadian doctors each time Remicade is infused in their offices – a practice that is in a legal grey area in one province, Ontario. Pharmaceutical policy experts, though, call it a thinly disguised incentive to prescribe Remicade.

Janssen says its sales and marketing tactics are guided by one principle: its desire to ensure physician choice and patient access to its drugs. The one-cent-a-vial offer, Janssen contends, was never intended to gain public coverage of Remicade for new patients after they left the hospital, but to make sure physicians and patients, including children with severe bowel disease, could still get the drug they needed. The biosimilar, called Inflectra, is not yet approved for children.

Janssen's Canadian division and its parent company, Johnson & Johnson, are hardly the only pharmaceutical giants who play hardball to protect their bottom lines. The manufacturers of other infused drugs, including Pfizer, which makes Inflectra, pay per-infusion fees to doctors, too. But Janssen's constellation of efforts on behalf of Remicade in Canada have succeeded in a way that puts the drug in a league of its own.

Canadians pay a higher sticker price for Remicade, and use much more of it per capita, than in the United States or Europe, according to the federal drug-pricing regulator – this despite the fact that Remicade's patent has expired and there are cheaper options available.

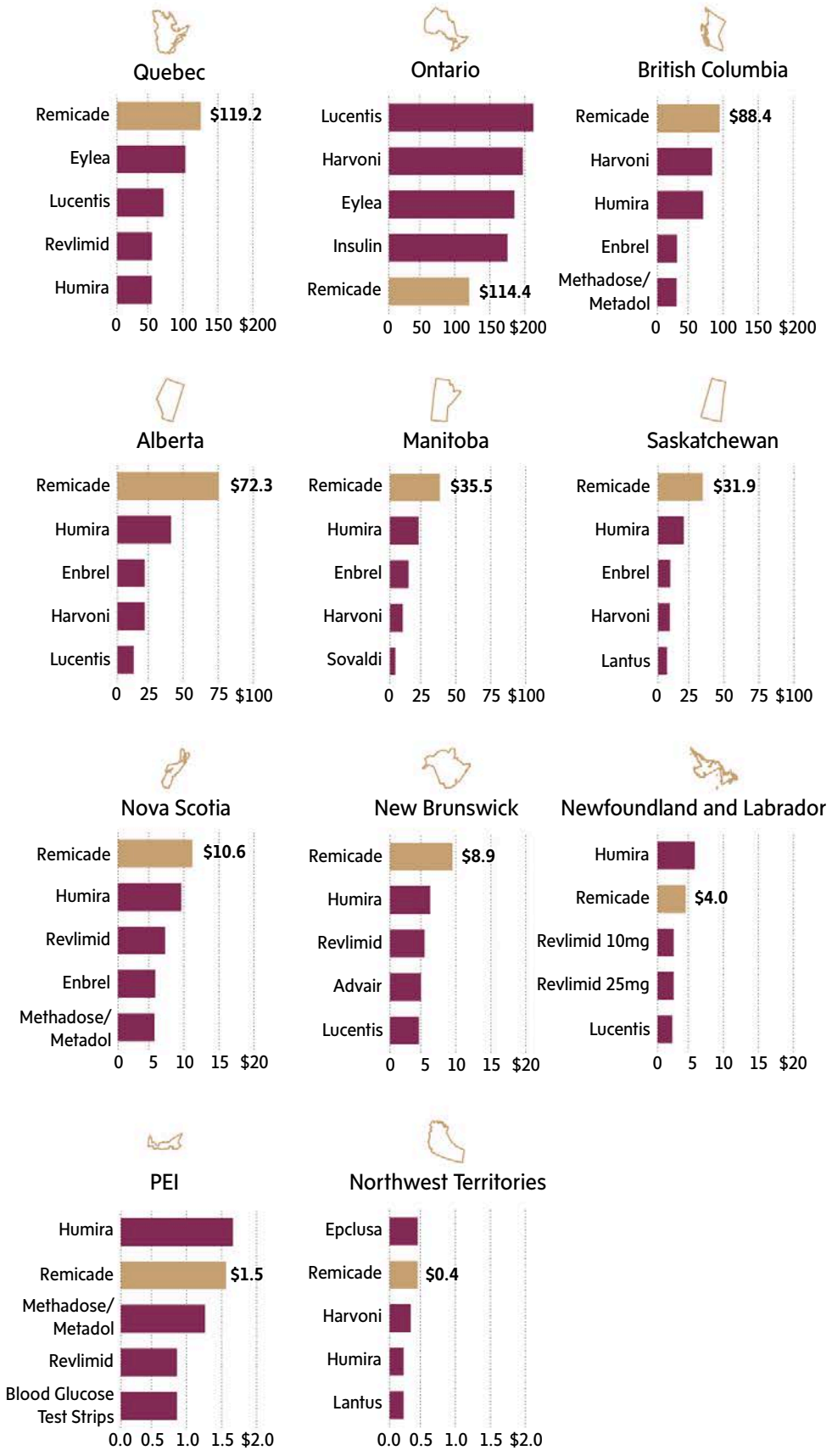
"When you compare Canada to other countries," says Marc-André Gagnon, a pharmaceutical-policy expert at Carleton University in Ottawa, "there is something going on with this drug."

During a 10-month investigation, The Globe examined documents obtained through 30 Freedom of Information Act requests and conducted more than 50 interviews with doctors, patients and drug-industry insiders. The result is an unvarnished look at how drug companies take advantage of a fractured system, in which Canadians pay for prescription drugs through more than 100 public and 100,000 private insurance plans. It is a system that is ripe for manipulation.

Remicade's success in Canada is not a story about a bad or ineffective drug thrust upon patients who don't need it. Remicade is a good drug – a wonder drug, even. But in revealing how it is sold and promoted in this country, and the health-care policies that allowed it to gain such a foothold, a picture emerges that helps explain why, per capita, only the United States and Switzerland among Organization for Economic Co-operation and Development countries spend more on drugs than Canada does.

Top 5 drugs by public spending, 2017

In millions of dollars



Note: Total government spending usually includes markups and dispensing fees. In Ontario and Nova Scotia, the totals for Remicade include a small amount of spending for Inflectra, a biosimilar of Remicade. No data available in Nunavut and Yukon.

CHEN WANG/THE GLOBE AND MAIL, SOURCE: PROVINCIAL AND TERRITORIAL HEALTH MINISTRIES

Read our note on data below

About 300,000 Canadians suffer from rheumatoid arthritis. Crohn's disease and ulcerative colitis afflict nearly 250,000 people in Canada, which has one of the highest reported prevalence rates of the conditions in the world – a fact that goes some of the way toward explaining why Canada uses more drugs like Remicade than most other countries.

All three conditions are autoimmune disorders, and all can be debilitating.

It used to be that physicians had little to offer these patients. Scientists did not understand precisely how autoimmune disorders turned the body's defence system against itself, inflaming the joints or gastrointestinal tract.

That started changing when Marc Feldmann, an Australian immunologist, began looking, in the 1980s, for an answer in cytokines, a group of small proteins that tell the cells in the immune system how to behave. Working in a London lab with tissue from the knee joints of rheumatoid-arthritis patients, Dr. Feldmann and his research partner, rheumatologist Ravinder Maini, found they could halt a cascade of inflammatory effects by blocking the haywire signals from one type of cytokine called tumour necrosis factor alpha, or TNFa.

That discovery led to the testing of a TNF-blocking molecule called infliximab – then owned by Centocor, a small Pennsylvania biotechnology company – on patients with rheumatoid arthritis. Delivered by intravenous drip, infliximab was a biologic, a complex drug manufactured in living cells. It nearly erased the horrific symptoms of rheumatoid arthritis, but only for about 10 weeks. The relapses signalled that Centocor had a breakthrough far more lucrative than a cure: a drug that could transform lives, but which patients would have to take – and pay for – for years to come.

In 1999, Johnson & Johnson bought Centocor. More than a decade later, it renamed the unit Janssen. (Janssen Canada, meanwhile, took over the marketing of Remicade from Merck in 2011.)

Today, more than 25 years after the initial clinical trial of infliximab, the drug that would eventually be sold under the brand name Remicade, TNF-blockers bring in more money worldwide than any other class of drug. Remicade is now the fifth-best-selling drug in the world, with global sales of US$7.2-billion in 2017, according to EvaluatePharma, a U.S. company that analyzes the pharmaceutical and biotechnology sectors.

In Canada, Remicade is not fifth, but first.

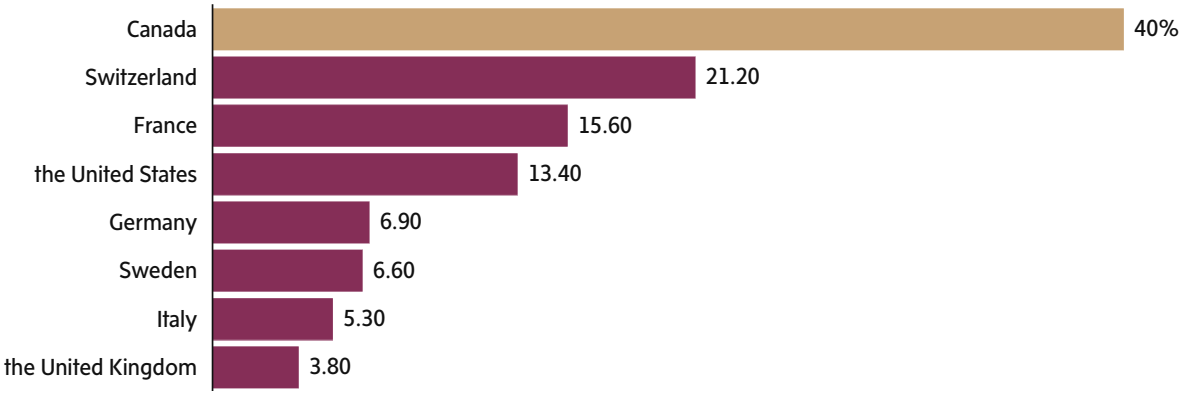
Janssen, however, contends that Remicade is no longer the Canadian sales behemoth it appears to be. Data from IQVIA show Remicade is losing ground to competitors among new patients, but they also show prescriptions for the drug have steadily risen for the past five years.

But when it comes to sales, it's hard to know the truth. All publicly available information about brand-name drug sales in Canada must be gleaned from "list" prices, which don't reflect confidential discounts and rebates now commonplace in the global pharmaceutical industry.

Even the Patented Medicine Prices Review Board, Canada's drug-pricing regulator, is left in a position of trying to divine what it can from those list prices. And Canada's Freedom of Information laws are no help on this front: Such laws exempt commercial secrets. (And those secrets are tightly guarded: When three Toronto hospitals were prepared to release details of the one-cent-vial offer through an FOI request, Janssen objected. The case is now in the hands of the province's Information and Privacy Commissioner. The Globe obtained a copy of the fax.)

Still, it's clear the footprint of Remicade is much larger in Canada than elsewhere. According to the federal drug-pricing regulator, Remicade accounted for 40 per cent of all the biologic disease-modifying antirheumatic drugs sold in Canada last year – compared with roughly 21 per cent in Switzerland, 13 in the United States, 7 in Germany and 4 in Britain. Janssen says the report that includes those figures is misleading and lacks context, but the regulator stands by the report.

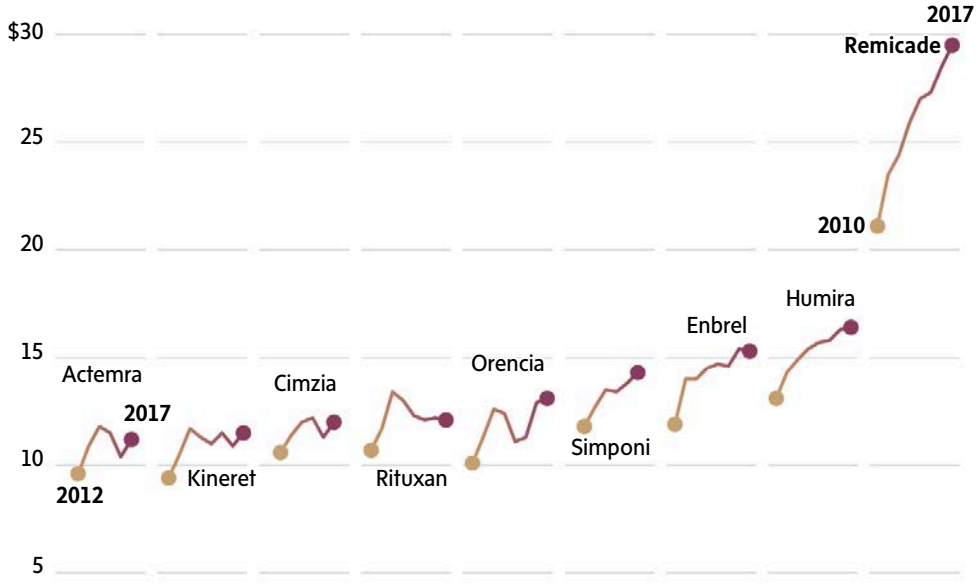
Proportion of Remicade in the total sales of biologic DMARDs* in Canada and PMPRB7, 2017**
percentage



THE GLOBE AND MAIL, SOURCE: PATENTED MEDICINE PRICES REVIEW BOARD, *DMARDS: DISEASE-MODIFYING ANTIRHEUMATIC DRUGS, **PMPRB7: FRANCE, GERMANY, ITALY, SWEDEN, SWITZERLAND, THE UNITED KINGDOM AND THE UNITED STATES

DATA SHARE

Annual treatment costs in public drug plans, by biologic DMARDs*, 2010 to 2017
In thousands of dollars



*DMARDs: Disease-modifying antirheumatic drugs.
Note: The start date for Actemra, Cimzia and Simponi is 2012.

