

**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

(State of incorporation)

22-1024240

(I.R.S. Employer Identification No.)

**One Johnson & Johnson Plaza
New Brunswick, New Jersey**

(Address of principal executive offices)

08933

(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 | <input checked="" type="checkbox"/> Accelerated filer | <input type="checkbox"/> |
| Non-accelerated filer | <input type="checkbox"/> Smaller reporting company | <input type="checkbox"/> |
| Emerging growth company | <input type="checkbox"/> | <input type="checkbox"/> |

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 Portions of registrant's proxy statement for its 2021 annual meeting of shareholders filed within 120 days after the close of the III: registrant's fiscal year (the "Proxy Statement"), are incorporated by reference to this report on Form 10-K (this "Report").

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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®/EPOREX® (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

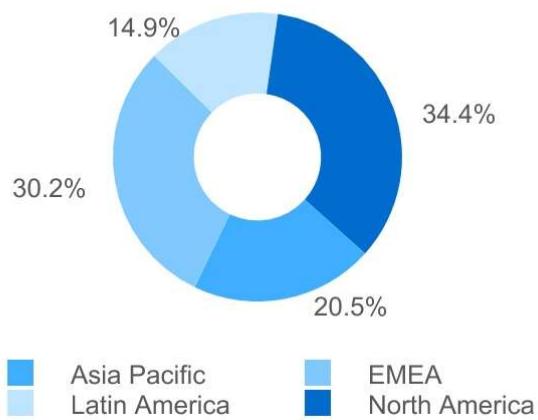
As of January 3, 2021 and December 29, 2019, the number of employees were approximately:

| | 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.

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 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 | <u>15,194</u> |

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 | <u>90</u> | <u>15,194</u> |

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.

| <u>Fiscal Period</u> | <u>Total Number of Shares Purchased⁽¹⁾</u> | <u>Avg. Price Paid Per Share</u> | <u>Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs</u> | <u>Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs</u> |
|---|---|----------------------------------|--|--|
| 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.

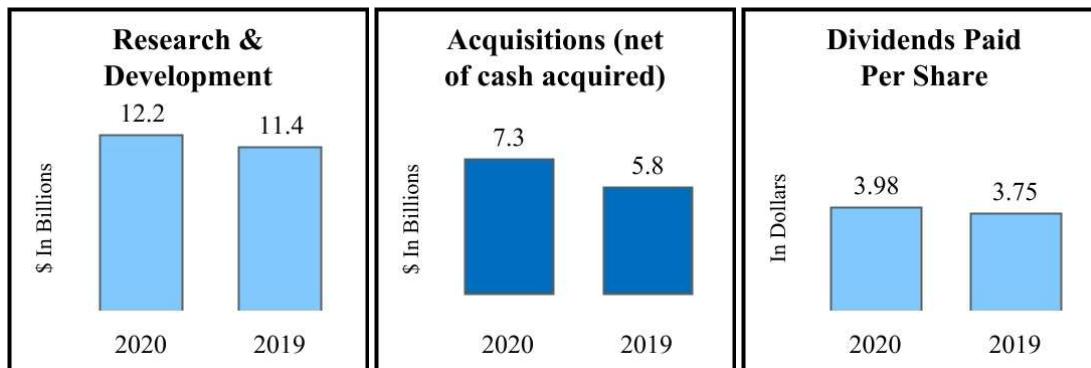
In all of its product lines, the Company competes with other companies both locally and globally, throughout the world. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, involving the development and the improvement 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.

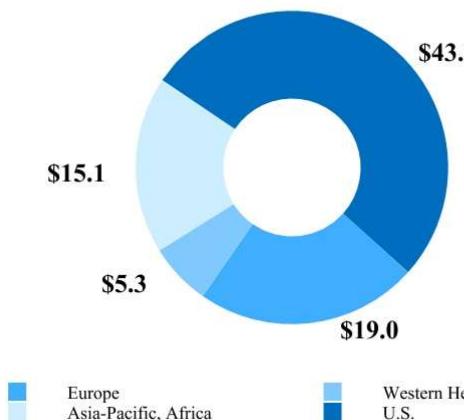
The five-year compound annual growth rates for worldwide, U.S. and international sales were 3.3%, 3.9% and 2.8%, respectively. The ten-year compound annual growth rates for worldwide, U.S. and international sales were 3.0%, 3.9% and 2.1%, respectively.