MURAT YÜKSELIR/THE GLOBE AND MAIL, SOURCE: PATENTED MEDICINE PRICES REVIEW BOARD

Read our note on data below

As the first widely sold intravenous therapy for a chronic disease, Remicade's arrival on the scene, in 2001, confounded a Canadian policy born in the age of simple pills: Hospital care is free to patients, but prescription drugs taken outside of a hospital are not. Which was Remicade?

Hospital outpatient clinics, mindful of shouldering the cost of one of the most expensive medications ever sold in Canada, were slow to make space for Remicade users, who usually require a two-hour IV drip every eight weeks. So Schering-Plough, the company that launched Remicade here on Centocor's behalf, did something radical: It set up its own infusion centres in strip malls and office blocks, helping to spawn a large private infusion industry that today operates alongside Canada's public health-care system.

"To some extent, it was a relief," says Steve Long, a pharmaceutical-industry consultant and a former head of Alberta's public drug program. More patients got Remicade and hospitals saved money, with those costs offloaded to private insurers and provincial government-sponsored drug plans.

Ontario's drug plan for patients with catastrophic annual drug costs saw its budget soar from about $50-million in 2000 to almost a half-billion dollars by 2016, according to a study published in March of this year. Although other high-priced drugs played a part, the program paid out twice as much for Remicade as for any other drug in 2015. Seven of 10 Canadian provincial governments say they spend more on Remicade than on any other prescription drug.

Today, about 90 per cent of all Remicade is delivered at private infusion centres, which also infuse other intravenous medications. Such centres are paid for by drug makers and run by third parties such as McKesson, the drug distributor and pharmacy company that owns the Rexall drug-store chain, and Innomar Strategies, whose clinics are exclusive providers of Inflectra, the Pfizer-owned biosimilar of Remicade. At most such clinics, nurses insert the intravenous lines and monitor the infusions, while doctors are paid to be on-call in case of serious drug reactions. As Janssen points out, these pharma-sponsored clinics save the public health-care system money.

Janssen has also insinuated itself directly into the public health-care system, in limited ways, by sponsoring infusion services inside at least two hospital outpatient clinics and even in the offices of doctors themselves. The company pays doctors who operate infusion chairs inside 46 offices across the country – most of those home to multiple practitioners – a fee of $275 for every infusion of Remicade, The Globe has learned. (Janssen would not confirm the amount of the fee, calling it confidential.) It is, of course, a fee that would not be paid if patients were prescribed one of the drugs that can be injected at home.

Pfizer, in a bid to keep pace with Janssen, says it also pays doctors $275 for every in-office infusion performed. Both companies say the fees are meant to help doctors defray their overhead costs, particularly the salary of infusion nurses.

And while the drug companies say the health-care system has left them with no choice but to pay per-infusion fees, that is not strictly true everywhere. Ontario's Ministry of Health and Long-Term Care says it has a billing code that doctors can charge for starting or supervising infusions of Remicade, even if the work is delegated to a nurse. What is true: The code pays significantly less than $275 per infusion.

Of the 40 or so doctors The Globe tried to contact, one of the few on-the-record responses came from Mary Morgan, the manager of the screening clinic at Toronto's non-profit Kensington Health, whose services include a long-term care home, a hospice, a surgical eye centre and the screening clinic that Ms. Morgan manages.

Beginning in the 2013-14 fiscal year, Kensington opened an infusion room. Janssen lent the clinic three lounge chairs – Janssen says it has since discontinued the practice of lending equipment such as chairs and IV poles – while McKesson lent a medical fridge, said Ms. Morgan. Under the terms of its deal with Janssen, the clinic receives "a per-infusion, per-person fee" every time a patient receives an IV drip of Remicade, Ms. Morgan said.

The clinic also receives a payment from McKesson for reconstituting, or mixing, the drug, Ms. Morgan said, adding that the amount of both fees is protected by a non-disclosure agreement. (A McKesson spokesman declined to answer a list of detailed questions, including whether it pays fees to doctors for infusions. "The implication that McKesson Canada impacts prescribing rates of Remicade is categorically false," spokesman Darius Kuras wrote in an e-mail.)

Ms. Morgan, a nurse who began managing the clinic last spring, said the ethics of accepting fees for infusions from a drug company has never come up as a concern for the clinic's doctors, who like that the infusion room allows them to keep a closer eye on patients. "We are a not-for-profit," she said. "We just need [our staff's] time to be reimbursed and our space to be reimbursed."

Innovative Medicines Canada, the industry group that represents makers of brand-name drugs, has a Code of Ethical Practices that prohibits its member companies from making payments to doctors that could be construed as an incentive to prescribe a particular medication. Both Janssen and Pfizer say infusion fees don't break the industry's Code of Ethics. "We've been through this with [Innovative Medicines Canada]," said Andy Williams, Janssen Canada's vice-president of sales and marketing for immunology drugs. "The practice is not a secret and it's certainly not unique to Janssen. All the elements of the practice have been scrutinized, per the code, and have been deemed to be not in violation."

On its face, infusion fees would also appear to break a 2004 Ontario law designed to prevent third parties from paying doctors to perform services that are paid for by the Ontario Health Insurance Plan (OHIP). Providing infusions of Remicade is an insured service in Ontario, according to the Ministry of Health and Long-Term Care. Doctors can bill $54.25 per infusion.

Janssen disputes this as well: Citing fine print in the schedule of benefits for physicians in Ontario – home to 31 of Janssen's 46 in-office infusion locations – the company argued that doctors cannot bill anything to the public system for providing infusions in their offices. The Ontario ministry, presented with Janssen's interpretation, disagreed.

Either way, Janssen spokeswoman Teresa Pavlin said, the company's contracts make clear that the fees are not to be treated as an incentive to prescribe and that doctors can't bill the public purse while also accepting infusion fees for the same service. "While the ultimate responsibility lies with physicians to ensure that they utilize available billing codes, Janssen has never been informed of the availability of such codes until now."

Ontario government bureaucrats, however, had concerns about the fees to doctors. A 2017 briefing note drawn up for Ontario's deputy health minister, and obtained by The Globe through a Freedom of Information request, flagged the risk that infusion fees "may be viewed as incentives for physicians to prescribe and administer select drugs."

Matthew Herder, the head of the Health Law Institute at Dalhousie University in Halifax, is even blunter. "It's a huge ethical question," Mr. Herder said of the per-infusion fees. "There are clear

grounds for a complaint on conflict of interest."

Nav Persaud, a family physician and associate scientist at St. Michael's Hospital in Toronto who studies pharmaceutical policy, called the per-infusion fee structure a "high-risk scenario" for undue influence on prescribing behaviour. "It's hard for me to think of a higher-risk situation."

The Ontario briefing note does not mention Janssen or Remicade by name, but it does enumerate the risks inherent in letting brand-name biologics makers pay infusion fees: "Physicians may be influenced to prescribe a certain biologic; physicians may be reluctant to switch or start their patients on biosimilars due to fees paid to the physician by the brand manufacturer; [and] the ministry's savings potential due to market entry of biosimilars may be less than expected if physicians continue to get administration fees for branded biologics." (The writers of the briefing note seemed unaware that Pfizer had also begun paying doctors $275 fees for infusions of Inflectra.)

Dr. Nav Persaud of St. Michael's Hospital in Toronto says per-infusion fees put physicians at undue risk of outside influence.

CHRISTOPHER KATSAROV/THE GLOBE AND MAIL

Despite those concerns, Ontario's former Liberal government took no public action against drug or specialty pharmacy companies who paid these fees, or doctors who accepted them, before the Progressive Conservatives swept them out of office in June. Now, Janssen says it is phasing out its in-office infusion program, because it has enough private clinics to satisfy the demand for Remicade.

Doctors' offices are not the only places accepting fees from drug companies, including Janssen, for every infusion.

Toronto Western Hospital, part of the University Health Network (UHN), also accepts a fee of $275 for every infusion of Remicade – and Pfizer's Inflectra, for that matter – provided in its outpatient infusion clinic, which was founded nearly 20 years ago to facilitate a clinical trial of Remicade.

In fact, a Janssen-paid patient support program co-ordinator had worked inside the Toronto Western clinic from 2000 until late last year, educating patients and helping them to secure insurance coverage of Janssen drugs. (UHN ordered the job description changed last fall after The Globe asked about a Janssen want ad seeking to replace the co-ordinator. The post has not been filled.)

The payments for infusions go to the budget of UHN's Division of Rheumatology – not into doctors' pockets – and cover nursing services at the clinic. But if UHN doctors prescribe alternative medications that patients swallow or inject at home, the hospital earns nothing.

In 2017-18, infusion payments brought in $153,725 for UHN, the vast majority for Remicade infusions.

Although Jorge Sanchez-Guerrero, the chief of the division of rheumatology at UHN, says "there are many, many advantages" to providing infusions in a hospital outpatient clinic, where doctors can

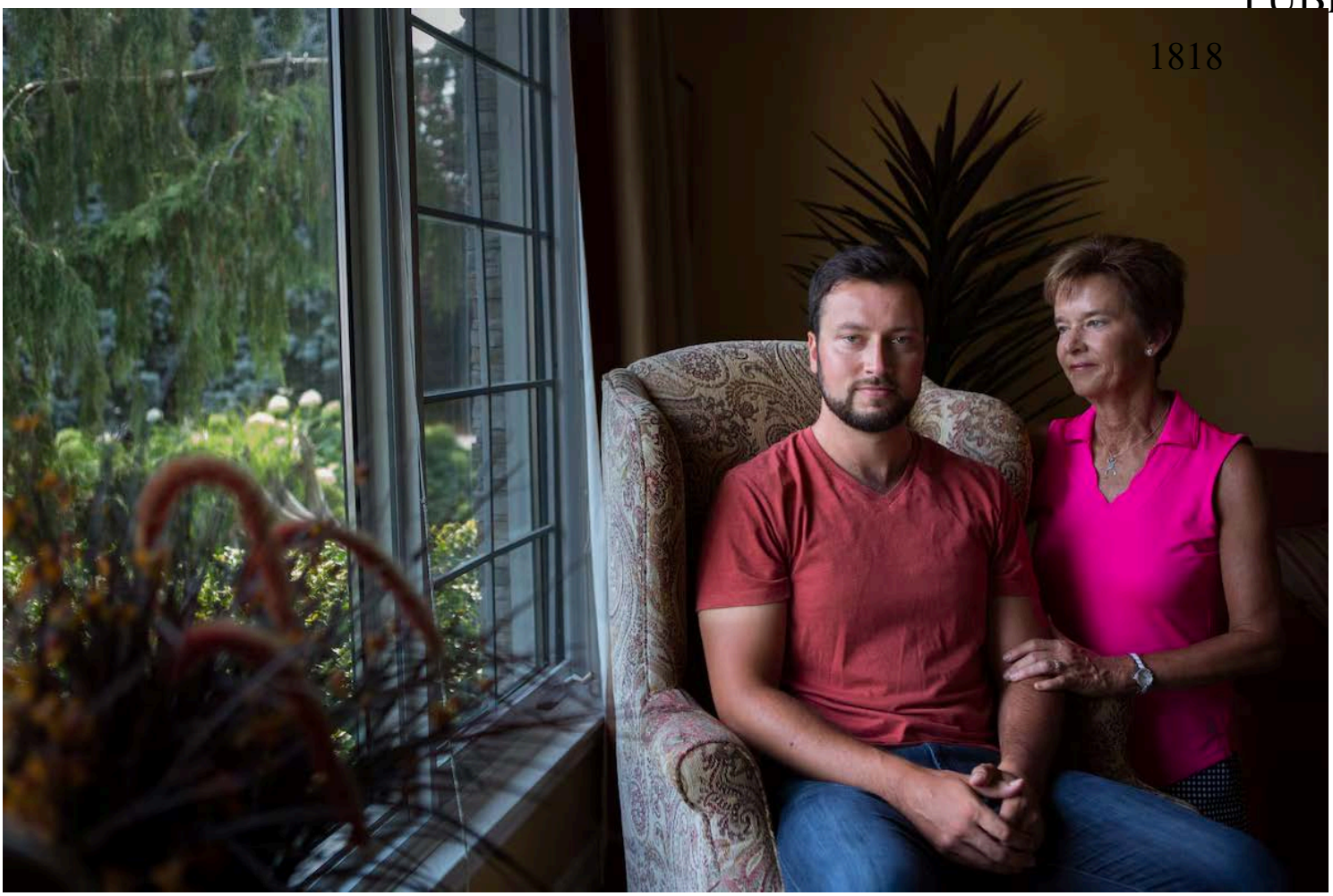
swoop in if a patient reacts badly to an infusion, he acknowledges a stark fact as well: UHN couldn't afford to run the clinic without financial support from the pharmaceutical industry.