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%.

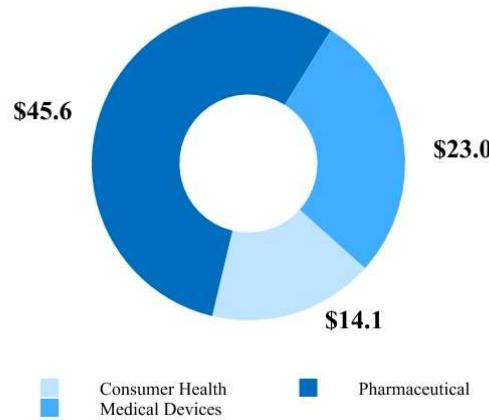
The 2020 results benefited from the inclusion of a 53rd week. (See Note 1 to the Consolidated Financial Statements for Annual Closing Date details). The Company estimated that the fiscal year 2020 sales growth rate was enhanced by approximately 1.0%. While the additional week added a few days to sales, 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.

2020 Sales by Geographic Region (in billions)



2020 Sales by Segment (in billions)



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 VELYSTM 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.

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:



(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:

- Leverage 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:

| (Dollars in Millions) | 2020 | | 2019 | |
|---|-----------|-------------|-----------|-------------|
| | 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:

| (Dollars in Millions) | Income Before Tax | | Segment Sales | | Percent of Segment Sales | |
|--|-------------------|--------|---------------|--------|--------------------------|------|
| | 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 |
| | non-cash expenses and other adjustments primarily for depreciation and amortization, stock-based compensation, asset write-downs and credit losses and accounts receivable allowances |
| 7.3 | partially offset by the deferred tax provision and net gain on sale of assets/businesses |
| 0.8 | decrease in accounts receivable |
| | an increase in accounts payable and accrued liabilities and other current and non-current |
| 5.9 | liabilities |
| (4.0) | an increase in inventories and other current and non-current assets |
| | contingent consideration reversal (related to the timing of certain developmental milestones |
| (1.2) | 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) | |
|-----------------------|---|
| \$ | primarily related to the acquisitions of Momenta, bermekimab and related assets from XBiotech |
| | (7.3) 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 | <u>\$ 9,518</u> | <u>32,658</u> | <u>(31,873)</u> | <u>10,303</u> |
| Reserve for doubtful accounts | 36 | 24 | (8) | 52 |
| Reserve for cash discounts | 65 | 1,034 | (1,029) | 70 |
| Total | <u>\$ 9,619</u> | <u>33,716</u> | <u>(32,910)</u> | <u>10,425</u> |
| 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 | <u>\$ 7,959</u> | <u>27,239</u> | <u>(25,680)</u> | <u>9,518</u> |
| Reserve for doubtful accounts | 47 | 2 | (13) | 36 |
| Reserve for cash discounts | 53 | 936 | (924) | 65 |
| Total | <u>\$ 8,059</u> | <u>28,177</u> | <u>(26,617)</u> | <u>9,619</u> |

(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 | <u>\$ 1,177</u> | <u>5,840</u> | <u>(5,653)</u> | <u>1,364</u> |
| Reserve for doubtful accounts | 155 | 95 | (48) | 202 |
| Reserve for cash discounts | 10 | 88 | (89) | 9 |
| Total | <u>\$ 1,342</u> | <u>6,023</u> | <u>(5,790)</u> | <u>1,575</u> |
| 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 | <u>\$ 1,374</u> | <u>6,266</u> | <u>(6,463)</u> | <u>1,177</u> |
| Reserve for doubtful accounts | 169 | 30 | (44) | 155 |
| Reserve for cash discounts | — | 106 | (96) | 10 |
| Total | <u>\$ 1,543</u> | <u>6,402</u> | <u>(6,603)</u> | <u>1,342</u> |

(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**

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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) | <u>\$ 7,323</u> | <u>5,810</u> | <u>899</u> |

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 | <u>(439)</u> |
| Total | <u>\$ (254)</u> |

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 | Unrecog nized 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:

| (Dollars in Millions) | January 3, 2021 | | | | December 29, 2019 | | | | | |
|--|-----------------|-----------------------|-------------|---------------------------|------------------------|-------|-----------------------|-------------|---------------------------|------------------------|
| | 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) | Derivatives Not Designated as Hedging Instruments Foreign Exchange Contracts | Location of Gain /(Loss) Recognized in Income on Derivative Other (income) expense | Gain/(Loss) Recognized In Income on Derivative | |
|-----------------------|---|--|---|-------------------|
| | | | January 3, 2021 | December 29, 2019 |
| | | | \$ 24 | (144) |

The following table is the effect of net investment hedges for the fiscal years ended January 3, 2021 and December 29, 2019:

| (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 | |
|------------------------------------|---|-------------------|---|---|-------------------|
| | 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:

| (Dollars in Millions) | December 29, 2019 | | | January 3, 2021 | |
|---|-------------------|---|---------------------------|-----------------|--------------------------|
| | 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 |

| (Dollars in Millions) | December 30, 2018 | | | December 29, 2019 | |
|---|-------------------|---|---------------------------|-------------------|--------------------------|
| | 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:

| (Dollars in Millions) | 2020 | | | 2019 | |
|---|-------------|--------------|----------|--------------|------------|
| | 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 (Dollars in Millions) | 2020 | 2019 |
|---|-----------|---------|
| 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:

| (Dollars in Millions) | 2020 | 2019 | 2018 |
|-------------------------------------|-------------|-------------|-------------|
| 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 | <u>34,434</u> (4) | <u>2.85 %</u> (1) | <u>27,594</u> (4) | <u>3.19</u> (1) |
| Less current portion | 1,799 | | 1,100 | |
| Total long-term debt | <u><u>\$ 32,635</u></u> | | <u><u>26,494</u></u> | |

- (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) | <u>2021</u> | <u>2022</u> | <u>2023</u> | <u>2024</u> | <u>2025</u> | <u>After 2025</u> |
|-----------------------|-------------|-------------|-------------|-------------|-------------|-------------------|
| | \$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) | <u>2020</u> | <u>2019</u> | <u>2018</u> |
|--------------------------------------|------------------------|---------------------|---------------------|
| Currently payable: | | | |
| U.S. taxes | \$ 1,026 | 1,941 | 1,284 |
| International taxes | 1,898 | 2,744 | 2,434 |
| Total currently payable | <u>2,924</u> | <u>4,685</u> | <u>3,718</u> |
| Deferred: | | | |
| U.S. taxes | (76) | (814) | 1,210 (1) |
| International taxes | (1,065) | (1,662) | (2,226) |
| Total deferred | <u>(1,141)</u> | <u>(2,476)</u> | <u>(1,016)</u> |
| Provision for taxes on income | <u>\$ 1,783</u> | <u>2,209</u> | <u>2,702</u> |

(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: | <u>\$ 16,497</u> | <u>17,328</u> | <u>17,999</u> |
| 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 | <u>10.8 %</u> | <u>12.7</u> | <u>15.0</u> |

(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:

| (Dollars in Millions) | 2020 Deferred Tax | | 2019 Deferred Tax* | |
|---|-------------------|-----------------|--------------------|-----------------|
| | 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 | <u>\$ 13,138</u> | <u>(11,819)</u> | <u>12,031</u> | <u>(10,170)</u> |

*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 | <u>\$ 3,373</u> | <u>3,853</u> | <u>3,326</u> |

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 | <u>11,318</u> | <u>11,177</u> |
| Less current benefits payable | 547 | 514 |
| Employee related obligations — non-current | <u><u>\$ 10,771</u></u> | <u><u>10,663</u></u> |