Dr. Sanchez-Guerrero also oversees the division of rheumatology at Mount Sinai hospital, a few blocks east of UHN's Toronto Western site. Mount Sinai's outpatient infusion clinic, a larger operation that infuses seven different drugs and employs 14 staff, earns between $400,000 and $600,000 in infusion fees per year, according to spokesperson Sally Szuster.

Ms. Szuster wouldn't divulge the per-infusion payment for each drug, citing confidentiality agreements. About one-third of the patients who received infusions of any kind at the clinic in the first six months of this year were on Remicade, she said.

Neither UHN nor Mount Sinai could point to any other outpatient services for which a third party's payments cover nursing. And health officials across the country told The Globe that when patients don't live near a private infusion clinic, Remicade – purchased by the patient from a pharmacy – is usually infused at a local hospital's outpatient area or emergency department, with the nursing costs covered by the hospital budget.

As Bruce Conway, a spokesman for Alberta Health Services, said of the per-infusion fees, "We have never explored that option due to the potential for a perceived conflict of interest."



Adam Scully, shown with his mother, Ruth, at their Toronto home, is a hockey goalie turned TSN producer who was prescribed the drug Remicade to treat Crohn's disease.

CHRIS DONOVAN/THE GLOBE AND MAIL

Adam Scully was on the cusp of his 18th birthday when he learned he had Crohn's disease. The diagnosis in January of 2010 explained the searing pain radiating from his small intestine and into his esophagus. "It was as if somebody stabbed me right here," Mr. Scully, now 26, says, pointing to the middle of his chest. "I couldn't move."

At first, he tried a steroid and an immunosuppressant to manage his symptoms, but by early 2012 his condition had worsened. He remembers howling in pain during a colonoscopy at Mount Sinai.

Immediately after the colonoscopy, Mr. Scully's gastroenterologist, Dr. Hillary Steinhart, invited Mr. Scully and his mother, Ruth, to his office to recommend that Mr. Scully start on an anti-TNF drug.

Dr. Steinhart told him he could choose between a drug Mr. Scully would inject at home and one that would require two-hour visits to an infusion clinic every eight weeks. His needle-phobia led him to pick the latter – Remicade. Someone from a program called BioAdvance would be in touch soon, Dr. Steinhart said. "Literally from the drive from Sinai to here, she had already called us," Ruth Scully said in an interview from the family's home, about half an hour from Mount Sinai. "It was like a godsend."

BioAdvance is Janssen's patient-support program. The person who so swiftly called was a Janssen-employed nurse and BioAdvance co-ordinator who would act as Mr. Scully's personal concierge, ushering him on to Remicade. For starters, she handled the paperwork required to have Mr. Scully's Remicade partly covered by his mother's insurance.

When, less than a year later, Mr. Scully graduated from college and started working as a freelance TSN producer without benefits, the BioAdvance co-ordinator showed him how to pay rent to his parents, which would help him qualify for a provincial drug plan that would have been off-limits to him if his meagre income had been lumped in with that of his parents.

She scheduled the tests Mr. Scully needed before his first Remicade infusion, and has helped schedule the subsequent infusions that have dramatically improved his health.

Cadillac service from a pharmaceutical company – especially service that builds loyalty to a particular brand of drug – might seem at odds with the pride Canadians take in publicly funded medicine. But because Canada lacks a national pharmacare program, unlike most prosperous countries, it is exceptionally reliant on the drug industry to fill consequent gaps in health care.

Pharmaceutical companies in Canada spent just over $900-million to serve 673,000 patients enrolled in Patient Support Programs in 2016, according to a report commissioned by the industry group Innovative Medicines Canada.

Many in Canada's pharmaceutical world trace the Patient Support Program phenomenon back to the wild success of the program set up to sell Remicade.

"[The private clinics] started out as a limited initiative that allowed the drug to be marketed. If you can't infuse it, you can't sell it," says Brian Feagan, a gastroenterologist at London Health Sciences Centre and a professor of medicine at the University of Western Ontario. "But that initiative actually allowed them to build value-added services … that aren't provided by the health-care system."

Schering-Plough (the company that launched Remicade in Canada), and later Janssen, offered lab tests during infusion appointments and, with patient permission, fed the results back to doctors, Dr. Feagan notes.

The company assigned personal nurse co-ordinators to every patient, to educate them about Remicade, schedule their infusion appointments, and handle the voluminous insurance paperwork required to start new users on a high-priced drug. Such time-consuming work would be left to doctors or their administrative staff if not for help from a company that stands to benefit financially every time a new patient starts on its drug.

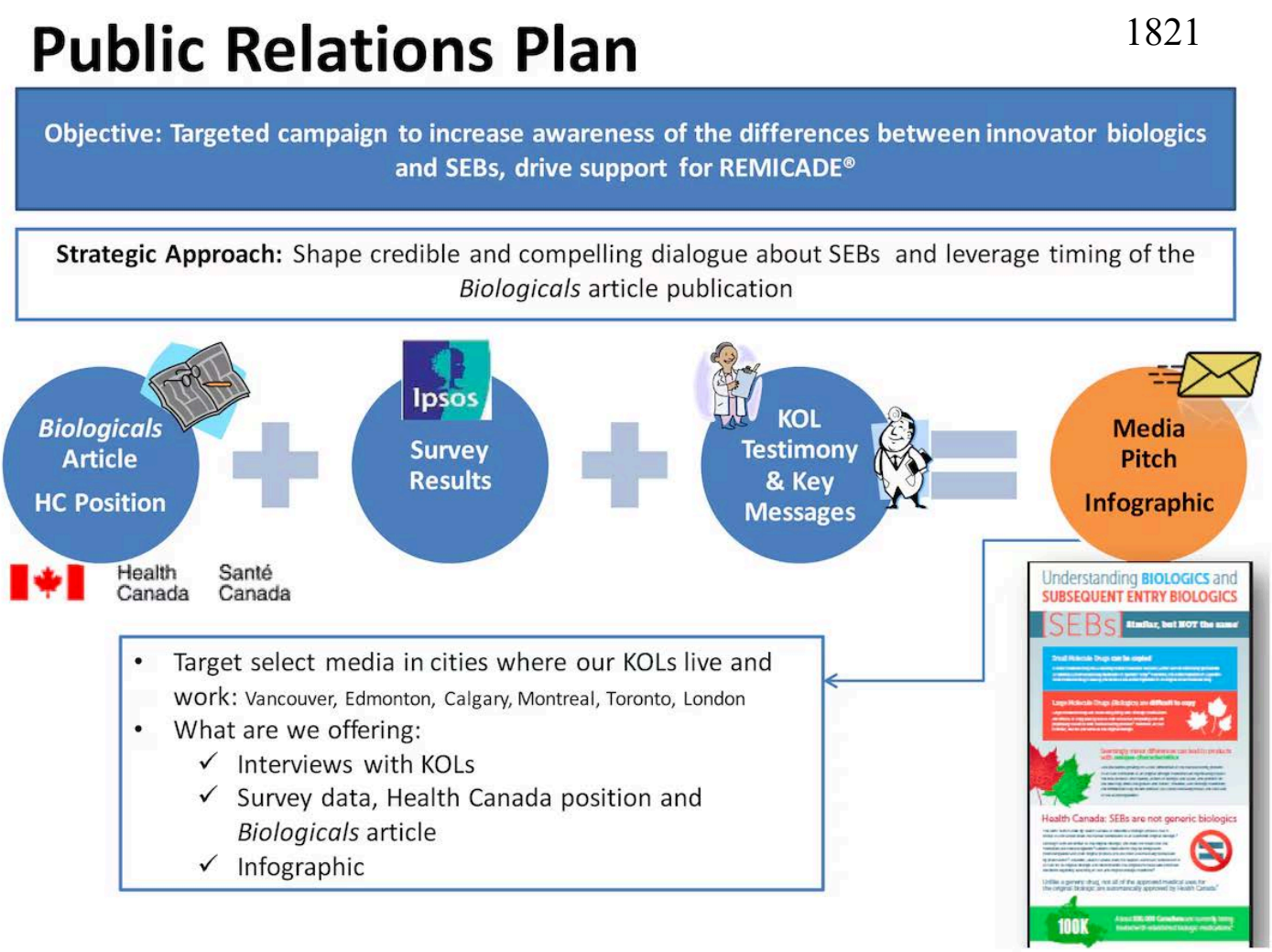
BioAdvance, and now other Canadian Patient Support Programs, often "bridge" patients with free drugs until their insurance coverage comes through. But BioAdvance, says Ms. Morgan, manager of the Kensington Screening Clinic, is the gold standard. "So when a doctor is trying to get his or her sick patient to treatment the fastest, they typically tend to go with BioAdvance."

And that means they tend to go with Remicade, or with one of the newer Janssen drugs that are now part of the BioAdvance program.

Competing drug makers have scrambled to keep up. Some pharmaceutical companies contract out their Patient Support Programs to third parties, as Pfizer has done with Inflectra, by using Innomar Strategies not only to run infusion clinics but also to administer the Canadian support program.

And drug companies, like any other successful business, move heaven and earth to keep a customer's loyalty once it's won. "As soon as you decide to change to another product, you can be sure that the nurse will call you the day after to ask you, well, what is happening? Why do you prefer to stop the treatment with us?" says Mr. Gagnon, the Carleton University professor.

When the not-for-profit benefits carrier Green Shield Canada launched a pilot project earlier this year that allowed participating companies to force their workers to switch from brand-name Remicade and Enbrel to a biosimilar – or pay the difference in cost – Janssen sent a letter directly to Remicade patients warning them they would lose their BioAdvance services if they switched.



A page from a Janssen PowerPoint presentation shows the public relations plan intended to drive support for Remicade.

In June of 2013, Janssen gathered eight eminent physicians in Toronto for a roundtable discussion. The company paid each of them approximately $4,000 to work on a paper, which would later be published in an obscure but peer-reviewed scientific journal called Biologicals. The subject of the article was biosimilars and "challenges" with one aspect of the approval process in Canada, the U.S. and Europe.

All the participants signed off on the paper's conclusions, but a Janssen employee drafted and revised it, a fact disclosed in the fine print.

Not disclosed, however, was Janssen's plan to use the article in a public-relations blitz against biosimilars. A November, 2014, Janssen PowerPoint presentation, obtained by The Globe and Mail, prepared for the company's community-and government-relations teams, outlined a plan to "drive support for Remicade," in part by "leverag[ing] timing of Biologicals article publication."

As London gastroenterologist Dr. Feagan, the paper's lead author, and Robin Thorpe, the journal's editor-in-chief, both pointed out in interviews, there is nothing incorrect or, on its face, biased in the article. The paper merely raised concerns at a time when biosimilars were relatively unknown.

But Richard Smith, a past editor of the BMJ (formerly the British Medical Journal) who has written widely about the pharmaceutical industry's manipulation of medical journals, said: "A little bit of doubt, in these circumstances, is going to go a long way."

Ambiguity is something that comes easily in the field of biologics. And with that ambiguity comes an opening for yet more doubt – and profitable doubt, at that.

First, the ambiguity: Knock-offs of biologic drugs are called biosimilars, not biosames, because such drugs are not absolutely identical, the way generics are, to the brand-name drugs they mimic. With each new batch of lab-produced cells, biologics morph, albeit in very tiny ways.

It's a distinction with practical implications. In Canada, pharmacists, at the behest of private and public payers, can swap in generic drugs without a doctor's say-so. But they are not allowed to do the same with biosimilars, because of rules in every province.