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:

| (Dollars in Millions) | Retirement Plans | | | Other Benefit Plans | | |
|-------------------------------------|------------------|------------|------------|---------------------|------------|------------|
| | 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:

| Worldwide Benefit Plans | Retirement Plans | | | Other 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:

| (Dollars in Millions) | Retirement Plans | | Other Benefit Plans | |
|---|-------------------|------------------------|---------------------|----------------|
| | 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 | | Other Benefit Plans | |
|---|------------------|-------|---------------------|-------|
| | 2020 | 2019 | 2020 | 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:

| (Dollars in Millions) | U.S. Plans | | | | International Plans | | | |
|-----------------------------------|-----------------|---------------------|--------------|----------------|---------------------|---------|-------|-------|
| | Qualified Plans | Non-Qualified Plans | Funded Plans | Unfunded Plans | 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 | |
| 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:

| (Dollars in Millions) | 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 | |
|--------------------------------------|--|---------------|---|---------------|---|------------|---|--------------|---------------|---------------|
| | 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 | 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 | <u><u>487,331</u></u> | <u><u>\$ 38,490</u></u> |

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 | <u><u>\$ (8,938)</u></u> | <u><u>1</u></u> | <u><u>(6,957)</u></u> | <u><u>652</u></u> | <u><u>(15,242)</u></u> |

⁽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 | <u>\$ 5.51</u> | <u>5.63</u> | <u>5.61</u> |

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 | <u><u>\$ 5,480</u></u> |
| 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 | <u><u>3,214</u></u> |
| 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 | <u><u>4,478</u></u> |
| Options granted | 20,723 | 151.41 | |
| Options exercised | (16,275) | 86.05 | |
| Options canceled/forfeited | (1,835) | 137.62 | |
| Shares at January 3, 2021 | <u><u>114,250</u></u> | <u><u>\$ 116.22</u></u> | <u><u>\$ 4,703</u></u> |

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>U.S.</u> | 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 |
| <u><u>REMICADE®</u></u> | | | | | |
| 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) |
| <u><u>SIMPONI / SIMPONI ARIA®</u></u> | | | | | |
| 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 |
| <u><u>STELARA®</u></u> | | | | | |
| 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 |
| <u><u>TREMFYA®</u></u> | | | | | |
| 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 |
| <u><u>OTHER IMMUNOLOGY</u></u> | | | | | |
| U.S. | — | — | — | — | — |
| International | 11 | 10 | 10 | 6.4 | 4.5 |
| Worldwide | 11 | 10 | 10 | 6.4 | 4.5 |

Infectious Diseases

| | | | | | |
|---|-------|-------|-------|--------|--------|
| <u>U.S.</u> | 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 |
| <u><u>EDURANT® / rilpivirine</u></u> | | | | | |
| 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 |
| <u><u>PREZISTA® / PREZCOBIX® / REZOLSTA® / SYMTUZA®</u></u> | | | | | |
| 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 |
| <u><u>OTHER INFECTIOUS DISEASES</u></u> | | | | | |
| 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 |
| <u>CONCERTA® / methylphenidate</u> | | | | | |
| 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 |
| <u>INVEGA SUSTENNA® / XEPLION® / INVEGA TRINZA® / TREVICTA®</u> | | | | | |
| 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 |
| <u>RISPERDAL CONSTA®</u> | | | | | |
| 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) |
| <u>OTHER NEUROSCIENCE</u> | | | | | |
| 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 |
| <u>DARZALEX®</u> | | | | | |
| 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 |
| <u>ERLEADA®</u> | | | | | |
| U.S. | 583 | 297 | 124 | 96.1 | ** |
| International | 176 | 35 | — | ** | ** |
| Worldwide | 760 | 332 | 124 | ** | ** |
| <u>IMBRUVICA®</u> | | | | | |
| 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 |
| <u>VELCADE®</u> | | | | | |
| U.S. | — | — | — | — | — |
| International | 408 | 751 | 1,116 | (45.7) | (32.7) |
| Worldwide | 408 | 751 | 1,116 | (45.7) | (32.7) |
| <u>ZYTIGA® /abiraterone acetate</u> | | | | | |
| 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) |

| <u>OTHER ONCOLOGY</u> | | | | | |
|--|--------|--------|--------|--------|--------|
| 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 |
| <u>OPSUMIT®</u> | | | | | |
| 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 |
| <u>UPTRAVI®</u> | | | | | |
| 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 |
| <u>OTHER</u> | | | | | |
| 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) |
| <u>XARELTO®</u> | | | | | |
| U.S. | 2,345 | 2,313 | 2,477 | 1.4 | (6.6) |
| International | — | — | — | — | — |
| Worldwide | 2,345 | 2,313 | 2,477 | 1.4 | (6.6) |
| <u>INVOKANA® / INVOKAMET®</u> | | | | | |
| 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) |
| <u>PROCRIT® / EPREX®</u> | | | | | |
| 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) |
| <u>OTHER</u> | | | | | |
| 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 |