Those rules are rooted in Health Canada's decision not to declare any biosimilar 100-per-cent "interchangeable" with its brand-name counterpart. That designation, the regulator fears, could unleash unlimited switching between many copies made by different drug companies, decades in the future. Such multiple switches could, at least in theory, provoke an immune response in some patients, diminishing the drug's effectiveness. As well, the brand-name drug and its copies could grow further apart, as minuscule differences in the molecules pile up over decades, a phenomenon known as manufacturing drift.

That said, it's perfectly safe for patients to switch once or even a few times – regardless of how long they've been taking the brand-name biologic, according to Anthony Ridgway, a senior regulatory scientist at Health Canada.

"When we say a drug is safe and efficacious for that clinical indication," he says, "then people should count on that as being correct."

Yet that message seems not to have filtered down to Canadian physicians, who tend to err on the side of caution with even the most theoretical of Health Canada's concerns. And so, from ambiguity, an opening for Janssen to sow yet more doubt – the kind that could help keep biosimilars from making it onto prescription pads.

In another PowerPoint presentation, this one produced for Janssen's Ontario government-relations and community-relations teams, staff laid out their strategy for influencing patient-advocacy groups, provincial officials – and doctors. This was two months before Health Canada approved Inflectra as a Remicade biosimilar.

The document singled out the Ontario Association of Gastroenterology (OAG) as one rich target for "advocacy development" in the first quarter of 2014. Keeping specialists in inflammatory bowel disease onside would be essential: About three-quarters of the Remicade used in Canada is for

Crohn's and colitis, which don't have nearly as many biologic treatment options as does rheumatoid arthritis.

"To date, OAG has lagged behind other physician associations with respect to both knowledge on SEBs [biosimilars] and advocacy ability," one slide reads. "Following OAG January conference which will include SEB session, encourage OAG to develop position statement on SEBs. … source potential [government relations] consultants to work with OAG."

The OAG turned down multiple interview requests with The Globe and declined to answer e-mailed questions about whether it had, in fact, developed a position statement on biosimilars at Janssen's urging. "At this time," Melonie Hart, a spokeswoman for the OAG, wrote in March, "the OAG leaders are not available to respond to your lengthy questionnaire as they are too busy attending to the needs of their patients."

Julia Brown, Janssen's vice-president of government affairs and market access, told The Globe that whatever ideas may have been discussed internally during a PowerPoint presentation, the company's internal compliance department would never green-light payments to third-party consultants to guide the OAG; nor would it allow the company to help any group craft a position statement without making Janssen's financial support clear in the document.

The OAG did, however, ultimately publish a position statement – which Janssen said it did not fund in any capacity – on biosimilars in September of 2016. That statement discouraged the "non-medical switching" of existing patients away from the brand-name biologic to a biosimilar.

CHRIS DONOVAN/THE GLOBE AND MAIL

If Canada had a single-payer national pharmacare program, it could (in theory, at least) force all patients taking Remicade to switch to a biosimilar tomorrow – simply by refusing to cover the cost of the brand-name version.

In B.C. alone, according to a 2016 briefing note for the province's health minister, "If switching were supported, then the province could save more than $30-million each year. If all payers took advantage of the lower cost [of biosimilars] then the total provincial savings would be about $50-million per year."

One way that Janssen tries to keep such "switching" from occurring is by striking what are known as product-listing agreements, or PLAs, with private insurers: In exchange for a discount off the list price of Remicade, private insurers provide some manner of protection for it, the details of which are confidential. The agreements for high-priced drugs of all kinds have become popular with insurers trying to tame runaway drug costs in the short run.

The Remicade deals are an especially big hit. According to a Nov. 18, 2016, e-mail from a Janssen official to an Alberta MLA, obtained through a Freedom of Information request, Janssen's offer to be "cost competitive with biosimilars has been enthusiastically received" by companies covering more than 90 per cent of privately insured Canadians.

Critics of the Remicade deals with private insurers, however, argue the confidential deals have helped block the biosimilar drug Inflectra from the market, stifling competition. Green Shield, the not-for-profit benefits carrier, has rejected such overtures, while elevating biosimilars to preferred status in its benefit plans. According to Ned Pojskic, the pharmacy strategy leader at Green Shield, even if the confidential deals merely put Remicade and the biosimilar on equal footing, the biosimilar would still be at a disadvantage. "What that practically translates into is nobody prescribes the biosimilar," he said. "[That's] because of lack of familiarity, lack of understanding and, quite frankly, some of the fear-mongering that went on in the market in the early days."

When Janssen began locking down its first round of product-listing agreements for Remicade, it's unlikely the country's private insurers knew what their counterparts in the public sector would achieve in their own price negotiations with Pfizer, the maker of biosimilar Inflectra. Ultimately, in 2015, Pfizer reached an agreement with the pan-Canadian Pharmaceutical Alliance – which negotiates group drug discounts on behalf of Ottawa and the provinces and territories – to offer Inflectra at $525 a vial, roughly half the list price of Remicade.

In an unusual move, the federal-provincial-territorial alliance and Pfizer agreed to reveal the size of that discount and make it available to all payers, government and private alike; the provinces, in turn, promised to promote cheaper biosimilars by refusing to cover Remicade for new patients. But before the deal was revealed, Janssen officials guessed the discount for Inflectra would be less generous than it ended up being – "possibly 25-30% less than Remicade (room to go lower)" – according to the November, 2014, PowerPoint presentation obtained by The Globe.

So, did private insurers lock in a price for Remicade that was higher than that ultimately settled on for Inflectra? With the private payers sworn to secrecy, only Janssen knows for sure, although Janssen says its confidential PLAs have made Remicade "cost competitive" with the biosimilar and don't in any way prevent physicians and patients from choosing other drugs.

"All of us have learned through the Remicade experience," said Stephen Frank, the president of the Canadian Life and Health Insurance Association, which represents private insurers. "There are things we're going to look to do differently in the future."

Janssen has aimed a similar divide-and-conquer strategy at individual provinces. The pan-Canadian Pharmaceutical Alliance asks pharmaceutical companies to make proposals to its central office, but Janssen has ignored that request and pursued side deals on Remicade anyway, according to a 2017 Quebec court case and other documents obtained by The Globe through Freedom of Information requests.

In an Oct. 31, 2016, letter to Janssen president Chris Halyk, the pan-Canadian Pharmaceutical Alliance explained that it was rejecting an unsolicited discount offer on Remicade. "[The] pCPA understands that the motivation behind the submitted proposal and willingness for Janssen to now offer value is due to the introduction of competition from [a biosimilar] …" the letter says. "The manufacturer is

kindly requested to communicate with the pCPA office directly and not approach the individual jurisdictions," the letter reads.

Quebec Superior Court Judge Brian Riordan thought the letter was extraordinary enough to quote in full in his Nov. 27, 2017, dismissal of a Janssen court challenge against Quebec's decision to stop covering Remicade for new patients. Janssen is appealing.

Janssen has cast its line in other provinces, too.

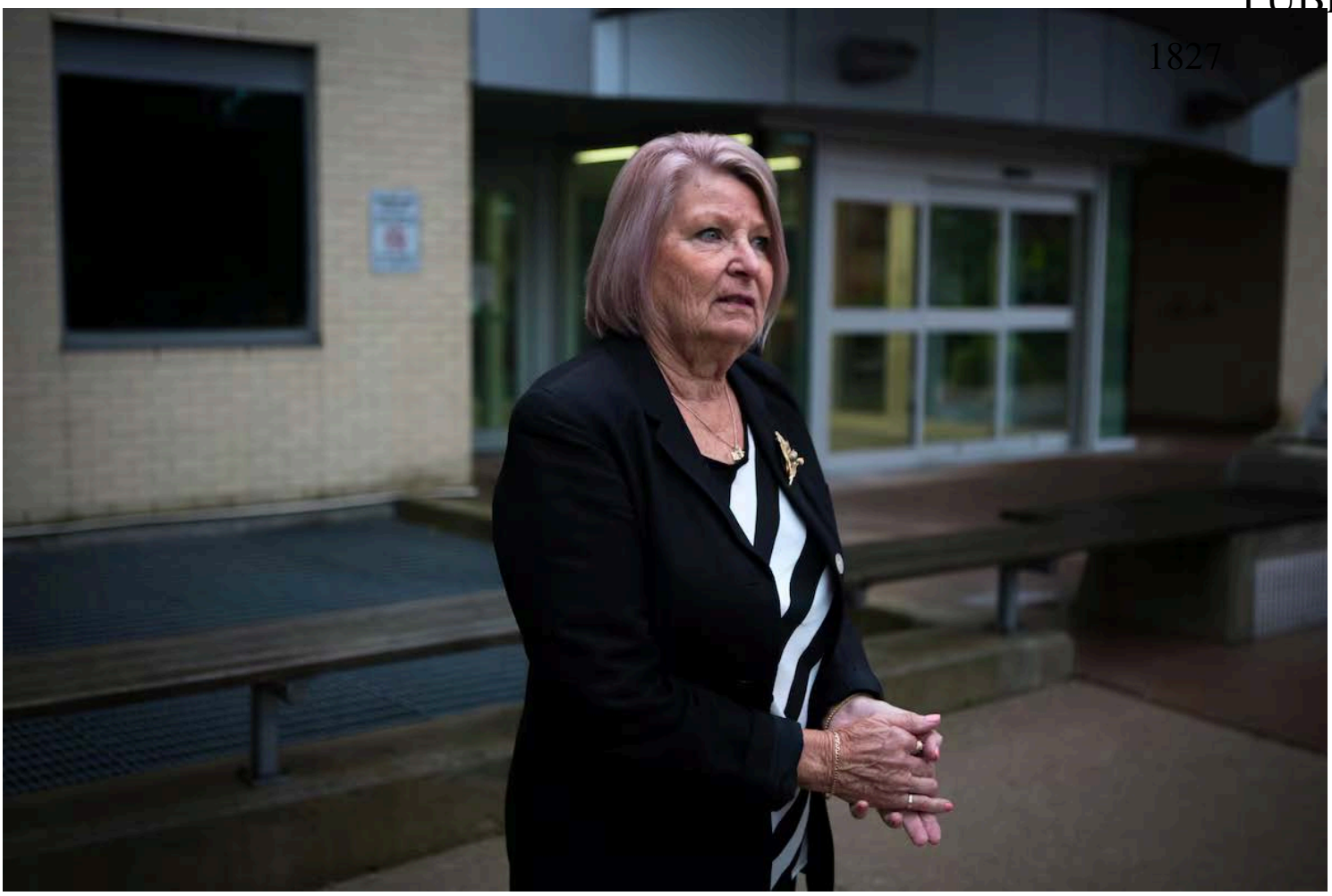
Adrian Dix, B.C.'s Health Minister, wouldn't divulge details of Janssen's offers to his province, but said the terms were unacceptable to a government that supports the pan-Canadian Pharmaceutical Alliance's efforts to promote biosimilars. "People talk about how one funds a national pharmacare program," Mr. Dix says. "One of the ways one does that, surely, is to reduce the overall costs of drugs through collective action."

But voluntary collective action apparently has its limits. In a Jan. 25, 2017, e-mail to colleagues, Grant Wyand, then PEI's acting director of pharmacare, floated the idea of accepting a Janssen offer by which the company would provide Remicade at less than the cost of Inflectra in exchange for the PEI government agreeing to cover Remicade for new patients on the island. "This is offside with pCPA," Mr. Wyand noted.

Further e-mails among the PEI bureaucrats revealed that, after the province passed its policy limiting new patients to Inflectra, physicians were simply prescribing other brand-name drugs, mainly the injectable, Humira, instead of the biosimilar.

In February of 2018, PEI announced that it had changed its rules to cover Remicade for new patients, breaking with the pan-Canadian Pharmaceutical Alliance.

Ms. Brown, the Janssen VP, says the company's offer to the negotiating alliance remains on the table. As for why Janssen kept making its offer in provincial capitals, she said: "We still knew there were provinces … who had concerns about patient choice and about cost and wanted to talk to us."



Three years ago, Renate Rasokas switched from Remicade to the biosimilar Inflectra, and is doing well on the new drug.
CHRIS DONOVAN/THE GLOBE AND MAIL

When Renate Rasokas of Tillsonburg, Ont., switched to Inflectra in September of 2015, it was "not a big production." Her rheumatologist, Janet Pope, said the biosimilar was cheaper and designed to work as well as Remicade, the drug that had been relieving her arthritis pain for 14 years. Ms. Rasokas, now 66, didn't hesitate: "I trust her," she said of Dr. Pope. "I knew she wouldn't lead me astray."

Dr. Pope, the chief of rheumatology at St. Joseph's Health Care in London, says her clinical group decided long ago to refuse infusion fees from drug companies. She doesn't enroll her patients in pharma-sponsored support programs, either, unless they need help paying for their drugs.

For that reason, Ms. Rasokas's transition to Inflectra was seamless. Dr. Pope's own staff kept booking her infusion appointments at the St. Joseph's outpatient clinic, just as they always had. Three years later, she's still doing well on the biosimilar.

Ms. Rasokas's switching experience is a lot like what happens in much of Europe, where public health-care systems, not drug companies, co-ordinate and provide infusions of biologics inside hospitals. Unlike Canada, those countries have national pharmacare.

Earlier this year, the federal government launched the Advisory Council on the Implementation of National Pharmacare, tapping former Ontario health minister Eric Hoskins to lead it. Currently crisscrossing the country in search of feedback, the council is scheduled to produce a final report next spring, six months before Canadians vote in an election that may be defined, in no small part, by competing visions of prescription drug coverage.

In an age when biosimilars hold out the hope of huge savings to governments, insurers and patients, the council's timing is certainly apt. Merck has just launched a second biosimilar of Remicade here. Canada pays the third-highest drug prices among the countries in the Organization for Economic Co-operation and Development, and spends more per capita on prescriptions than any country except the United States and Switzerland.

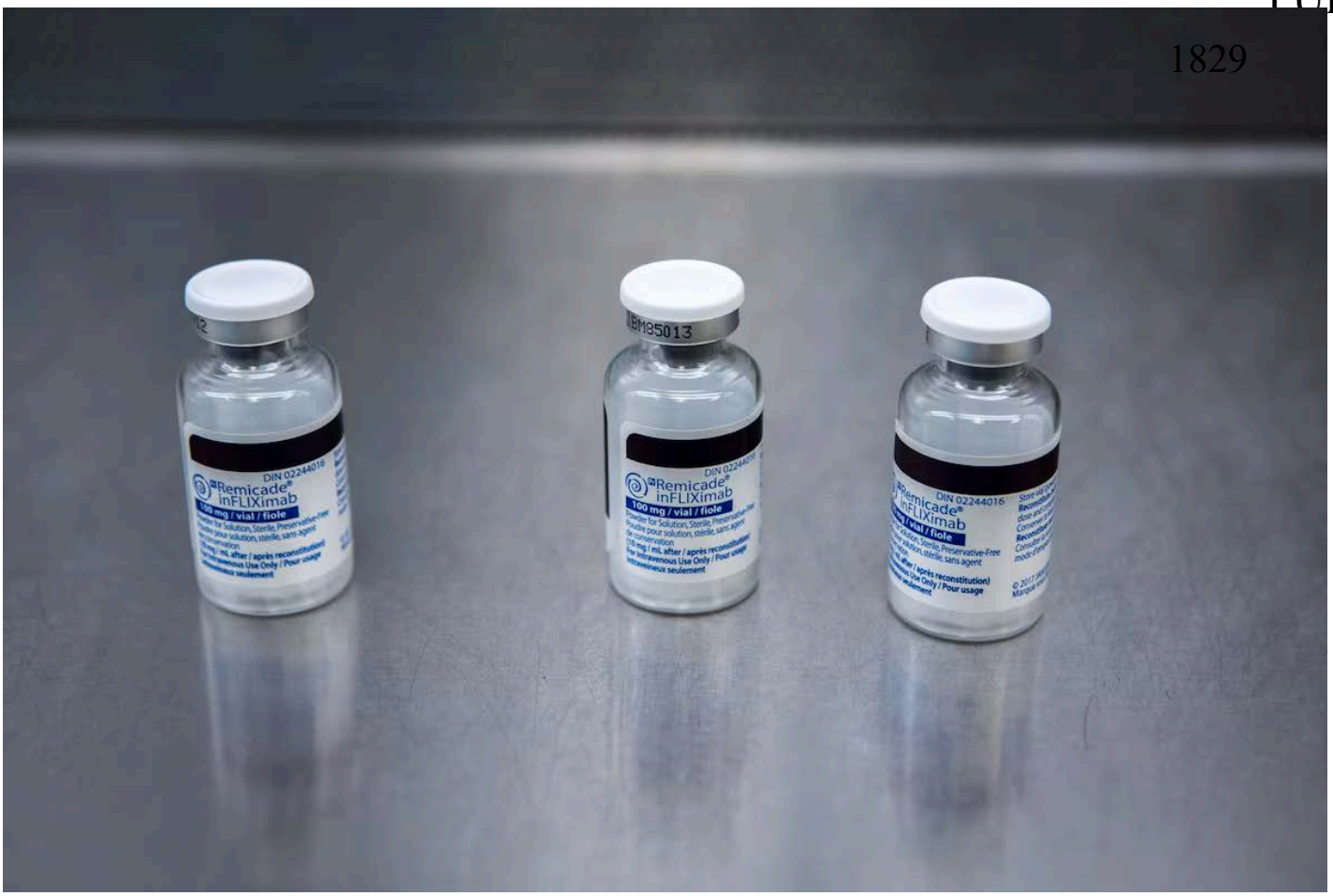
Canada's drug-pricing regulator predicts the biosimilar versions of Remicade alone could save the system anywhere from $91-million to $514-million every single year – but not if the near-copies can't get a toehold here.

Indeed, Janssen has managed, with its suite of tactics, to block biosimilar Inflectra from the market almost completely: Of every $100 of infliximab that is sold in Canada today, $97 of it is still sold as Remicade. By contrast, several European countries with single-payer pharmacare systems have already cajoled or forced the majority of patients to switch to a biosimilar, saving immense amounts of money.

More than 90 per cent of the infliximab sold in each of Poland, Norway and Finland is a biosimilar. In Britain, it's 80 per cent. In Sweden, it's 70. The OECD average is 35 per cent. In Canada, only 2.7 per cent of the infliximab sold in 2017 was a biosimilar.

Like generic drugs before them, biosimilars could free up money for governments and private insurers to cover the newest generation of miracle cures, including expensive gene therapies, said Michael Guirguis, a drug stewardship pharmacist with Alberta Health Services, the agency that runs front-line health care in Alberta.

Although he spoke for himself, not AHS, he is worried about what will happen if Canada misses the boat on money-saving biosimilars. "This is a once-in-a-generation opportunity for health care in Canada."



CHRIS DONOVAN/THE GLOBE AND MAIL

A note on data and sources

The Globe obtained the figures for these graphics from IQVIA (formerly Quintiles IMS and IMS Brogan), an international prescription-drug tracking company; provincial and territorial health ministries; and the Patented Medicine Prices Review Board (PMPRB), Canada's drug-pricing regulator. IQVIA's figures and the spending figures provided by most of the provinces and territories are based on list prices, which do not reflect confidential discounts or rebates that pharmaceutical companies sometimes provide to big payers. None of the parties to those deals is willing to make the real prices public. Janssen disputes some of the PMPRB's figures; the agency stands by its work. You can read Janssen's letters of complaint to the PMPRB here and here and the PMPRB's replies here and here. You can also read the PMPRB's original report on biologic response modifier agents and an updated version.

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The backstory

The Globe and Mail's investigation of Remicade began with a dry report from a government agency most Canadians have never heard of. The Patented Medicine Prices Review Board sets ceiling prices for brand-name prescription drugs and reports on trends in pharmaceutical prices and spending.

In the fall of 2016, the agency published a study about how Canadians used expensive biologic drugs for autoimmune diseases such as rheumatoid arthritis and Crohn's disease.

One fact jumped out at Globe health reporter Kelly Grant: The market share of a drug called Remicade was 40 per cent in Canada, nearly twice as high as the share in any of the other well-off countries against which Canada benchmarks its drug prices. At $27,289 a year, on average, Remicade costs significantly more than any of the other brand-name biologics that treat the same diseases. On top of that, Remicade is delivered as a two-hour IV infusion every eight weeks, while most of the competing drugs come as pre-filled syringes that patients can inject at home.

So why was Canada using so much of what appeared to be the most expensive and least convenient treatment?

In a bid to answer that question, Ms. Grant began talking to drug-industry insiders, pharmaceutical policy researchers and doctors about how Remicade is provided and promoted in Canada. She learned quickly that much of the information she needed – including the real prices of drugs, after increasingly common confidential discounts are factored in – was subject to non-disclosure agreements with pharmaceutical companies. Even the report that first caught Ms. Grant's attention was based on what are called "list" prices that don't reflect those rebates. (That is one of the reasons that Janssen, the company that makes Remicade, disputes the agency's figures, and calls its report misleading. The Patented Medicine Prices Review Board stands behind its work.)

To cite one example, when Ms. Grant heard from her sources that Janssen had decided to give away vials of the drug to hospitals for a penny, she started calling hospitals to find out whether it was true. Of the 38 hospitals, regional health authorities and provincial health ministries she called, all but five said the pricing was confidential. When The Globe sent Freedom of Information Act requests to three hospitals – Sunnybrook, St. Michael's and Mount Sinai, all in Toronto – seeking a copy of the offer, Janssen appealed the release of the documents. Ultimately, The Globe obtained a copy of the offer. Janssen later confirmed the one-cent offer had been made to every hospital in the country.

Janssen's hospital pricing strategy was, however, only a tiny part of the bigger story. As Ms. Grant gathered more information from Freedom of Information requests to nine provinces, Health Canada and other hospitals, she learned that, oftentimes, even government officials don't understand how Canada's Byzantine system for paying for and delivering complex, infused biologics like Remicade actually works.

But smart drug companies do, and that allows them to take advantage of the gaps in Canada's health-care system. Figuring out how to close those gaps is now the job of a national advisory council on pharmacare, which is expected to present its recommendations to Canadians this spring.

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More from Canada

Queer Prom celebrates a rite of passage with joy and authenticity

Head of the National Microbiology Lab in Winnipeg stepping down

Authorities shutter Vancouver pharmacy citing multiple violations of federal drug laws

Jagmeet Singh makes his case to Alberta's new NDP leader amid party separation talks

Toronto councillors approve motion urging city to take control of Ontario Science Centre

Morning Update: Cracking the Canada Day crossword

Exhibit “J36”

This is Exhibit “J36” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

_____

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

PUBLIC

1834

Government of Canada | Gouvernement du Canada

Product information

From Health Canada

New search

The product monograph is developed by a drug sponsor according to guidelines published by Health Canada that provide direction on the content and format. The veterinary labelling is developed by the drug sponsor according to the Food and Drug Regulations. While Health Canada reviews the product monograph or the veterinary labelling as part of the drug review process, it remains the responsibility of the drug sponsor to ensure that the product monograph or the veterinary labelling is complete and accurate.

Current status:

Marketed

Current status date:

2015-03-19

Original market date: [1]

2014-09-04

Product name:

INFLECTRA

Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section.

DIN:

PUBLIC

02419475

1835

Product Monograph/Veterinary Labelling:

Date: 2020-07-06

Product monograph/Veterinary Labelling (PDF version ~ 175K)

Company:

CELLTRION HEALTHCARE CO LTD

19 Academy-Ro 51 Beon-Gil

Yeonsu-Gu, Incheon

--

Korea, Republic Of 22014

Class:

Human

Dosage form(s):

Powder For Solution

Route(s) of administration:

Intravenous

Number of active ingredient(s):

1

Schedule(s):

Schedule D , Prescription

Biosimilar Biologic Drug:

Yes

American Hospital Formulary Service (AHFS): [3]

92:36.00

Anatomical Therapeutic Chemical (ATC): [4]

L04AB02 INFLIXIMAB

Active ingredient group (AIG) number: [5]

PUBLIC

0144162001

1836

List of active ingredient(s)

Active ingredient(s)	Strength
INFLIXIMAB	100 MG / VIAL

Risk Management Plans [7]

A Risk Management Plan (RMP) for this product was submitted.

Additional Risk Minimization Measures
Patient Wallet Card

New search Same active ingredient group number

Footnotes

1 The earliest marketed date recorded in the Drug Product Database.

3 The American Hospital Formulary Service permits an easy review of information on a group of drugs with similar activities and uses and allows the reader to determine quickly the similarities and differences among drugs within a group. *AHFS® Pharmacologic/Therapeutic Classification©* used with permission. © 2022, the American Society of Health-System Pharmacists, Inc. (ASHP). The Data is a part of the AHFS Drug Information®; ASHP is not responsible for the accuracy of transpositions from the original context.

4 The purpose of the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification system is to be used as a tool for drug utilization research in order to improve quality of drug use. Drugs are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutical properties.