| <u>CONTACT LENSES / OTHER</u> | | | | | |
|-------------------------------|-----------|--------|--------|--------|-------|
| 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 |
| <u>SURGICAL</u> | | | | | |
| 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

| (Dollars in Millions) | Income (Loss) Before Tax | | | Identifiable Assets | |
|--|---------------------------------|-----------------|-----------------|----------------------------|----------------|
| | 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 |

| (Dollars in Millions) | Additions to Property, Plant & Equipment | | | Depreciation and Amortization | | |
|------------------------------|---|--------------|--------------|--------------------------------------|--------------|--------------|
| | 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 | | | Long-Lived Assets ⁽⁶⁾ | |
|-----------------------------------|--------------------|---------------|---------------|----------------------------------|----------------|
| | 2020 | 2019 | 2018 | 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 | <u>\$ 82,584</u> | <u>82,059</u> | <u>81,581</u> | <u>\$ 174,894</u> | <u>157,728</u> |

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 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 INVOKAMET® 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 United 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

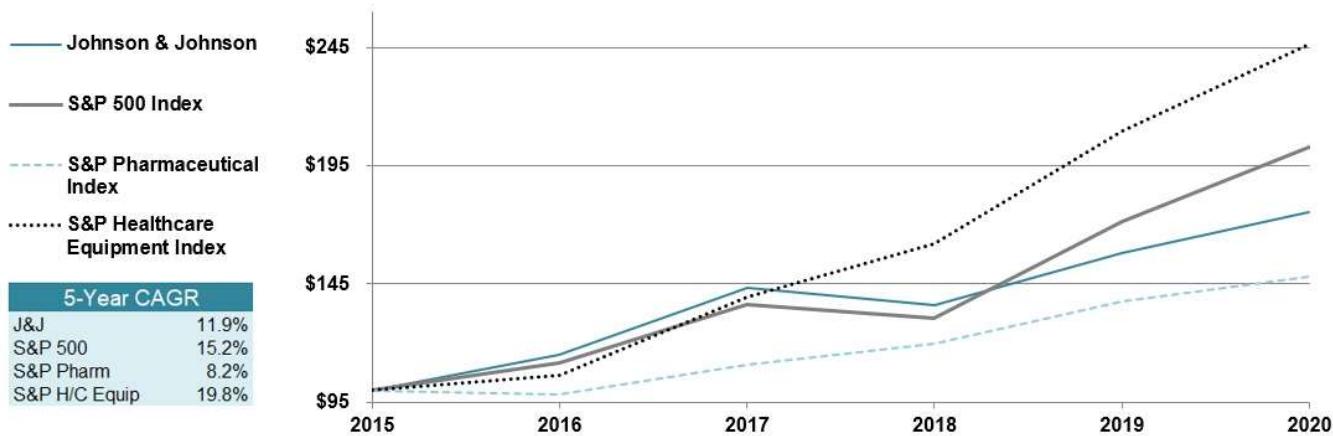
/s/ Joseph J. Wolk

Joseph J. Wolk
Executive Vice President, Chief Financial Officer

Shareholder Return Performance Graphs

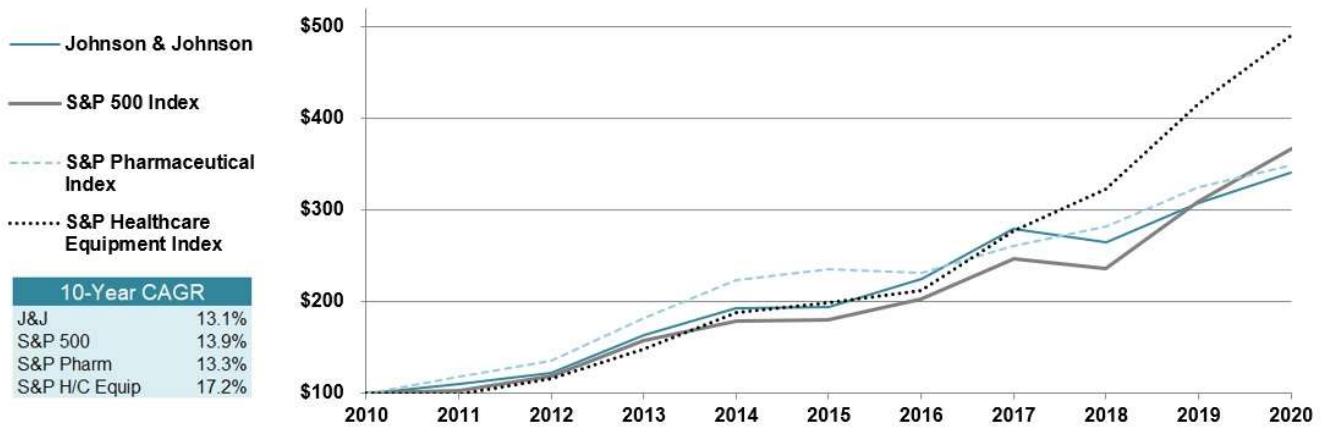
Set forth below are line graphs comparing the cumulative total shareholder return on the Company's Common Stock for periods of five years and ten years ending January 3, 2021, against the cumulative total return of the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and 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.

| <u>Signature</u> | <u>Title</u> | <u>Date</u> |
|--|--|-------------------|
| /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 | Director | | February 22, 2021 |
| M. A. Hewson | | | |
| /s/ H. Joly | Director | | February 22, 2021 |
| H. Joly | | | |
| /s/ M. B. McClellan | Director | | February 22, 2021 |
| M. B. McClellan | | | |
| | Director | | |
| /s/ A. M. Mulcahy | | | February 22, 2021 |
| A. M. Mulcahy | | | |
| | Director | | |
| /s/ C. Prince | | | February 22, 2021 |
| C. Prince | | | |
| | Director | | |
| /s/ A. E. Washington | | | February 22, 2021 |
| A. E. Washington | | | |
| | Director | | |
| /s/ M. A. Weinberger | | | February 22, 2021 |