5	The AIG number is a 10 digit number that identifies products that have the same active ingredient(s) and ingredient strength(s). The AIG is comprised of three portions: • the first portion (2 digits) identifies the number of active ingredients, • the second portion (5 digits) identifies the unique groups of active ingredients(s), • the last portion (3 digits) identifies the active ingredient group strength. The strength group has a tolerance of -2% to +10%.	1837 1837
7	Refer to the Health Canada Guidance Documents - "Submission of Risk Management Plans and Follow-up Commitments" as well as "Submission of targeted Risk Management Plans Follow-up Commitments for Prescription Opioid-containing Products" for additional details.	

Application information

Search tips

Drug product database terminology

Drug product database data extracts

Related information

MedEffect Canada

Adverse drug reaction - veterinary drugs

Notice of compliance database

Licensed natural health products database

Contact us

Content support

Technical support

Version 4.0.2

Date modified: 2024-02-28

Exhibit “J37”

This is Exhibit “J37” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

PUBLIC

1841

Government of Canada Gouvernement du Canada

Product information

From Health Canada

New search

The product monograph is developed by a drug sponsor according to guidelines published by Health Canada that provide direction on the content and format. The veterinary labelling is developed by the drug sponsor according to the Food and Drug Regulations. While Health Canada reviews the product monograph or the veterinary labelling as part of the drug review process, it remains the responsibility of the drug sponsor to ensure that the product monograph or the veterinary labelling is complete and accurate.

Current status:

Marketed

Current status date:

2018-03-22

Original market date: [1]

2018-03-22

Product name:

RENFLEXIS

Description:

SINGLE USE VIAL

Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help

section.

DIN:

02470373

Product Monograph/Veterinary Labelling:

Date: 2023-10-04

Product monograph/Veterinary Labelling (PDF version ~ 175K)

Company:

SAMSUNG BIOEPIS CO., LTD
76, Songdogyoyuk-Ro, Yeonsu-Gu
Incheon
Incheon
Korea, Republic Of 21987

Class:

Human

Dosage form(s):

Powder For Solution

Route(s) of administration:

Intravenous

Number of active ingredient(s):

1

Schedule(s):

Prescription , Schedule D

Biosimilar Biologic Drug:

Yes

American Hospital Formulary Service (AHFS): [3]

92:36.00

Anatomical Therapeutic Chemical (ATC): [4]

L04AB02 INFLIXIMAB

Active ingredient group (AIG) number: [5]

0144162001

List of active ingredient(s)

Active ingredient(s)	Strength
INFLIXIMAB	100 MG / VIAL

Risk Management Plans [7]

A Risk Management Plan (RMP) for this product was submitted.

Pharmacovigilance/Monitoring Activity
Observational Studies
Registry

New search Same active ingredient group number

Footnotes

1 The earliest marketed date recorded in the Drug Product Database.

3 The American Hospital Formulary Service permits an easy review of information on a group of drugs with similar activities and uses and allows the reader to determine quickly the similarities and differences among drugs within a group. *AHFS® Pharmacologic/Therapeutic Classification*© used with permission. © 2022, the American Society of Health-System Pharmacists, Inc. (ASHP). The Data is a part of the AHFS Drug Information®; ASHP is not responsible for the accuracy of transpositions from the original context.

4 The purpose of the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification system is to be used as a tool for drug utilization research in order to improve quality of drug use. Drugs are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutical properties.

5 The AIG number is a 10 digit number that identifies products that have the same active ingredient(s) and ingredient strength(s). The AIG is comprised of three portions:

- the first portion (2 digits) identifies the number of active ingredients,
- the second portion (5 digits) identifies the unique groups of active ingredients(s),
- the last portion (3 digits) identifies the active ingredient group strength. The strength group has a tolerance of -2% to +10%.

7 Refer to the Health Canada Guidance Documents - "Submission of Risk Management Plans and Follow-up Commitments" as well as "Submission of targeted Risk Management Plans Follow-up Commitments for Prescription Opioid-containing Products" for additional details.

Application information

Search tips
Drug product database terminology
Drug product database data extracts

Related information

MedEffect Canada
Adverse drug reaction - veterinary drugs
Notice of compliance database
Licensed natural health products database

Contact us

Content support
Technical support

Version 4.0.2

Date modified: 2024-02-28

Exhibit “J38”

This is Exhibit “J38” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

Government of Canada Gouvernement du Canada

Product information

From Health Canada

New search

The product monograph is developed by a drug sponsor according to guidelines published by Health Canada that provide direction on the content and format. The veterinary labelling is developed by the drug sponsor according to the Food and Drug Regulations. While Health Canada reviews the product monograph or the veterinary labelling as part of the drug review process, it remains the responsibility of the drug sponsor to ensure that the product monograph or the veterinary labelling is complete and accurate.

Current status:

Marketed

Current status date:

2020-06-01

Original market date: [1]

2020-06-01

Product name:

AVSOLA

Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section.

DIN:

02496933

1849

Product Monograph/Veterinary Labelling:

Date: 2022-05-17

Product monograph/Veterinary Labelling (PDF version ~ 175K)

Company:

AMGEN CANADA INC
300 6775 Financial Drive
Mississauga
Ontario
Canada L5N 0A4

Class:

Human

Dosage form(s):

Powder For Solution

Route(s) of administration:

Intravenous

Number of active ingredient(s):

1

Schedule(s):

Prescription , Schedule D

Biosimilar Biologic Drug:

Yes

American Hospital Formulary Service (AHFS): [3]

92:36.00

Anatomical Therapeutic Chemical (ATC): [4]

L04AB02 INFLIXIMAB

Active ingredient group (AIG) number: [5]

PUBLIC

0144162001

1850

List of active ingredient(s)

Active ingredient(s)	Strength
INFLIXIMAB	100 MG / VIAL

Risk Management Plans [7]

A Risk Management Plan (RMP) for this product was submitted.

New search Same active ingredient group number

Footnotes

1 The earliest marketed date recorded in the Drug Product Database.

3 The American Hospital Formulary Service permits an easy review of information on a group of drugs with similar activities and uses and allows the reader to determine quickly the similarities and differences among drugs within a group. *AHFS® Pharmacologic/Therapeutic Classification*© used with permission. © 2022, the American Society of Health-System Pharmacists, Inc. (ASHP). The Data is a part of the AHFS Drug Information®; ASHP is not responsible for the accuracy of transpositions from the original context.

4 The purpose of the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification system is to be used as a tool for drug utilization research in order to improve quality of drug use. Drugs are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutical properties.

5	The AIG number is a 10 digit number that identifies products that have the same active ingredient(s) and ingredient strength(s). The AIG is comprised of three portions: • the first portion (2 digits) identifies the number of active ingredients, • the second portion (5 digits) identifies the unique groups of active ingredients(s), • the last portion (3 digits) identifies the active ingredient group strength. The strength group has a tolerance of -2% to +10%.	1851 1854
7	Refer to the Health Canada Guidance Documents - "Submission of Risk Management Plans and Follow-up Commitments" as well as "Submission of targeted Risk Management Plans Follow-up Commitments for Prescription Opioid-containing Products" for additional details.	

Application information

Search tips

Drug product database terminology

Drug product database data extracts

Related information

MedEffect Canada

Adverse drug reaction - veterinary drugs

Notice of compliance database

Licensed natural health products database

Contact us

Content support

Technical support

Version 4.0.2

Date modified: 2024-02-28

Exhibit “J39”

This is Exhibit “J39” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

Government of Canada Gouvernement du Canada

Product information

From Health Canada

New search

The product monograph is developed by a drug sponsor according to guidelines published by Health Canada that provide direction on the content and format. The veterinary labelling is developed by the drug sponsor according to the Food and Drug Regulations. While Health Canada reviews the product monograph or the veterinary labelling as part of the drug review process, it remains the responsibility of the drug sponsor to ensure that the product monograph or the veterinary labelling is complete and accurate.

Current status:

Approved

Current status date:

2021-01-28

Product name:

REMSIMA SC

Description:

PRE-FILLED SYRINGE OR PRE-FILLED SYRINGE WITH NEEDLE GUARD

Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section.

DIN:

02511576

1856

Product Monograph/Veterinary Labelling:

Date: 2024-02-15

Product monograph/Veterinary Labelling (PDF version ~ 175K)

Company:

CELLTRION HEALTHCARE CO LTD

19 Academy-Ro 51 Beon-Gil

Yeonsu-Gu, Incheon

--

Korea, Republic Of 22014

Class:

Human

Dosage form(s):

Kit , Solution

Route(s) of administration:

Subcutaneous

Number of active ingredient(s):

1

Schedule(s):

Prescription , Schedule D

Biosimilar Biologic Drug:

Yes

American Hospital Formulary Service (AHFS): [3]

92:36.00

Anatomical Therapeutic Chemical (ATC): [4]

L04AB02 INFLIXIMAB

Active ingredient group (AIG) number: [5]

PUBLIC

0144162002

1857

List of active ingredient(s)

Active ingredient(s)	Strength
INFLIXIMAB	120 MG / ML

Risk Management Plans [7]

A Risk Management Plan (RMP) for this product was submitted.

Additional Risk Minimization Measures
Patient Wallet Card

New search Same active ingredient group number

Footnotes

3 The American Hospital Formulary Service permits an easy review of information on a group of drugs with similar activities and uses and allows the reader to determine quickly the similarities and differences among drugs within a group. *AHFS® Pharmacologic/Therapeutic Classification*© used with permission. © 2022, the American Society of Health-System Pharmacists, Inc. (ASHP). The Data is a part of the AHFS Drug Information®; ASHP is not responsible for the accuracy of transpositions from the original context.

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7	Refer to the Health Canada Guidance Documents - "Submission of Risk Management Plans and Follow-up Commitments" as well as "Submission of targeted Risk Management Plans Follow-up Commitments for Prescription Opioid-containing Products" for additional details.	

Application information

Search tips

Drug product database terminology

Drug product database data extracts

Related information

MedEffect Canada

Adverse drug reaction - veterinary drugs

Notice of compliance database

Licensed natural health products database

Contact us

Content support

Technical support

Version 4.0.2

Date modified: 2024-02-28

Exhibit “J40”

This is Exhibit “J40” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

Inquiry into alleged anti-competitive conduct by Janssen

Position Statement

See the news release that corresponds to this position statement.

OTTAWA, February 20, 2019—Today, the Interim Commissioner of Competition announced that he has discontinued an inquiry into allegations that Janssen Inc. (**Janssen**), a subsidiary of Johnson & Johnson, has engaged in conduct contrary to the abuse of dominance provisions of the *Competition Act* (**Act**). The Competition Bureau's inquiry considered whether Janssen's alleged conduct inhibited the entry or expansion of biosimilar products in Canada that compete with Janssen's biologic product Remicade (active ingredient "infliximab").

This statement summarizes the Bureau's inquiry and the reasons for its discontinuance. It also identifies and provides guidance on some of the competition issues relevant to biologic and biosimilar pharmaceutical products.

In brief, the Bureau's inquiry confirmed that Janssen has engaged in, and continues to engage in, conduct that could raise concerns under the Act in certain circumstances. However, the Bureau did not find adequate evidence at this time that this conduct was likely to substantially lessen or prevent competition. Since Janssen's conduct remains ongoing, the Bureau will continue to monitor the developing biologic and biosimilar industry for potential violations of the Act.

Overview of the biologic and biosimilar industry

Biologic drugs (**biologics**) are a class of pharmaceutical products derived from living organisms, such as a microorganism or animal cell. Biologics tend to be larger, more complex, and more variable than traditional small molecule drugs, which are chemically synthesized.

There has been a significant shift in pharmaceutical sales towards biologics over the last decade. Whereas only one biologic made the list of the ten top-selling patented pharmaceutical products in 2006, biologics accounted for seven products on this list in 2017 representing 42% of patented medicine sales in Canada. [1]

Biologics are one of the fastest growing pharmaceutical product segments in Canada. The high cost of biologics—with treatment costs ranging from thousands to tens of thousands of dollars per year per patient—as well as their continued growth in usage, have contributed to a significant increase in pharmaceutical expenditure.

Biosimilars, a relatively new category of drugs in Canada, have the potential to provide Canadians with the benefits of competition in this growing segment of the economy. A biosimilar is a highly similar version of a brand name biologic already authorized for sale. In order for a biosimilar to be marketed in Canada, it must first obtain approval from Health Canada. To date, Health Canada has approved biosimilars for at least 9 biologics. Biosimilars are generally less costly than original biologics. Canada's public and private insurers stand to potentially realize substantial cost savings by promoting the use of these drugs.

Competitive dynamics between biologics and biosimilars

Competition between branded and generic small molecule drugs generally follows a common pattern. For a period of time, branded products generally benefit from patent and regulatory protection for their innovation. This often allows for high prices and steady volume. However, once patents and other protections expire, generic competition emerges and quickly captures much of the market at a lower price.