| M. A. Weinberger | | | |
| | Director | | |
| /s/ N.Y. West | | | February 22, 2021 |
| N. Y. West | | | |
| | Director | | |
| /s/ R. A. Williams | | | February 22, 2021 |
| R. A. Williams | | | |

EXHIBIT INDEX

| Reg. S-K Exhibit Table Item No. | Description of Exhibit |
|---------------------------------------|--|
| <u>3(i)</u> | 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. |
| <u>3(ii)</u> | 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. |
| <u>3(iii)</u> | 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. |
| <u>4(b)</u> | 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. |
| <u>10(a)</u> | 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).* |
| <u>10(b)</u> | 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.* |
| <u>10(c)</u> | 2012 Long-Term Incentive Plan — Incorporated herein by reference to Appendix A of the Registrant's Proxy Statement filed on March 15, 2017.* |
| <u>10(d)</u> | 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.* |
| <u>10(e)</u> | 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.* |
| <u>10(f)</u> | 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.* |
| <u>10(g)</u> | 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.* |
| <u>10(h)</u> | 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.* |
| <u>10(i)</u> | 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.* |
| <u>10(j)</u> | 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.* |
| <u>10(k)</u> | 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.* |
| <u>10(l)</u> | 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.* |
| <u>10(m)</u> | 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.* |
| <u>10(n)</u> | 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.* |
| <u>10(p)</u> | 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.* |
| <u>10(q)</u> | 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 |
|------------------------------|---|
| <u>10(r)</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.* |
| <u>10(s)</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.* |
| <u>10(t)</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.* |
| <u>21</u> | Subsidiaries — Filed with this document. |
| <u>23</u> | Consent of Independent Registered Public Accounting Firm — Filed with this document. |
| <u>31.1</u> | Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document. |
| <u>31.2</u> | Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document. |
| <u>32.1</u> | Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document. |
| <u>32.2</u> | 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.