This pattern, known as the "patent cliff", has not yet materialized in Canada for biologic and biosimilar pharmaceutical products. Instead, many biologics—especially those that treat chronic conditions—continue to capture most of the market for many months (or even years) following the expiry of their patents. A number of unique features of biologics and biosimilars may explain this trend not typically seen in the traditional branded and generic small molecule industry.

For one, the degree of risk associated with developing a biosimilar is likely to exceed that assumed by firms that produce generic small molecule drugs as their development requires additional time and capital and assuming the risk that the investment may not lead to a marketable discovery. The prolonged development time and substantial financial investment required to develop biosimilars may limit the number of manufacturers willing to enter the market, as well as prevent the entry of smaller manufacturers. Additionally,

with the prolonged time for biosimilar development, there is a risk of new alternative therapies becoming available prior to the biosimilar entering the market. As a result, the potential market for the biosimilar could be significantly smaller by the time of entry.

Features of the regulatory approval process may also contribute to a longer period to bring a biosimilar product to market. In order to approve a biosimilar, Health Canada requires biosimilar manufacturers to demonstrate that there are no clinically meaningful differences in safety and efficacy between the biosimilar and its reference biologic. While generic manufacturers can provide this information through an abbreviated new drug submission, biosimilar manufacturers must submit a new drug submission, which requires more information (including clinical trials) and takes more time to complete and receive approval. Health Canada's different regulatory framework and submission requirements for biosimilars, as compared to its approach with traditional generic small molecule drugs, reflect the increased complexity and variability of biologics and biosimilars.

In addition, biosimilar manufacturers must provide Health Canada with detailed information for each indication they wish to seek for the product. [2] While a generic drug will be interchangeable with an original branded drug for all indications, a biosimilar manufacturer may not request or obtain approval for all of the indications treated by the reference biologic. Where this occurs, the biosimilar will only be able to compete for a subset of the patients served by the reference biologic.

This challenge is compounded by the fact that, at least at present, there is a lack of consensus regarding the implementation of switching policies for biologic and biosimilar drugs, notwithstanding observations by market participants that emerging scientific literature suggests these policies are safe for patients. Although some public and private payors have taken steps to encourage patients that are currently stable on a biologic to switch to a biosimilar, the vast majority have not. This distinguishes biologics and biosimilars from small molecule drugs, which are subject to automatic substitution policies. These policies, which have been implemented by many public and private insurers, encourage pharmacists to dispense generic drugs in place of costlier branded drugs.

Consequently, while it is common for patients to be substituted from a branded to a generic small molecule drug, there is currently limited substitution from a biologic to a biosimilar. As a result, in Canada, competition between biologics and biosimilars generally centres on attracting new patients that have not started on either pharmaceutical product. [3] This group of patients generally represents a small fraction of the total market served by the reference biologic (often between 10-25% of the market in a given year).

A final factor that may help explain why certain biosimilars have achieved limited growth relates to the role of infusion clinics. Certain biologic and biosimilar drugs must be administered via infusion. This has resulted in biologic and biosimilar manufacturers partnering with third parties to develop networks of infusion clinics across the country, sometimes on an exclusive basis. Information from market participants suggests that it can take biosimilar companies a number of months to develop a network of clinics that rivals their competitor's network, thus impeding, at least for a period of time, their ability to compete for patients throughout the country.

The Bureau's inquiry

The biologic at issue in the Bureau's inquiry was Remicade. Remicade was first introduced in Canada in June 2001 and is now Johnson & Johnson's top earning pharmaceutical product, with revenue exceeding $6.3 billion (USD) worldwide in 2017. In Canada, Remicade accounted for around $1 billion in sales in 2017.

In Canada, Remicade is indicated for the treatment of a number of conditions in adult populations, including rheumatoid arthritis, psoriatic arthritis, plaque psoriasis, ankylosing spondylitis, Crohn's disease and ulcerative colitis. Remicade has also obtained Health Canada's approval for a subset of these indications for the paediatric population. There are currently two approved biosimilars of Remicade in Canada: Inflectra (marketed by Pfizer Canada Inc.) and Renflexis (marketed by Merck Canada Inc.). Inflectra is currently approved for all of Remicade's adult indications and Renflexis is currently approved for all Remicade indications (including for the paediatric population).

In 2018, the Bureau commenced an inquiry in response to concerns that Janssen was allegedly engaging in a series of practices to inhibit biosimilar competition to Remicade. In assessing these allegations, the Bureau interviewed key market participants, including pharmaceutical manufacturers, public and private insurers, hospitals, physicians, infusion clinic networks and trade associations, while also gathering relevant records from many of these parties.

The alleged conduct under inquiry included:

- supplying many, if not all, hospitals with Remicade for 1 cent per vial; [4]
- providing free Remicade to patients that are not eligible to receive reimbursement for the drug under a public or private insurance plan;

- entering into contracts with hospitals and public and private insurers that require or induce them to favour Remicade over its biosimilars; and
- entering into exclusive contracts with third-party infusion clinics that prohibit them from infusing biosimilars to Remicade.

The Bureau's inquiry confirmed that Janssen was engaging in many of the alleged practices. In particular, market participants confirmed that Janssen was supplying many hospitals throughout Canada with Remicade for 1 cent per vial, providing free Remicade to a large number of patients without insurance coverage for the drug, and had negotiated exclusivity with certain third-party infusion clinic networks, which prevent them from administering patients with certain other biologic and biosimilar drugs, including biosimilars to Remicade.

On the other hand, the Bureau's review revealed that Janssen does not have contracts with hospitals and public and private insurers that require or induce them to favour Remicade over its biosimilars. Instead, these contracts, which have only been negotiated with certain private and public insurers (i.e., not with hospitals), have resulted in these insurers not implementing policies that would result in biosimilar drugs being reimbursed on more favourable terms than Remicade.

As summarized below, the Bureau's review assessed whether these four sets of practices individually or collectively contravened the restrictive trade practices provisions of the Act, with a focus on the abuse of dominance provisions.

Analysis

Abuse of dominance occurs when a dominant firm or group of firms in a market engages in a practice of anti-competitive acts, with the result that competition has been or is likely to be prevented or lessened substantially. The Bureau's inquiry focused on the last part of the abuse of dominance test—namely, whether Janssen's alleged conduct was likely to substantially prevent or lessen competition in a market. Consistent with recent Bureau guidance [5], the Bureau's analysis in this case assumed that the relevant market was the market for the sale of infliximab products in Canada.

The Bureau assessed the competitive impact of Janssen's conduct through two overarching theories of harm. First, the Bureau assessed whether Janssen's conduct was predatory (i.e., deterred entry or expansion through below-cost pricing). Second, the Bureau assessed

whether Janssen's alleged conduct was exclusionary (i.e., raised the costs of its competitors and thus made them less effective).

On balance, the evidence reviewed by the Bureau during the course of its inquiry did not support either of these theories of harm. In reaching this conclusion, the Bureau was guided by the following findings:

- **Predation theory:** consumers benefit from competitive prices. Low pricing is thus often an indication of vigorous competition unless the pricing is found to be predatory. Predatory pricing occurs when a firm sets prices below cost for long enough to eliminate, discipline or deter entry by a competitor. This involves an expectation that the firm will be able to recoup its losses later, by raising prices again. In this case, the Bureau's review confirmed that Janssen was offering Remicade at a price below cost to certain hospitals and patients. However, the Bureau did not find credible evidence that Janssen's low pricing strategy was sufficiently widespread that it was likely to eliminate, discipline or deter entry by one or more competitors, so as to substantially prevent or lessen competition in the relevant market. In particular, while Janssen's low prices may have shifted demand from biosimilar products to Remicade, the Bureau did not find that the practice was likely to induce competitors to exit the market or otherwise substantially affect competition at this time.
- **Exclusionary theory:** the Bureau did not find credible evidence that absent Janssen's conduct biosimilar firms would have likely competed more vigorously with Janssen on dimensions of competition like price, quality and service. Specifically, the Bureau did not find adequate evidence that Janssen's contracts with private and public insurers resulted in higher costs for infliximab. This is because Janssen negotiated these contracts by offering increasing rebates to public and private insurers following the entry of Inflectra and Renflexis, which significantly reduce Remicade's net price (i.e., list price subtracting discounts and/or rebates). Furthermore, although Janssen's exclusive contracts with third-party infusion clinics may have caused biosimilar firms to incur additional costs in establishing a comparable infusion clinic network, the Bureau did not find adequate evidence that these costs are likely to lessen a biosimilar firm's ability to act as a meaningful competitive constraint to Remicade.

In light of these and other findings, the Bureau has concluded that, at this time, there is insufficient evidence to find that Janssen's conduct has had, is having or is likely to have the effect of substantially lessening or preventing competition in the relevant market.

Continued monitoring by the Bureau

Notwithstanding these conclusions, the Bureau will continue to monitor the evolving biologic and biosimilar industry. Through its monitoring efforts, which will likely involve continued contact with market participants such as public and private insurers, the Bureau will be well positioned to respond quickly to developments that have the potential to disrupt current market dynamics.

An area of particular interest to the Bureau relates to the potential implementation of switching policies by public and private insurers. While many public insurers—and a few private insurers—have taken preliminary steps to encourage the use of biosimilars (e.g., requiring that new patients begin treatment on a biosimilar), they generally have not implemented mandatory switching policies. Such policies, which are similar in concept to the well-accepted automatic substitution rules that govern branded and generic small molecule drugs, encourage patients that are currently stable on a biologic to switch to a biosimilar.

Policies like these have been introduced in other jurisdictions, including certain countries in Europe. The decision to introduce these policies appears to be informed by a growing body of scientific literature that suggests it is safe and effective to switch a patient from a biologic to a biosimilar (and vice versa). Through these policies, other jurisdictions have been able to shift a significant percentage of total volume from a reference biologic to a biosimilar, allowing them to more immediately realize the cost savings of biosimilars.

The Bureau anticipates that public and private insurers in Canada may choose to implement switching policies, or other similar policies that encourage biosimilar uptake (e.g., policies that incentivize physicians to prescribe biosimilars), in the foreseeable future. Given the potential commercial impact of these policies on companies that sell reference biologics, the Bureau will monitor how these companies respond to the implementation of these policies, keeping an eye out for conduct that may seek to undermine their effectiveness. Such conduct could include spreading false or misleading information about the safety and efficacy of biosimilars with physicians, patients, patient advocacy groups and public and private insurers.

The Bureau's monitoring efforts will also help to identify other types of conduct by companies that sell reference biologics that could raise concerns under the Act. This includes conduct that has recently been reported in other jurisdictions, such as:

1. agreements with insurers (public or private) that prohibit them from providing reimbursement for biosimilars, or that only allow for reimbursement if a patient has first failed treatment on the reference biologic;
2. providing loyalty-inducing rebates based on volume that make it cost prohibitive for insurers to switch a portion of their insureds from a biologic to a biosimilar; and
3. refusing to supply drug samples required by biosimilar companies to perform comparative testing.

Conclusion

The Commissioner has elected to discontinue his inquiry because there is insufficient evidence to conclude that Janssen's alleged conduct has, at this time, substantially lessened or prevented competition in a relevant market. The Commissioner will, however, continue to monitor the Canadian biologic and biosimilar industry with a view to identifying and assessing the impact of key market developments.

The Commissioner's enforcement decisions are based on the available evidence. Should new and compelling evidence come to light of harm in the Canadian marketplace, the Bureau will not hesitate to take appropriate action.

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The Competition Bureau, as an independent law enforcement agency, ensures that Canadian businesses and consumers prosper in a competitive and innovative marketplace.

Footnotes

1 See Patented Medicine Prices Review Board, Annual Report 2017.

2 An indication is the use of a drug to treat a disease or medical condition. Clinical data may not be required for each indication requested where Health Canada is satisfied that there has been a rigorous demonstration of similarity between the biosimilar and its reference biologic. See Health Canada's Factsheet on Biosimilars.

3 This pattern of competition arises especially in situations where the biologic and biosimilar pharmaceutical products at issue treat chronic, rather than acute, conditions.

4 In this context, a vial is simply a vessel or bottle that is used to store medication. The number of vials of Remicade required for an infusion will vary according to a patient's body weight and stage of disease progression.

5 See, for instance, section III.A. in the Bureau's position statement titled "Competition Bureau Statement Regarding Its Investigation into Alleged Practices of Celgene, Pfizer, Sanofi".

Date modified:
2022-01-20

ontact the Competition Bureau

Exhibit “J41”

This is Exhibit “J41” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

Government of Canada Gouvernement du Canada

Product information

From Health Canada

New search

The product monograph is developed by a drug sponsor according to guidelines published by Health Canada that provide direction on the content and format. The veterinary labelling is developed by the drug sponsor according to the Food and Drug Regulations. While Health Canada reviews the product monograph or the veterinary labelling as part of the drug review process, it remains the responsibility of the drug sponsor to ensure that the product monograph or the veterinary labelling is complete and accurate.

Current status:

Approved

Current status date:

2020-12-29

Product name:

OMVYENCE

Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section.

DIN:

02510308

Product Monograph/Veterinary Labelling:

Date: 2022-12-23

Product monograph/Veterinary Labelling (PDF version ~ 175K)

Company:

JANSSEN INC
19 Green Belt Drive
Toronto
Ontario
Canada M3C 1L9

Class:

Human

Dosage form(s):

Powder For Solution

Route(s) of administration:

Intravenous

Number of active ingredient(s):

1

Schedule(s):

Schedule D , Prescription

American Hospital Formulary Service (AHFS): [3]

92:36.00

Anatomical Therapeutic Chemical (ATC): [4]

L04AB02 INFLIXIMAB

Active ingredient group (AIG) number: [5]

0144162001

List of active ingredient(s)

Active ingredient(s)	Strength
INFLIXIMAB	100 MG / VIAL

1876

Risk Management Plans [7]

A Risk Management Plan (RMP) for this product was submitted.

Additional Risk Minimization Measures
Patient Wallet Card

New search Same active ingredient group number

Footnotes

3 The American Hospital Formulary Service permits an easy review of information on a group of drugs with similar activities and uses and allows the reader to determine quickly the similarities and differences among drugs within a group. *AHFS® Pharmacologic/Therapeutic Classification*© used with permission. © 2022, the American Society of Health-System Pharmacists, Inc. (ASHP). The Data is a part of the AHFS Drug Information®; ASHP is not responsible for the accuracy of transpositions from the original context.

4 The purpose of the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification system is to be used as a tool for drug utilization research in order to improve quality of drug use. Drugs are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutical properties.

5	The AIG number is a 10 digit number that identifies products that have the same active ingredient(s) and ingredient strength(s). The AIG is comprised of three portions: • the first portion (2 digits) identifies the number of active ingredients, • the second portion (5 digits) identifies the unique groups of active ingredients(s), • the last portion (3 digits) identifies the active ingredient group strength. The strength group has a tolerance of -2% to +10%.	1877
7	Refer to the Health Canada Guidance Documents - "Submission of Risk Management Plans and Follow-up Commitments" as well as "Submission of targeted Risk Management Plans Follow-up Commitments for Prescription Opioid-containing Products" for additional details.	

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Date modified: 2024-02-28

Exhibit “J42”

This is Exhibit “J42” referred to in the Affidavit of Sukhad Juneja, sworn before me this 25th day of July, 2024.

A Commissioner for Taking Affidavits, etc.

Arash Rouhi

Completion of Preliminary Investigation into Relabelled Biologic drugs

Position Statement

See the news release that corresponds to this position statement.

June 27, 2022 – Gatineau (Québec) — Promoting and protecting competition and innovation in the Canadian health care sector is a key priority for the Competition Bureau. As such, the Bureau is committed to providing guidance to the pharmaceutical industry on practices that may be of concern under the *Competition Act* (the Act).

Biologic drugs (biologics) are a type of pharmaceutical product derived from living organisms. There are two types of biologics:

- Originators, produced by the manufacturer who first developed and commercialized the drug; and
- Biosimilars, which are highly similar versions of an originator biologic generally offered at a lower price.

The Bureau recently closed a preliminary investigation into the introduction of certain secondary brand name originator biologics in Canada (referred to as relabelled biologics). The Bureau examined their potential for anticompetitive harm under the abuse of dominance provisions of the Act.

Information gathered suggests that, in some cases, introducing these drugs could harm competition by making it less likely that patients will switch away from the originator drug. In this way, introducing relabelled biologics may reduce incentives for pharmaceutical companies to develop and market biosimilars.

This preliminary investigation follows an earlier investigation into alleged anti-competitive conduct relating to biologics. The Bureau will be particularly concerned about the introduction of relabelled biologics if they are accompanied by other practices that may raise barriers to entry and expansion for biosimilars.

The Bureau closed its investigation because the drugs under review have not been marketed in Canada. In the event that a relabelled biologic is marketed in Canada and there is compelling evidence of harm to competition, the Bureau will investigate the conduct of the originator manufacturer and take appropriate action.

On this page:

Background

Biologic drugs are derived from living organisms, such as a microorganism or animal cell. They tend to be larger, more complex and variable than traditional small molecule drugs, which are chemically synthesized. A biosimilar is a highly similar version of a brand name biologic already authorized for sale. Biosimilars must first obtain approval from Health Canada to be marketed in Canada and are generally priced lower than originators. Therefore, Canada's public and private insurers may realize cost savings by promoting the use of these drugs.

An important difference between biosimilars and small molecule generic drugs is that biosimilars are not deemed bioequivalent to the originator biologic. Accordingly, biosimilars do not benefit from some of the same policies that encourage the uptake of generic small molecule drugs, like provincial interchangeability designations.

Certain biologics are given to patients intravenously, requiring more assistance than with many small molecule drugs. This has resulted in manufacturers developing patient support programs where their products are dispensed at infusion clinics. Originator and biosimilar manufacturers may partner with third parties to develop networks of infusion clinics across the country, sometimes on an exclusive basis. As a result, switching from an originator to a biosimilar may require patients to switch support programs and clinics.

To promote the use of biosimilars, many provinces and territories have introduced, or are in the process of introducing, mandatory switching policies for patients who qualify for public reimbursement. While the details of these policies will vary among jurisdictions, they generally only cover biosimilars. With exceptions, patients must switch to a biosimilar to receive reimbursement from the provincial plan. Other policies may not cover originators

for new patients where a biosimilar is available. Although private insurance companies can still provide coverage for originators, it is the Bureau's understanding that some of them also promote the use of biosimilars to reduce the cost of their plans.

Following the introduction of these policies some manufacturers have sought approval to market their originator under a second brand name. These relabelled biologics are therefore the same product as their respective originator, and only require an administrative relabelling approval from Health Canada. Relabelled biologics may be priced similarly to biosimilars, and therefore may be more attractive for public and private payors than the originator. Pharmaceutical companies might prefer to introduce a relabelled biologic at a lower price rather than reduce the price of the originator. This can be done for various commercial reasons, such as avoiding international price comparisons that could result in a decrease in the price of the originator in other jurisdictions.

The abuse of dominance provisions

The Bureau considered the introduction of relabelled biologics under the abuse of dominance provisions (sections 78 and 79) of the Act. An abuse of dominance can occur when:

- The firm being investigated is dominant, meaning it has a substantial degree of market power – the ability to set prices above competitive levels or reduce other factors, such as product quality, below competitive levels.
- The dominant firm has engaged in a practice of anti-competitive acts that is intended to have a negative predatory, exclusionary, or disciplinary impact on a competitor.
- The dominant firm's anti competitive practices have substantially reduced the overall level of competition in a market or are likely to do so.

Where these conditions are met, the Bureau can seek an order from the Competition Tribunal for various kinds of corrective measures and administrative monetary penalties.

Competition issues

Because the relabelled biologics under investigation had not been marketed, the Bureau closed its investigation. However, the investigation suggested that if relabelled biologics were to be marketed and covered by public and private payors as an option for patients, they may harm competition in certain circumstances. In markets where patients remain

stable on a medication for a significant duration and have non-medical preferences for staying with an originator, the existence of a relabelled biologic may exclude an important patient base that would otherwise switch to biosimilars.

In some cases, patient support programs may contribute to these preferences. As highlighted above, where biologics are infused intravenously, switching patient support programs may require patients to go to a different infusion clinic. This sort of dynamic may provide significant advantages to a brand manufacturer simply due to the patient having taken an originator historically, rather than due to the quality of the product or service.

If originator biologics were able to leverage these dynamics to transfer their customer base over to the relabelled version, there may be little market for biosimilars to compete for. This could reduce incentives for biosimilars to enter, or expand in the market, and reduce competition. Even where relabelled biologics have similar prices to biosimilars, this may only be because of the threat of biosimilar competition. If biosimilar competition is excluded or deterred, the manufacturer of an originator may be able to maintain prices above competitive levels.

The Bureau expects that a key contextual factor in any future investigation will be how relabelled biologics are reimbursed by public and private payors. The Bureau expects transferring a customer base to a relabelled biologic would be substantially more difficult in the absence of reimbursement. Public and private payors may appear to have incentives to reimburse relabelled biologics, such as where they are priced lower than their originator. However, there would be a greater probability for the harms described above to occur if relabelled biologics qualify for equivalent reimbursement to biosimilars.

The Bureau believes that the presence of other potentially anti-competitive conduct may significantly increase the likelihood of competitive harm from relabelled biologics, aligning to form a practice of anti-competitive acts. For example, the Bureau's inquiry into the conduct of Janssen Inc. determined that manufacturers of originators may at times provide free medication to hospitals and patients. Such conduct may induce consumers to start or remain on an originator and, if coupled with the introduction of a relabelled biologic, may anti-competitively shield the brand manufacturer from biosimilar competition. Alternatively, if the relabelled biologic is marketed below an appropriate measure of its cost of production, this could undercut competitors in a predatory manner and increase the harm from the introduction of the relabelled biologic. In future investigations, the

Bureau will consider whether the introduction of a relabelled biologic, accompanied by other potentially anti-competitive conduct, has the cumulative effect of causing a substantial prevention or lessening of competition.

While the Bureau's analysis is focused on the potential competitive concerns that may be raised by relabelled biologics, there may be situations where the marketing of a relabelled biologic does not raise concerns under the Act, for example where it does not cause a substantial lessening or prevention of competition.

This guidance is being provided in the specific context of biologic drugs, where particular market dynamics, regulatory systems and experience in previous investigations informed the Bureau's decision to investigate relabelled biologics. In most cases, an incumbent manufacturer launching a new brand or product line following the entry of competitors does not raise issues under the abuse of dominance provisions [1].

Conclusion

The Bureau remains very mindful of the importance of competition in the pharmaceutical industry given the significant existing barriers to entry stemming from patent protection, stringent regulations and development costs.

While relabelled biologics have yet to be marketed in Canada, the Bureau is of the view that manufacturers engaging in the type of conduct described in this statement has the potential to contravene the abuse of dominance provisions of the Act – particularly if accompanied by other potentially anti-competitive conduct.

In the event that a relabelled biologic is marketed in Canada and there is compelling evidence of harm to competition, the Bureau will investigate the conduct of the originator manufacturer and take appropriate action.

This publication is not a legal document. The Bureau's findings, as reflected in this Position Statement, are not findings of fact or law that have been tested before a tribunal or court. Further, the contents of this Position Statement do not indicate findings of unlawful conduct by any party.

However, in an effort to further enhance its communication and transparency with stakeholders, the Bureau may publicly communicate the results of certain investigations, inquiries and merger reviews by way of a Position Statement. In the case of a merger review, Position Statements briefly describe the Bureau's analysis of a

particular proposed transaction and summarize its main findings. The Bureau also publishes Position Statements summarizing the results of certain investigations, inquiries and reviews conducted under the *Competition Act*. Readers should exercise caution in interpreting the Bureau's assessment. Enforcement decisions are made on a case-by-case basis and the conclusions discussed in the Position Statement are specific to the present matter and are not binding on the Commissioner of Competition.

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The Competition Bureau is an independent law enforcement agency that protects and promotes competition for the benefit of Canadian consumers and businesses. Competition drives lower prices and innovation while fueling economic growth.

Footnotes

1 It is relevant to note that section 78(1)(d) of the Act provides that the introduction of a fighting brand selectively on a temporary basis to discipline or eliminate a competitor can be an anti-competitive act for the purposes of section 79.

Date modified:
2022-06-27

ontact the Competition Bureau

File No. CT-2024-006

COMPETITION TRIBUNAL

IN THE MATTER OF the *Competition Act*, R.S.C. 1985, c. C-34 (the "**Act**");

AND IN THE MATTER OF an application by JAMP Pharma Corporation for an order pursuant to section 103.1 of the Act granting leave to bring an application under section 79 of the Act;

AND IN THE MATTER OF an application by JAMP Pharma Corporation for an order pursuant to sections 79 of the Act;

BETWEEN:

JAMP PHARMA CORPORATION

Applicant

– and –

JANSSEN INC.

Respondent

AFFIDAVIT OF SUKHAD JUNEJA
(Pursuant to section 103.1 of the *Competition Act*)

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